Outcomes for adult cochlear implant recipients with functional pre-operative hearing

Michelle Catherine Moran

ORCID ID – 0000-0003-1187-0311

Submitted in total fulfilment of the requirements of the degree of

Doctor of Philosophy

January 2019

Faculty of Medicine, Dentistry and Health Sciences

Department of Audiology and Speech Pathology

The University of Melbourne
Abstract

Background and Aims
In recent years, the population of persons with hearing loss attending cochlear implant (CI) centres for candidacy discussions has shifted to include those with greater hearing than in the past. Specifically, persons may have residual low frequency hearing ranging from normal to moderately severe with profound loss in the high frequencies (i.e. partial deafness (PD)). To support CI clinicians’ provision of evidence-based recommendations to adults with PD, new clinical outcome data, candidacy guidelines, and predictive factors associated with preservation of acoustic hearing are required to address the following: assessment of speech perception benefits for adults with PD using CIs, quantifying risk for loss of residual hearing, and evaluating outcome by electrode array type.

Method
This ambidirectional study design used a prospective cohort of adults with PD and two retrospective analyses of adults who received a CI at the Royal Victorian Eye and Ear Hospital (RVEEH).

To assess speech perception benefits for adults with PD as compared with traditional CI recipients (defined as severe-to-profound or poorer audiometric thresholds pre-implant), a group of 27 adults with PD were compared to a matched group of traditional CI recipients with all data sourced from the RVEEH database. All recipients were using perimodiolar arrays.

To assess hearing preservation outcomes, 154 adults with PD were studied prospectively. These adults were identified as proceeding with the device of interest, a CI with a thin straight electrode array (TSEA).

To assess speech perception outcomes by electrode array type, a group of 70 adults with PD using perimodiolar CIs sorted from the database were compared with a group of 63 adults with PD using TSEAs.
Results

There were no significant differences in speech perception outcomes for adults with PD compared with those with profound hearing loss who received perimodiolar arrays.

Median change in low frequency hearing for adults with PD using a TSEA was -22.5 dB HL. Hearing preservation was assessed further for a subset of 78 defined as having ‘functional’ low frequency hearing pre-implant (≤70 dB HL). For persons who had a pre-implant low frequency pure tone median of ≤45 dB HL, functional hearing was preserved in 75% of cases.

No significant differences were found for speech perception outcomes based on electrode array type for the two groups of adults with PD. For persons using a TSEA, it was found that those who had preserved hearing and used electro-acoustic stimulation (EAS) performed significantly better than their peers with electric-only hearing.

Conclusion

The present study demonstrated that clinicians may use existing CI candidacy guidelines to counsel adults with PD who are considering a CI. The presence of low frequency hearing ≤45 dB HL pre-implant was associated with preservation of functional acoustic hearing in 75% of cases post-implant. Electrode array type was not found to be significantly associated with speech perception outcomes for adults with PD, however those that preserved hearing and used EAS demonstrated superior outcomes.

These data provide evidence-based guidelines for counselling adults with PD pre-implant with respect to their potential to benefit and the associated risks to hearing.
Declaration

This is to certify that:

1. The thesis comprises only my original work towards the PhD except where indicated in the preface

2. Due acknowledgement has been made in the text to all other material used

3. The thesis is fewer than 100,000 words in length exclusive of tables, maps, bibliographies, and appendices

Michelle Catherine Moran

31st January 2019
Preface

This research was supported by the HEARing Cooperative Research Centre, established under the Australian Government’s Cooperative Research Centre (CRC) Program. The CRC Programme supports industry led end-user driven research collaborations to address the major challenges facing Australia.

Ethical approval for this project was obtained through the Human Research Ethics Committee of the Royal Victorian Eye & Ear Hospital (RVEEH) under project numbers 04/564 and 15/1207H. Clinical management of cochlear implant recipients was provided by the RVEEH Cochlear Implant Clinic.

Three journal publications and a number of conference presentations were generated as a result of this research (see list of publications). Chapters 4 to 6 of this thesis were derived from these journal articles.
Acknowledgements

First and foremost, thank you to the CI recipients involved in this project, many of whom I worked with as a clinician. Throughout my time as both a clinical and a research audiologist I have heard your stories, listened during the anxious times at the beginning of your CI journeys, and most importantly I have shared in your successes. I have learnt so much from your personal journeys and I thank you for giving your own time for the advancement of this field.

I would like to acknowledge and thank Professor Robert Cowan and the HEARing CRC for financial and academic support and providing a collaborative and supportive environment in which to study.

Thank you to the University of Melbourne Department of Audiology & Speech Pathology, my former colleagues and my fellow graduate research students. This has been such a caring and supportive space to work within. In particular, I would like to acknowledge Dr Jaime Leigh and Dr Alex Rousset who have shared in this journey of part-time PhD student/clinical audiology work/pregnancy/motherhood, and have provided me with endless advice, support, and an ear to listen when things were getting tough. Thank you both from the bottom of my heart.

I would like to also acknowledge and thank Associate Professor Robert Briggs for his support through this process, not only for assistance with data analysis and contribution to papers but also for general discussion about the topic in a clinical and research sense. It is always motivating to see work being put into practice. Thank you, Rob.

To my supervisors – you have guided me, supported me and provided a constant stream of helpful and constructive comments along the way. Thank you to Professor Richard Dowell for your advice, giving your time for project discussions, and of course for your wizardry when the stats were causing me trouble. Your devotion to furthering knowledge in the cochlear implant field is inspiring. Thank you to Dr Andrew Vandali for never failing to motivate me along the way, whether that meant looking at the topic from a different angle or getting out on my bike for a bit of head space. Finally, thank you Dr Shani Dettman for your encouragement, your mastery of language, and always sharing suggestions or useful papers as they arose.
Lastly, I would like to thank my family. Thank you to Dad for all the interesting discussions we have had, for always supporting me and encouraging me in my studies and in every aspect of my life. Thank you to Mum for always believing in me, for being such a positive role model with your own study when I was younger, and for taking care of my little girl to enable me to do some of this work. I couldn’t have done this without both of your support. To my brother, thank you for always encouraging me and talking me up to myself whenever I needed it. And finally to my husband Paul and our little Evie bear - you are my sunshine and my inspiration. Thank you for your patience, love, and understanding.

Thank you all for enabling me to achieve this milestone.
For Evie
Statement of contribution to jointly authored works contained in this thesis

For each publication contained in this thesis, the PhD candidate was primarily responsible for the review of literature, research plan and design, data collection, analysis and interpretation of results and writing.

Professor Dowell contributed to the research plan and design and reviewed the data analysis, interpretation and writing. Associate Professor Briggs contributed to the data analysis and interpretation of the manuscripts contained in the thesis.

Dr Vandali, Dr Dettman and Professor Cowan contributed to the research plan and design and reviewed the data analysis, interpretation and writing for one of the manuscripts contained in the thesis. Dr Claire Iseli contributed to the data analysis, interpretation and writing for one of the manuscripts. Ms Umansky and Ms Corbett contributed to the research design of one of the manuscripts.

All other contributions are acknowledged in the publications. Persons who have contributed to the work but not at the level that constitutes authorship have been acknowledged in the text.
Published works by the author incorporated into the thesis

Three peer reviewed publications are incorporated in their entirety in the thesis.

1) The following publication constitutes Chapter 4, published by Journal of Hearing Science in 2014:


2) The following publication constitutes Chapter 5, published by Otology & Neurotology in 2017:


3) The following publication constitutes Chapter 6, published by Otology & Neurotology in 2019:

# Table of Contents

Abstract ............................................................................................................................. III
Declaration ........................................................................................................................... V
Preface ............................................................................................................................... VII
Acknowledgements ............................................................................................................ IX
Statement of contribution to jointly authored works contained in this thesis .................. XIII
Published works by the author incorporated into the thesis ........................................... XV
List of Tables ....................................................................................................................... XXI
List of Figures ..................................................................................................................... XXIII
Abbreviations ...................................................................................................................... XXVII

1. Introduction .................................................................................................................... 1
   1.1. Overview ................................................................................................................ 1
   1.2. Statement of Research Questions ....................................................................... 3
       1.2.1. Aims .............................................................................................................. 3
       1.2.2. Hypotheses ................................................................................................... 4
   1.3. Structure of Thesis (Chapter Outline) ................................................................. 7

2. Summary and Analysis of the Relevant Literature ....................................................... 9
   2.1. Hearing loss ......................................................................................................... 9
   2.2. Amplification options in adults with high frequency SNHL .............................. 13
   2.3. Cochlear Implantation ....................................................................................... 15
       2.3.1. Background and changes in indications ...................................................... 15
       2.3.2. How a cochlear implant works ................................................................. 16
   2.4. Factors associated with cochlear implant outcomes ....................................... 19
       2.4.1. Duration of deafness ................................................................................... 19
       2.4.2. Age at implantation .................................................................................... 20
       2.4.3. Age at onset of hearing loss ..................................................................... 21
       2.4.4. Placement of the electrode array ............................................................... 22
       2.4.5. Variance in CI outcomes .......................................................................... 27
   2.5. Music perception for adult cochlear implant recipients .................................. 29
2.5.1. Music perception and appreciation in adult CI users ....................... 29
2.5.2. Music perception for adult CI users with acoustic hearing ............ 31
2.6. Cochlear implantation and hearing preservation ............................. 35
2.6.1. Cochlear Implantation for Partial Deafness ................................ 35
2.6.2. Factors Associated with Hearing Preservation ................................. 40
2.6.3. Hearing Preservation – Success and Measurement .......................... 44
2.7. Clinical questions remaining .......................................................... 51
2.8. Review of the research questions .................................................... 53
3. Methodology ....................................................................................... 55
3.1. Introduction ...................................................................................... 55
3.2. Participants ....................................................................................... 57
3.3. Experimental methods ................................................................. 59
3.4. Surgery and Post-operative Radiological Analysis ............................... 61
3.5. Statistical Analysis ......................................................................... 63
3.6. Institutional Approval ....................................................................... 63
4. Outcomes for patients with sloping hearing loss implanted with standard cochlear implants ................................................................. 65
4.1. Abstract ......................................................................................... 67
4.2. Introduction ..................................................................................... 69
4.3. Material and Methods .................................................................... 73
4.3.1. Subjects ...................................................................................... 73
4.3.2. Test Materials ............................................................................. 74
4.3.3. Surgery and Devices ................................................................. 75
4.3.4. Statistics .................................................................................... 75
4.4. Results .......................................................................................... 79
4.4.1. Demographics ............................................................................ 79
4.4.2. Monaural Analysis ..................................................................... 79
4.4.3. Binaural Analysis ...................................................................... 81
4.4.4. Correlation Analysis .................................................................. 81
4.5. Discussion ..................................................................................... 87
4.6. Conclusions ................................................................................... 91
5. Hearing preservation outcomes for 139 cochlear implant recipients using a thin straight electrode array ......................................................... 93
7.3. Hearing Preservation ........................................................................................................... 147
7.4. Clinical Implications .......................................................................................................... 151
7.5. Study Limitations ............................................................................................................... 153
7.6. Future Directions .............................................................................................................. 157
7.7. Summary ............................................................................................................................ 159
8. Conclusions ............................................................................................................................ 163
9. List of Associated Publications and Presentations ............................................................. 165
10. References ............................................................................................................................. 167
12. Appendix B – Publication Reprint (Chapter 4) ..................................................................... 189
13. Appendix C – Publication Reprint (Chapter 5) ..................................................................... 201
14. Appendix D – Publication Proofs Reprint (Chapter 6) ......................................................... 209
List of Tables

Table 2.1: Potential mechanisms of trauma related to cochlear implantation, adapted from O'Connell et al. (2016) .......................................................... 24

Table 2.2: Overview of hearing preservation research ........................................... 47

Table 4.1: Demographic data of the PD and Profound Loss matched groups .......... 76

Table 4.2: Correlation analysis for PD group .......................................................... 83

Table 4.3: Correlation analysis for the Profound Loss group ............................... 84

Table 5.1: Assessment of change in low frequency hearing versus patient-specific and surgical factors in 78 TSEA recipients. Asterisk on 'Laterality' represents the factor is controllable to an extent - there may be ability to control for side however this will not always be the case ........................................................................................................ 113

Table 6.1: Demographic comparisons for the TSEA Group and the Perimodiolar Group. The post-implant speech perception scores represent the average score for each test at either 3 or 12 months post-op using the most recent test scores for each individual. Note: Some participants did not complete sentence in noise testing, as a result for Sentences in Noise and therefore TSPS have lower participant numbers in the analysis (Pre-implant TSEA n=53, Perimodiolar n=62; Post-implant TSEA n=58, Perimodiolar n=67) ......................................................................................................... 130

Table 6.2: Comparison of the TSEA Group sub-groups based on type of sound processor used. The post-implant speech perception scores represent the average score for each test at either 3 or 12 months post-op using the most recent test scores for each individual. Note: Some participants did not complete sentence in noise testing, as a result for Sentences in Noise and therefore TSPS have lower participant numbers in the
analysis (Pre-implant TSEA-EAS n=15, TSEA-Standard n=38; Post-implant TSEA-EAS n=17, TSEA-Standard n=41).
List of Figures

Figure 2.1: Classification of hearing impairment severity, adapted from Harrell (2002) ................................................................. 11

Figure 2.2: Anatomy of the ear, adapted from HEARnet Learning (2016) ......................... 12

Figure 2.3: How a CI works. 1) Microphones on a sound processor capture speech and environmental sound and convert it into digital code. 2) The sound processor transmits the coded sound through the external coil. 3) The receiver-stimulator receives the code and converts it into electrical impulses. These are sent to the electrode array placed inside the cochlea. 4) The impulses from the electrode array stimulate spiral ganglion neurons and this message is sent along the auditory nerve to the brain. Image courtesy of Cochlear Ltd. ........................................................................................................ 16

Figure 2.4: CI signal processing ........................................................................................................... 18

Figure 2.5: Comparison of two types of CI electrode arrays. The Contour Advance is a perimodiolar array and the Slim Straight is a lateral wall array. Image: Cochlear Limited. ........................................................................................................... 22

Figure 2.6: Demonstrating Wrapping Factor - example insertions for electrode arrays and corresponding wrapping factor (image from Holden (2013)) ................................. 26

Figure 2.7: Melody and Instrument recognition results from Gfeller, Olszewski, Turner, Gantz, and Oleson (2006). LE = long electrode (i.e. standard length), Hybrid = Nucleus Hybrid electrode using EAS, NH = normal hearing ......................................................... 33

Figure 2.8: Example of audiometric configuration for an individual with PD. Pre-op audiogram for patient LG included in present study (see Figure 2.9 for post-operative audiogram). ........................................................................................................ 36
Figure 2.9: Example of post-operative audiogram following CI with hearing preservation techniques. This audiogram is patient LG observed at 12 months post-CI (see pre-op audiogram Figure 2.8).

Figure 2.10: CI processors designed for use with EAS. Shown above are the Nucleus 7 Hybrid, Nucleus 6 Hybrid and Sonnet EAS. Images sourced from Cochlear Ltd. and MED-EL.

Figure 4.1: Hearing levels for each participant in the PD group. The group average is shown with black squares and dotted line.

Figure 4.2: Hearing levels for each participant in the Profound Loss group. The group average is shown with black squares and dotted line.

Figure 4.3: Comparison of the pre-implant and 3-month post-implant speech perception scores for the PD and Profound Loss (PrL) groups. The left panel shows the pre- and post-implant monaural scores; the right panel shows the corresponding binaural scores.

Figure 4.4: Comparison of the percentage speech perception improvement for the PD and Profound Loss (PrL) groups (measured by difference in scores at 3 months post-implant compared to pre-implant). The left panel shows the monaural improvement; the right panel shows the binaural improvement.

Figure 5.1: Flowchart of Participants in the study to 3 months post-implant.

Figure 5.2: Median pre- and post-operative audiometric thresholds for 139 TSEA recipients at 3 months post-implant. Error bars represent 95% confidence intervals.

Figure 5.3: The pre- and post-implant LFPTM for 78 TSEA recipients with functional pre-implant low frequency hearing. The diagonal line represents the ideal scenario where post-implant hearing is the same as pre-implant.
Figure 5.4: Change in LFPTM over time, comparing Group 1 (n=31) and Group 2 (n=47) .............................................................. 109

Figure 5.5: Scatterplots of angular depth of insertion versus change in LFPTM from pre-implant to 3 months post-op for n=78 adult recipients of a TSEA. No significant relationships were found (p=0.177) .............................................................................. 109

Figure 5.6: Comparison of pre-operative hearing between Group 1 and Group 2. A significant difference was found in the pre-operative LFPTM between the groups (p<0.001). .............................................................................................................. 112

Figure 6.1: Comparison of pre- and post-operative hearing for the TSEA Group (6.1a) and PM Group (6.1b). Group average hearing levels shown in dB HL pre-operatively and 3 months post-implant, error bars indicating 95% confidence interval of the mean. .......................................................................................................................... 132
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4FA</td>
<td>Four Frequency Average</td>
</tr>
<tr>
<td>ACE</td>
<td>Advanced Combination Encoder</td>
</tr>
<tr>
<td>AGC</td>
<td>Automatic Gain Control</td>
</tr>
<tr>
<td>ANOVA</td>
<td>Analysis of Variance</td>
</tr>
<tr>
<td>CI</td>
<td>Cochlear Implant</td>
</tr>
<tr>
<td>CNC</td>
<td>Consonant-Nucleus-Consonant</td>
</tr>
<tr>
<td>CT</td>
<td>Computed Tomography</td>
</tr>
<tr>
<td>CUNY</td>
<td>City University of New York</td>
</tr>
<tr>
<td>dB HL</td>
<td>Decibels Hearing Level</td>
</tr>
<tr>
<td>dB SPL</td>
<td>Decibels Sound Pressure Level</td>
</tr>
<tr>
<td>EAS</td>
<td>Electro-Acoustic Stimulation</td>
</tr>
<tr>
<td>ECochG</td>
<td>Electrocochleography</td>
</tr>
<tr>
<td>HA</td>
<td>Hearing Aid</td>
</tr>
<tr>
<td>Hz</td>
<td>Hertz</td>
</tr>
<tr>
<td>ILTASS</td>
<td>International Long Term Average Speech Spectrum</td>
</tr>
<tr>
<td>LFPTM</td>
<td>Low Frequency Pure Tone Median</td>
</tr>
<tr>
<td>PD</td>
<td>Partial Deafness</td>
</tr>
<tr>
<td>RVEEH</td>
<td>Royal Victorian Eye &amp; Ear Hospital</td>
</tr>
<tr>
<td>SNHL</td>
<td>Sensorineural Hearing Loss</td>
</tr>
<tr>
<td>SNR</td>
<td>Signal-to-noise Ratio</td>
</tr>
<tr>
<td>SRT</td>
<td>Speech Reception Threshold</td>
</tr>
<tr>
<td>ST</td>
<td>Scala Tympani</td>
</tr>
<tr>
<td>SV</td>
<td>Scala Vestibuli</td>
</tr>
<tr>
<td>TEN</td>
<td>Threshold-Equalizing Noise</td>
</tr>
<tr>
<td>TSEA</td>
<td>Thin Straight Electrode Array</td>
</tr>
<tr>
<td>TSPS</td>
<td>Total Speech Perception Score</td>
</tr>
</tbody>
</table>
1. Introduction

1.1. Overview

Since the multi-channel CI became commercially available in the early 1980s, clinics have seen improvements in technology and outcomes over time. The population considering a CI has shifted from only persons with severe-to-profound audiometric thresholds or worse bilaterally (the ‘traditional’ CI candidate), to recent candidacy guidelines that suggest that persons with moderate to profound sensorineural hearing loss (SNHL) in the ear to be implanted may consider proceeding with a CI (Leigh, Moran, Hollow, & Dowell, 2016). The changes to the pre-implant hearing status for persons considering unilateral or bilateral CIs have necessitated a shift in outcome expectations and as a result altered discussions that clinicians and surgeons are engaging in.

The purpose of this project was to examine the CI outcomes in this current population of adult CI candidates who have significant residual hearing, also referred to in the literature as ‘partial deafness’ or PD (Skarzynski, Lorens, & Piotrowska, 2003). In doing so, the aim is to produce data to support evidence-based recommendations for this population of CI candidates, to support accurate pre-implant counselling discussions for the clinical/surgical teams, and thus improve the decision-making process for each adult with PD undertaking their own CI journey.
1.2. Statement of Research Questions

1.2.1. Aims

This study aims to assess the hearing preservation and speech perception outcomes for a large group of adults with PD whose pre-implant hearing was defined as functional in the low frequencies (≤70 dB HL) with profound hearing loss in the high frequencies. These persons received a CI at the RVEEH.

Specifically, the project will have three primary aims:

1. To assess whether there is a difference in speech perception outcomes for adults with PD using CIs compared to the traditional CI candidates. To address this aim, comparisons will be drawn between persons implanted with a CI that is closer to the modiolus (i.e. a perimodiolar electrode array, specifically Cochlear Nucleus Contour Advance) using electric-only hearing. These findings will guide clinical decision-making for adults with PD with respect to potential to benefit from a CI.

2. To assess the hearing preservation outcomes for adults with PD using a CI and investigate predictive factors relating to degree of change in hearing. To address this aim, hearing preservation outcomes for adults using a TSEA (specifically, the Cochlear Nucleus CI422 Slim Straight) will be studied. These findings will endeavour to provide guidance to clinicians and surgeons regarding realistic expectations for hearing preservation.

3. To assess whether there is a difference in speech perception outcomes of adults with PD using a CI based on the type of electrode array implanted. To address this aim, comparisons will be drawn between persons implanted with a CI with a TSEA and persons implanted with a perimodiolar array who have PD pre-implant. These findings will provide guidance as to whether the type of electrode array chosen has an effect on speech perception outcomes, and this information could potentially be used to maximise outcomes for adults with PD.

Determination of the speech perception outcomes will be made based on data collected at 3 and 12 months post-implant for traditional CI recipients (to address Aim 1) and
adults with PD using lateral wall and perimodiolar electrode arrays (to address Aims 1 and 3). For inclusion in the speech perception analyses, the persons using CIs had an acquired (postlingual) deafness, had no additional disabilities and no known cognitive issues.

Determination of the prevalence of hearing preservation will be made using established methods such as change in hearing in decibels hearing level (dB HL) and the HEARRING Group method (Fraysse et al., 2006; Gstoettner et al., 2004; Skarzynski, Lorens, Piotrowska, & Anderson, 2007; Skarzynski et al., 2013), and novel techniques assessing ‘functional’ hearing. These methods will be applied across the population of adult TSEA recipients at the RVEEH. Comparisons will be made between degree of change in low frequency hearing with angular implant insertion depth in addition to other patient-specific factors (to address Aim 2).

### 1.2.2. Hypotheses

To address the above aims, a number of specific hypotheses were tested in the research:

1. Adults with PD who receive a CI with a perimodiolar electrode array will demonstrate equivalent post-operative speech perception performance to those adults with a profound hearing loss pre-implant (i.e. traditional CI recipient) also using a perimodiolar array, where only electric hearing is used. Speech perception will be measured CI alone using monosyllabic words and sentences in quiet and noise to build a Total Speech Perception Score (TSPS). The TSPS will be analysed for each group stratified by pre-implant hearing loss.

2. For adults with PD using a TSEA (CI422), poorer hearing preservation outcomes will be demonstrated as angular depth of insertion of the electrode array increases. Hearing preservation will be measured by change in post-operative pure tone audiometry as compared to pre-operative results. Angular depth of insertion of the CI electrode array will be measured by analysis of post-operative x-rays by experienced ENT surgeons.

3. For adults with PD using a TSEA, those with better pre-implant low frequency hearing will demonstrate better preservation of functional low frequency hearing post-implant (i.e. lower pure tone thresholds). This will be measured by analysis
of low frequency pure tone thresholds for adults with PD with respect to their post-implant hearing.

4. When pre-operative hearing is controlled to include only those with functional hearing pre-implant, adults with PD using a perimodiolar electrode array will demonstrate better post-operative speech perception outcomes than adults with PD using a TSEA. Speech perception will be measured CI alone (electric-only or with EAS depending on each person’s everyday listening condition) using monosyllabic words and sentences in noise to obtain a TSPS. The TSPS will be analysed for each group stratified by electrode array type.

5. For adults with PD using a TSEA, better post-operative speech perception outcomes will be demonstrated for persons with preserved hearing using EAS compared to those with electric-only hearing. Speech perception will be measured CI alone (electric-only or with EAS depending on each person’s everyday listening condition) using monosyllabic words and sentences in noise to build a TSPS. The TSPS will be analysed for each group stratified by sound processing type (i.e. electric-only or EAS).
1.3. **Structure of Thesis (Chapter Outline)**

A brief summary of hearing loss as a statement of the problem, followed by an overview of the cochlear implant, signal processing and factors related to outcomes with CI are provided in Chapter 2. This is followed by an analysis and summary of the literature relevant to the present research.

Chapter 3 provides an overview of the methodology for the present research.

Chapters 4 to 6 report on three studies conducted within the present research. Peer-reviewed journal articles were published for three studies during the course of the doctoral study, with the third submitted and undergoing review presently (refer to Moran et al. 2014, Moran et al. 2017 and Moran et al. (in press)). As the content of these chapters was derived almost entirely from the journal articles, it is important to note there is some overlap between the introductory comments in each of these chapters and the literature review presented in Chapter 2.

In Chapter 4, Aim 1 is reported on with specific reference to Hypothesis 1.

In Chapter 5, Aim 2 is reported on with specific reference to Hypothesis 2 and 3.

In Chapter 6, Aim 3 is reported on with specific reference to Hypothesis 4 and 5.

Chapter 7 discusses the outcomes for each study, their combined relevance to the aims and hypotheses for this research, and the implications from these findings. Overall conclusions for the thesis are provided in Chapter 8.

Chapters 9 to 14 comprise the list of publications/presentations arising from the present research, the complete reference list for the thesis, and appendices respectively.
2. Summary and Analysis of the Relevant Literature

2.1. Hearing loss

Hearing loss is a condition affecting both adults and children which represents a significant health issue. The World Health Organization estimated that in 2018, there were 466 million people living with disabling hearing loss across the globe, considered to be thresholds of hearing greater than 40 dB HL. Of these 466 million, 93% were adults; 1 in 3 over the age of 65 demonstrating a disabling hearing loss (WHO, 2018). Hearing loss presents both significant direct costs such as health system costs for provision of hearing devices and services, and indirect costs/financial burdens in terms of productivity losses and costs of carers. The economic impact of hearing loss was estimated to be $11.75 billion in Australia in 2005, or 1.4% of GDP (Access Economics, 2006). The 2018 World Health Organization estimated the overall annual cost of hearing loss was 750 billion international dollars globally (WHO, 2018).

In addition to the significant costs associated with hearing loss, there is impact on the social and emotional wellbeing of affected individuals. Reduction in activity participation, social isolation, and an increased risk of distress, anxiety and/or depression have been found in individuals with significant hearing loss, with studies suggesting that hearing loss is associated with a reduced quality of life (Brodie & Ray, 2018). Research has found that rehabilitative devices such as hearing aids (HA) and CIs, which provide individuals with greater access to environmental sound and communication, have demonstrated significant quality of life improvements for individuals with hearing loss (Brodie, Smith, & Ray, 2018; Chisolm et al., 2007; Hawthorne et al., 2004).

Hearing sensitivity is measured by an audiological assessment including pure tone audiometry. The results of pure tone audiometry assist classification by type, severity and frequency. Where an individual has hearing loss, the severity of the loss is determined by the intensity level of the audiometric thresholds (measured in dB HL), as described in Figure 2.1. The type of hearing loss relates to the source of the impairment, and may be a conductive, sensorineural or mixed hearing loss (see Figure 2.2 for more
The audiological assessment may also provide an initial indication of type of hearing loss, that is generally confirmed in consultation with medical management (Robinette & Cevette, 2002). This study will focus in particular on adults with severe to profound high frequency SNHL.

High frequency, or ‘sloping’ sensorineural hearing loss is a common configuration of audiometric results in adults and can be caused by a number of etiologies including ageing (presbycusis), noise exposure, ototoxicity and genetic factors. This type of hearing loss typically reduces the audibility of spectral cues of speech, in particular place of articulation cues for high frequency consonants, with subsequent negative effects on the clarity of speech (Miller & Nicely, 1955; Turner, 2006). Sloping hearing loss or PD, in which the hearing loss is mild to moderate or better in the low frequencies, and severe to profound at 1 kHz and above, can present a significant challenge for audiological rehabilitation. Conventional amplification may not always provide adequate benefit to patients with high frequency hearing loss, as issues such as feedback, recruitment, distortion or cochlear dead regions can limit the effective programming of a HA.

Cochlear dead regions have been defined as regions in the cochlea where inner hair cells are non-functional and are prevalent in individuals with SNHL. The presence of cochlear dead regions can be determined using psychophysical tuning curves or the Threshold-Equalizing Noise (TEN) test (see Moore, 2001 and Moore, 2004 for review). Results presented in the literature suggest that cochlear dead regions are likely to be present when absolute hearing thresholds are at 90 dB HL or greater, and 75-80 dB HL in the low frequencies. Vinay and Moore (2007) assessed a sample of 308 adults attending an audiology clinic and found 57.4% of the adults had a dead region in one or both ears. Their study concluded that while the presence or absence of cochlear dead regions could not be reliably predicted from the audiogram, there was a greater prevalence of dead regions when the absolute hearing thresholds were above 70 dB HL. Vickers, Moore, and Baer (2001) examined the speech perception of a group of adults (18 ears) using vowel-consonant-vowel nonsense syllables in quiet with low-pass filters to alter the degree of high frequency information. Individuals without cochlear dead regions demonstrated increased speech perception with increasing low-pass filter cutoff frequency (i.e. the more high frequency information, the better the nonsense syllable
Individuals who had been determined to have cochlear dead regions demonstrated increased speech perception with increasing filter cutoff frequency, however only to the point where this frequency exceeded their estimated dead region frequency. Following this, increasing the low-pass filter cutoff frequency either provided no benefit or led to a decrease in speech perception. A similar pattern was found by Baer, Moore, and Kluk (2002) when examining the perception of nonsense syllables in noise for individuals with and without cochlear dead regions. Their results suggested that individuals with high frequency hearing loss with cochlear dead regions may not benefit from amplification of frequencies above the determined dead region. Increasing amplification in high frequency regions where the hearing loss exceeds 55 dB HL has been found to offer little to no improvement in speech perception performance in a variety of studies, and can sometimes lead to a decrease in scores (Ching, Dillon, & Byrne, 1998; Hogan & Turner, 1998; Turner & Cummings, 1999).

![Classification of hearing impairment severity](image)

Figure 2.1: Classification of hearing impairment severity, adapted from Harrell (2002)
Figure 2.2: Anatomy of the ear, adapted from HEARnet Learning (2016).
2.2. Amplification options in adults with high frequency SNHL

A HA, as defined by Staab (2002), is a device that functions to “amplify sounds to a degree and in a manner that will enable a person with hearing impairment to use his or her remaining hearing in an effective manner” (Staab, 2002, p.631). According to Dillon (2012), the amplification provided by HAs works to partially overcome the difficulties a hearing impaired person experiences. As noted in Section 2.1, individuals with significant high frequency SNHL may not demonstrate benefit from amplification using HAs if the degree of hearing loss is too great.

One method proposed to overcome the issues involved in amplifying sound to those with significant high frequency SNHL is frequency shifting. The aim of frequency shifting is to take sounds from the high frequency portion of the spectrum that cannot be effectively used or processed by the corresponding region of the cochlea, and convert these to lower frequency sounds that may be better used by the individual (Braida et al., 1979). This has been implemented in digital HAs in recent years as frequency compression and frequency transposition (Kuk, 2006; Nyffeler, 2008). Results in the literature on experimental outcomes have been mixed, with no clear consensus on the benefits of frequency compression or transposition aids in individuals with sloping high frequency SNHL (Glista et al., 2009; Kuk, Keenan, Korhonen, & Lau, 2009; Simpson, Hersbach, & McDermott, 2006; Simpson, McDermott, & Dowell, 2005). The literature suggests that frequency compression or frequency transposition HAs may not be the ideal solution for individuals with a more severely sloping audiometric configuration. While Simpson et al. (2005), Glista et al. (2009) and Kuk et al. (2009) demonstrated improvements in speech recognition in groups of participants with moderately sloping hearing losses, a study by Simpson and colleagues (2006) which investigated listeners with severely sloping audiograms, demonstrated no measurable benefit with a frequency compression device in comparison to conventional amplification. It should be noted that the participants in the Simpson et al., (2006) study all had hearing levels in the profound range above 1000Hz. O’Brien, Yeend, Hartley, Keidser, and Nyffeler (2010) studied the sound localization and speech perception in noise for a group of adults with PD using frequency compression HAs. The results of their study suggested frequency
compression provided no benefit to front-back localization and had no significant effect on speech perception in noise.

While altering the sound processing has not necessarily provided a benefit for adults with PD (i.e. adults with at least a severe high frequency SNHL) using HAs, some benefit has been found by altering the earmould. The earmould is an essential part of the HA fitting, it is shaped to the individual’s ear and aids in the retention of the device and the passage of sound transmission (Dillon, 2012). Earmoulds range from closed and completely occluding to open with large venting, with modern systems incorporating open domes as a retention option. Noble, Sinclair, and Byrne (1998) reported that for a group of adults with high frequency SNHL and normal/near-normal low frequency hearing, open earmoulds led to better sound localization. It was proposed that the open earmould provided improved access to natural low frequency sound and enabled use of natural inter-aural time difference cues.

Given limited speech perception benefits from amplification, other options must be available to optimise hearing for adults with PD. With the known benefits provided by natural low frequency hearing, it is not surprising that clinicians and patients are motivated to retain natural low frequency hearing and combine this with optimised speech perception via a CI.
2.3. Cochlear Implantation

CI is now widely considered to be the standard of care for adults and children with a severe to profound SNHL. Modern CI systems have proven to be successful in providing significant auditory benefit, enabling patients improved access to sound and greater open-set speech perception. It has been widely established in the literature that a CI can provide a significant benefit to communication and speech discrimination for adults with an acquired hearing loss, with significant improvements documented in open-set speech perception assessments (Blamey et al., 2013; Skinner et al., 2002). Benefits of CIs to children have also been observed, whereby children who have received CIs from an early age can demonstrate speech and language skills commensurate with the normal range for their typically developing peers (Dettman et al., 2016; Dettman, Leigh, Dowell, Pinder, & Briggs, 2007; Leigh, Dettman, Dowell, & Briggs, 2013).

2.3.1. Background and changes in indications

While the first successful multichannel CI was implanted in 1978, this milestone was preceded by a considerable volume of research into electrical stimulation of the auditory nerve, first documented by Djourno and Eyries in 1957 (Djourno & Eyries, 1957). The development of single-channel CI systems followed in 1972 (Fretz & Fravel, 1985) by House and colleagues, which were implanted in adults and children during the 1970s and 80s. Single-channel CIs provided some auditory benefit and were an aid to lip-reading. During the same period, several research groups were investigating CI development with multiple channels, including teams at Stanford University, the University of California San Francisco (UCSF), Clark and colleagues at the University of Melbourne, in addition to House (Mudry & Mills, 2013; Roland & Tobey, 2013). The first commercial multi-channel CI was successfully developed and implanted by Clark and colleagues in 1978 and was approved for use by the United States Food and Drug Administration in 1985 (Clark, 2006; Clark, Pyman, & Bailey, 1979). At this time, it was first indicated for individuals with profound-to-total sensorineural hearing loss and 0% speech discrimination (Clark et al., 1984).

Since this time, further advances in technology have seen modifications to both the internal and external components of CI systems in addition to improvements in sound
coding strategies. These developments have led to documented improvements in speech discrimination for CI recipients from less than 38% open-set sentence recognition with the prototype multi-channel CI system with early sound coding strategies (n=2) (Clark et al., 1984), to median open-set sentence recognition of 89% (Leigh et al., 2016). Significant numbers of adults have demonstrated scores of 100% on open-set sentence discrimination (Clark, 2006; Dowell, Mecklenburg, & Clark, 1986; Leigh et al., 2016; Skinner et al., 2002). Improved outcomes for adults using CIs influenced candidacy recommendation guidelines. Where once an adult was required to have profound-to-total bilateral SNHL to be considered for a CI, the current evidence-based criteria for recommending a CI at the RVEEH is a moderate-to-profound SNHL in the ear to be implanted, with equal to or less than 55% discrimination of phonemes on a monosyllabic word test (Leigh et al., 2016).

2.3.2. How a cochlear implant works

A typical CI system consists of an external microphone and sound processor, typically

![Figure 2.3: How a CI works.](image)

1) Microphones on a sound processor capture speech and environmental sound and convert it into digital code. 2) The sound processor transmits the coded sound through the external coil. 3) The receiver-stimulator receives the code and converts it into electrical impulses. These are sent to the electrode array placed inside the cochlea. 4) The impulses from the electrode array stimulate spiral ganglion neurons and this message is sent along the auditory nerve to the brain. Image courtesy of Cochlear Ltd.
worn on the pinna, combined with an internal prosthesis with a receiver-stimulator and array of intra-cochlear electrodes which is surgically implanted. See Figure 2.3 for a diagram of the placement of a CI. As a broad overview, the microphones on the external sound processor capture speech and environmental sounds. The signal is filtered into a number of tonotopically arranged band-pass frequency bands, similar to the auditory filters in a normally hearing cochlea, which perform a spectral analysis of the signal. The processed signal is converted into a stream of electrical stimulus signals and sent to the sound processor coil. The signal is sent from the external coil to the internal receiver-stimulator via radio frequency. The receiver-stimulator converts this code into electrical current pulses which are sent to the relevant location along the electrode array inside the cochlea. Whereby the normal process of activation of hair cells would trigger an action potential in the underlying spiral ganglion cells, the CI electrode array directly stimulates this internal cochlear architecture, and the impulse is propagated along the auditory nerve to the brain (Clark, 2006).

Today there are various CI manufacturers with their own sound processing algorithms and enhancements, but similarities exist across all modern devices. The main CI sound processing strategies used in commercially-available CI systems are the Advanced Combination Encoder (ACE), Continuous Interleaved Sampling (CIS) and Spectral-Peak (SPEAK) (James et al., 2002; Vandali, Whitford, Plant, & Clark, 2000). The signal processing of these strategies can be described generally as per Figure 2.4. In accordance with this, the microphones pick up environmental sounds and speech which is processed initially at the front end following conversion to digital code. The front end amplifies the signal and performs pre-processing including microphone directionality determination, in addition to being the first site of processing using automatic gain control (AGC). AGC is used to adjust the sound dynamically in response to the input level, and can be designed to act at various time constants (i.e. “fast”, “slow” or “mid” AGC). The signal is then taken to the band-pass filterbank and separated into multiple bands based on the frequency of the signal. Each of these bands represents a channel or electrode that is used in the individual’s custom fit CI program or ‘map’, and the location of stimulation is designed to mimic that of a normally hearing ear. For example, a low pitch input signal will be allocated to a lower frequency band and if selected for stimulation, the channel/electrode stimulated will be in the apical region of
the cochlea. Conversely, an incoming high pitch signal will be allocated to a higher frequency band and if selected for stimulation, the channel/electrode stimulated will be in the basal region of the cochlea. Following the filterbank allocation, the signal is sampled based on the amplitude envelope of the signal, and stimulation channels are selected for based on the strategy used. From here, the amplitude of current pulses on the various electrodes is encoded based on the individual’s map (i.e. Threshold and Comfort levels as per the Nucleus system), the code is sent via radio frequency (RF) link to the implant and electrical pulses are produced on the electrode array (Boyle, Buchner, Stone, Lenarz, & Moore, 2009; Patrick, Busby, & Gibson, 2006; Swanson et al., 2007).

In addition to these basic steps, individual CI manufacturers have their own advances that provide enhancement to the sound signal for their recipients hence the signal flow diagram presented in Figure 2.4 highlights the generic sound processing and commonalities amongst devices.

Figure 2.4: CI signal processing
2.4. Factors associated with cochlear implant outcomes

As discussed in Section 2.3.1, modern CI systems have proven to be successful in providing significant auditory benefit, enabling patients improved access to sound and greater open-set speech perception. Research has shown that adults with an acquired, or postlingual hearing loss have the potential to achieve great improvements in their speech perception performance with a CI (Dowell, 2005; Leigh, Hollow, Winton, Tari, & Dowell, 2010). As an example, a study of 22 adult cochlear implant recipients by Gifford and colleagues (2010) demonstrated a highly significant improvement in the implanted ear where the mean implant-alone monosyllabic word score post-implant was 67% compared to 31% pre-implant in the ear to be implanted (p<0.001). While research on CI outcomes for adults with an acquired hearing loss has demonstrated excellent outcomes with modern technology, a large degree of variability is still observed in outcomes (Blamey et al., 1996; Leigh et al., 2016). In one of the largest studies of CI outcomes, Blamey et al. (1996) examined the factors associated with speech perception in 808 adult CI users accounting for changes in technology. Their study identified the following factors associated with outcomes, which will be discussed further: duration of deafness; age at implantation; and age at onset of hearing loss (Blamey et al., 1996).

2.4.1. Duration of deafness

The terminology of ‘duration of deafness’ typically refers to the amount of time in years for which an individual has experienced severe-to-profound hearing loss. It has been proposed that an extended duration of deafness and the subsequent auditory deprivation may lead to degeneration of the cochlea, reductions in spiral ganglion cell survival, and deterioration of central auditory processing skills (Blamey et al., 1996). It is therefore reasonable that these changes may have an impact on an individual’s potential outcomes with a CI.

In the cohort examined by Blamey et al. (1996), duration of deafness accounted for 13% of the variance in speech perception outcomes. A significant correlation was found between poorer speech discrimination scores with increasing duration of deafness. Similar findings were obtained in subsequent studies with increasing duration of deafness being shown to have a negative effect on speech perception performance outcomes (Blamey et al., 2013; Dowell, 2005; Holden et al., 2013).
In a follow-up study of 2251 CI recipients implanted since 2003, Blamey et al. (2013) found that while duration of deafness had a significant negative correlation with speech perception outcomes it accounted for less variance than in their aforementioned study. The authors concluded this was due to a decrease in the number of recipients with extended durations of deafness and reflected the changing population of individuals receiving CIs (Blamey et al., 2013). Holden et al. (2016) also did not find any significant correlation between duration of deafness and speech perception outcomes. The authors proposed this was related to the individuals in their study having significant residual hearing; they continued to utilise HAs pre-CI, thereby potentially mitigating the effects of auditory deprivation. In other words, it could be proposed that these recipients were not functionally profoundly deaf pre-implant (Holden et al., 2016).

2.4.2. Age at implantation

Age at implantation refers to the age in years for each individual at the time of CI surgery. While there is no upper age limit for CI surgery, it has been suggested that a greater age at CI may be associated with decreased auditory performance due to age-related natural degeneration in areas such as the spiral ganglion, and poorer central auditory processes in addition to cognitive factors (Blamey et al., 1996). Several studies have demonstrated that increasing age at implantation was significantly negatively correlated with speech perception performance (Blamey et al., 1996; Friedland, Runge-Samuelson, Baig, & Jensen, 2010; Holden et al., 2013; Holden et al., 2016; Rubinstein, Parkinson, Tyler, & Gantz, 1999). In a case-control study, Friedland et al. (2010) examined the results for 28 adults implanted over the age of 65 years with a matched group of adults implanted between 18 to 64 years. Their study found that while both groups showed significant speech perception improvement with their CIs compared to pre-implant, the speech perception scores were significantly poorer for the older-at-implant group at 12 months post-implant compared with the younger-at-implant group (70% versus 83% for open-set sentences in quiet, 38% versus 53% for monosyllabic words). Their study also demonstrated a trend for poorer open-set sentence scores with increasing age (Friedland et al., 2010). Wong et al., (2016) examined three groups of older CI recipients (75-79, 80-84, and 85+ years at implant). While there were no significant differences in speech perception scores between the age groups, there was greater variability in scores obtained by the 85+ age group.
Comparing the results from the Wong study to those presented Leigh et al. (2016) with data comprised of postlingually deafened adult CI recipients where age at implant ranged from 19.2-93.4 years, a difference is noted in the speech perception outcomes. While the speech perception outcomes for open set words and phonemes are similar, the median sentence in quiet scores for the 85+ age group were lower than those presented in Leigh et al. (89% in Leigh compared with approximately 65% in Wong at 12 months post implant).

The mechanism or reasoning behind poorer speech perception outcomes for older persons using CIs was not addressed by the above studies. It is likely that changes in auditory and cognitive processing in these mature age groups confound our understanding of potential CI benefit (Gates, Feeney, & Mills, 2008; Holden et al., 2016; Lin et al., 2012; Wong, Moran, & O’Leary, 2016). Lin et al. (2012) presented a comprehensive examination of the speech perception outcomes in older adults using CIs, controlling for age at onset of hearing loss which has been found to influence outcomes (see Section 2.4.3). In their study of 445 adults implanted over the age of 65, post-CI scores were negatively associated with increasing age. There was 1.3 percentage points less speech perception gain for each added year of age at implant (Lin et al., 2012). The authors proposed that this association was due to the top-down cognitive processing required for an individual to make sense of the CI input; a function that is known to decline with increasing age (Lin et al., 2012).

2.4.3. Age at onset of hearing loss

The age at onset of hearing loss has been associated with speech perception outcomes for adult CI recipients. Adults who have experienced an onset of hearing loss prior to the acquisition of language (i.e. a prelingual hearing loss) have been shown to have poorer speech perception outcomes with a CI than their peers who acquired hearing loss after the acquisition of language (i.e. postlingual hearing loss) (Boisvert, McMahon, Dowell, & Lyxell, 2015; Dowell, Hollow, & Winton, 2004).

Speech perception outcomes are more variable for prelingually deaf adult CI recipients, as demographic factors such as aetiology and mode of communication are also highly variable in this population. While some studies have shown that significant speech perception benefit from CIs is possible despite a prelingual onset of hearing loss, other
studies have demonstrated poorer open-set speech recognition compared to persons with a postlingual onset of hearing loss (Kaplan, Shipp, Chen, Ng, & Nedzelski, 2003; Santarelli, De Filippi, Genovese, & Arslan, 2008). Despite differences in their post-operative outcomes, both pre- and postlingually deafened adult CI recipients have demonstrated significant quality of life improvements following implantation (Hawthorne et al., 2004; Kaplan et al., 2003; Palmer, Niparko, Wyatt, Rothman, & de Lissovoy, 1999). This point emphasises the need for clinicians to consider discussing potential quality of life benefits and not merely speech perception scores when providing CI candidacy and expectations counselling.

2.4.4. Placement of the electrode array

The placement of the electrode array has been shown to be correlated with speech perception outcomes for adults using CIs. In the discussion of placement, this manuscript will discuss placement firstly in relation to surgical positioning (i.e. the electrode array sitting within Scala Tympani, ST, or Scala Vestibuli, SV) and secondly in relation to electrode array design (i.e. lateral wall versus perimodiolar positioning).

The multi-channel cochlear implant was initially designed with a straight electrode array that, when inserted, would track inside the cochlear duct and approximate the lateral wall of the cochlea in the ST. Commercial CI manufacturers now produce perimodiolar electrode arrays, designed to sit close to the modiolus in the cochlea, in addition to mid-scalar electrode arrays that sit between the modiolus and lateral wall (Frisch, Carlson, Lane, & Driscoll, 2015; Patrick et al., 2006; Tykocinski et al., 2001).

Figure 2.5: Comparison of two types of CI electrode arrays. The Contour Advance is a perimodiolar array and the Slim Straight is a lateral wall array. Image: Cochlear Limited.
For the purpose of this analysis, only lateral wall and perimodiolar electrodes will be discussed. Examples of these devices are shown in Figure 2.5.

Certain surgical and device factors have been related to speech perception outcomes for adult CI recipients. Placement of the electrode array in the cochlea appears to be important, in that ST location has been shown to provide superior outcomes to SV location (Aschendorff, Kromeier, Klenzner, & Laszig, 2007; O'Connell, Hunter, & Wanna, 2016; Wanna et al., 2014). In a comprehensive analysis of 522 adult CI recipients from the literature, O'Connell, Hunter, et al. (2016) demonstrated that post-operative speech perception scores were significantly better for ST insertion compared to SV insertion. Additionally, Skinner et al. (2007) analysed post-CI imaging data with speech perception outcomes for 15 CI recipients and found a significant negative correlation between monosyllabic words scores and number of electrodes in SV. This negative correlation may be related to the notion of insertion trauma, as a result of the electrode array translocation from ST to SV. Finley et al. (2008) discussed the possibility of “cross-turn stimulation” for an electrode array in SV, whereby activation of a single electrode site has the possibility of stimulating two populations of spiral ganglion cells in different cochlear turns, leading to frequency confusions and therefore diminished speech perception. If the electrode array trajectory translocates from ST to SV, this will lead to acute mechanical trauma, including fixation of the basilar membrane at the point of penetration; loss of the surviving hair cells; or potentially loss of spiral ganglion cells, and reduced benefits (O'Connell, Hunter, et al., 2016; Roland, 2005; Skinner et al., 2007). For an overview of the proposed mechanisms for insertion trauma, see Table 2.1.

The proximity of the electrode array to the modiolus has also been indicated to be a contributor to speech perception outcomes. CI electrode arrays that are curved and positioned adjacent to the modiolus (i.e. perimodiolar electrode) are closer to the target neural receptors than those that are straight and positioned closer to the cochlear outer wall (i.e. lateral wall electrodes). By comparison, perimodiolar arrays have lower current requirements than lateral wall arrays, leading to reduced channel interaction and the likelihood of better speech perception outcomes (Chatterjee & Shannon, 1998; Chatterjee, Galvin, Fu & Shannon, 2006; K. A. Gordon & Papsin, 2013; Litvak, Spahr & Emadi, 2007; Saunders et al., 2002). In a multi-centre study of 21 adults using a
Table 2.1: Potential mechanisms of trauma related to cochlear implantation, adapted from O'Connell et al. (2016).

<table>
<thead>
<tr>
<th>Potential mechanisms of trauma related to cochlear implantation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute mechanical trauma</strong></td>
</tr>
<tr>
<td>Fracture of the osseous spiral lamina, with injury to dendrite processes</td>
</tr>
<tr>
<td>Damage to the modiolus, with injury to spiral ganglion cells along medial wall of ST</td>
</tr>
<tr>
<td>Damage to the lateral wall of the cochlea, with injury to spiral ligament, organ of Corti or stria vascularis</td>
</tr>
<tr>
<td>Rupture of the cochlear partitions resulting from electrode translocation from ST to SV</td>
</tr>
<tr>
<td>Compression or tearing of cochlear vasculature</td>
</tr>
<tr>
<td><strong>Acute non-mechanical trauma</strong></td>
</tr>
<tr>
<td>Acoustic trauma related to drilling of cochlea and/or temporal bone</td>
</tr>
<tr>
<td>Disruption of cochlear fluid via mixing of endolymph and perilymph as a result of mechanical trauma (see above), excessive suctioning or the introduction of blood into the ST</td>
</tr>
<tr>
<td><strong>Sub-acute or delayed events</strong></td>
</tr>
<tr>
<td>Labyrinthitis secondary to introduction of middle ear flora into the cochlea</td>
</tr>
<tr>
<td>Reaction to the electrode array (i.e. “foreign body”)</td>
</tr>
<tr>
<td>Fibrosis or ossification</td>
</tr>
<tr>
<td>Activation of apoptotic pathways with resultant delayed neural injury</td>
</tr>
</tbody>
</table>

Nucleus 24 implant with a perimodiolar electrode array compared with 36 adults using a Nucleus 24 implant with a straight array, Saunders et al. (2002) demonstrated that persons using the perimodiolar device had significantly lower psychophysical intensity-reception measures (Threshold and Comfort levels) than their peers using a straight device. Their study also examined the group using perimodiolar electrode arrays,
comparing psychophysical measures with radial distance determined by x-ray. They found a significant relationship between Threshold and Comfort levels based on radial distance, suggesting that proximity to the modiolus and neural elements of the cochlea was related to the electrical current requirements for perception of stimulation (Saunders et al., 2002). The relationship between electrode-to-modiolus distance and charge has also been highlighted in more recent studies, with electrodes placed further from the modiolus shown to required higher upper stimulation levels and higher levels required to produce an electrically-evoked Compound Action Potential (Davis et al., 2016; Park et al., 2017).

The concept that the position of the CI electrode array in the cochlea and how loosely or tightly coiled it is around the modiolus, i.e. the electrode ‘wrapping factor’ as described by Holden et al. (2013) and demonstrated in Figure 2.6, would be associated with less spread of excitation in the cochlear may be due to reduced current requirements. Hughes and Goulson (2011) studied spread of excitation using electrically evoked compound action potentials, and compared six perimodiolar electrode arrays (Nucleus Freedom Contour Advance) with six lateral wall arrays (AB HiFocus). Their study did not find any significant difference between the device types, however large variance was noted with small participant numbers. It is also worth noting that while their study compared electrode array types, the CIs were manufactured by two different companies so there may have been inherent differences in the modes of stimulation. It would be of interest to compare spread of excitation for groups of CI users who differed only on the variable of interest; for example electrode array type or wrapping factor.

Studies that have reviewed speech perception outcomes in combination with electrode position in the cochlea include a retrospective study of 465 adult CI recipients who received their CI between 1994 and 2006 (Dowell, 2012). In their study, persons using a perimodiolar electrode array demonstrated significantly better speech perception outcomes than persons using lateral wall arrays; this was particularly the case for the sentence perception in noise. While there was a 5% difference in speech perception performance for the monosyllabic word test and the sentence test in quiet, the perimodiolar group demonstrated a 20% improvement in sentence in noise outcomes (10 dB signal-to-noise ratio (SNR)) compared to the lateral wall group (Dowell, 2012). In a study of 114 adults using a variety of CIs, Holden et al. (2013) assessed the
Computed Tomography (CT) imaging of each participant to determine scalar location. For those participants whose electrode array resided wholly in the ST, speech perception outcomes were correlated with wrapping factor. The wrapping factor was determined from CT imaging as a ratio of lateral wall length and distance between the basal-most and apical-most electrodes to provide a metric of how loosely or tightly wrapped the electrode array was with respect to the modiolus. Using the wrapping factor algorithm as proposed in Holden et al. (2013), a smaller wrapping factor represents an electrode array more tightly coiled around the modiolus, as shown in Figure 2.6. This study found a significant inverse relationship between wrapping factor and monosyllabic word score, in that the positioning of the electrode array closer to the modiolus was associated with better speech perception (Holden et al., 2013). Van der Beek, Boermans, Verbist, Briaire, and Frijns (2005) reported comparable results following analysis of speech perception outcomes for the Clarion CII HiFocus implant with and without electrode array positioner. The positioner enabled the electrode array to sit closer to the modiolus in the basal end of the cochlea, and persons with the positioner demonstrated significantly greater speech perception scores for a monosyllabic word test compared to persons without positioner (i.e. electrode arrays

![Figure 2.6: Demonstrating Wrapping Factor - example insertions for electrode arrays and corresponding wrapping factor (image from Holden (2013))](image-url)
were further from the modiolus) (Van der Beek et al., 2005).

2.4.5. Variance in CI outcomes

Whilst several factors known to have a relationship with the speech perception outcome for adults using CI have been identified (Sections 2.4.1 - 2.4.4) it is acknowledged that the majority of variance in speech perception outcomes remains unaccounted for. The aforementioned study of 800 adult CI recipients by Blamey et al. (1996) proposed a model for outcome prediction using some of the factors discussed, in addition to aetiology and duration of CI use. The authors reported that these combined factors accounted for 21% of speech perception variance. After accounting for the inherent variability of the data (i.e. patient sampling, test-retest variability of speech perception tasks), a large amount of variance is still ‘unexplained’. This unexplained variance is likely to include patient-specific factors such as cognitive abilities, plasticity of the central nervous system, integrity of the auditory system of the individual, in addition to various unknown idiosyncratic factors. Blamey et al. (1996) termed these patient-specific factors ‘primary factors’, which while difficult to measure may be inherently related to secondary factors such as those described above. For example, the secondary factor of duration of deafness may be intrinsically linked with the integrity of a person’s auditory system (i.e. surviving ganglion cell population).

When Blamey et al. (2013) replicated their study some years later with 2251 adult CI users across 15 centres, the original list of factors affecting speech perception outcomes were still significant but their relative importance had changed. For example, the impact of duration of deafness had a reduced effect on speech perception which the authors proposed was due to changing selection CI criteria leading to a reduction in pre-CI auditory deprivation (Blamey et al., 2013). Their list of identified factors accounted for 10% of the variance in the speech perception outcomes. The same 2251 adult CI recipients were analysed by Lazard et al. (2012) examining the influence of other factors such as pre-implant HA use, duration of moderate hearing loss, pre-implant residual hearing, CI manufacturer and percentage of active electrodes. When these were included in the model, the percentage of variance explained increased to 22%. This study highlighted the influence of central auditory processing and integrity of the auditory pathways in the modern CI candidate population (Lazard et al., 2012).
Other studies have highlighted similar proportions of unexplained variance in patient outcomes (Dowell, 2012; Green et al., 2007; Holden et al., 2016). Dowell (2012) reported that approximately 30% of the variance in outcomes was explained by the factors age at onset of hearing loss (postlingual versus prelingual), duration of deafness, age at implant, electrode array position (perimodiolar versus straight), in addition to pre-operative speech perception. Clinicians and surgeons involved in pre-CI patient counselling may use the above findings to provide evidence-based recommendations and facilitate their patient’s informed decision-making.
2.5. Music perception for adult cochlear implant recipients

While adults using a CI have the potential to achieve excellent speech perception outcomes as discussed in Section 2.4, it is generally accepted that adults using CI experience poorer music perception compared to their peers with normal hearing. It is thought that much of this can be attributed to poorer perception of pitch, given the ability to discriminate between different pitches is necessary to follow melody in music (McDermott, 2004). For a review of pitch perception in persons with normal hearing and CIs, refer to Moore (2003) and Moore and Carlyon (2005). The following sections will discuss music perception and appreciation for adults using a CI.

2.5.1. Music perception and appreciation in adult CI users

Perception of pitch has been assessed through studies of melodic pattern identification and also familiar melody recognition for adult CI users. Using the Primary Measures of Musical Audiation (PMMA) test (E. E. Gordon, 1979), a standardised test developed to assess music perception in the tonal and rhythmic domains, Gfeller and colleagues investigated the melodic pattern identification of adult CI users. It was found that while CI users were able to complete this task reasonably well with scores of 76-78% correct across studies, they were performing significantly poorer than the comparative group with normal hearing who scored 91% correct for the same task (Gfeller & Lansing, 1992; Gfeller & Lansing, 1991; Gfeller, Woodworth, Robin, Witt, & Knutson, 1997). Leal and colleagues (2003) have also investigated the ability of adults with cochlear implants to hear pitch changes. In a study of 29 adult cochlear implant recipients, it was found that adults with CIs could discriminate the difference between simple melodies with a mean performance level of 89% correct for a “same or different” task. The same group performed poorer when the task became more complex, with average performance of 71% correct (Leal et al., 2003).

Familiar melody recognition has been found to be significantly poorer in adult cochlear implant recipients than their normal hearing adult counterparts. It has been found that the inclusion of lyrics influences the ability of a CI recipient to identify the song. Fujita and Ito (1999) demonstrated that adults with CIs showed a good ability to recognise sung versions of songs with instrumental accompaniment, but that ability deteriorated in the absence of lyrics. A similar finding was reported by Leal (2003), where mean
recognition scores of melodies by adult implantees with and without verbal cues was reported to be 75% and 20% respectively. It has also been found that retention of the original rhythmic cues influences the ability of the CI user to identify a melody. A study by Kong (2004) examined the performance of adults with CIs and with normal hearing on a task of melody perception where the rhythm was either included or absent (i.e. only the melody was present, no rhythmic cues). The individuals with normal hearing achieved 98% correct in both rhythm and no-rhythm tasks, whereas the CI recipients performed significantly less accurately in both conditions achieving 63% in the rhythm-present task and 12% correct in the rhythm-absent task. Similarly, Gfeller (2002) found that songs that were correctly identified more often by both normal hearing and CI recipients were songs identified as rhythmic compared to those identified as arhythmic. This highlights that rhythm perception for adult CI users is similar to those with normal hearing, and a perceptual attribute of music that is well maintained in electric stimulation (Gfeller et al., 1997; Kong et al., 2004).

Likely a result of the reduced ability to perceive pitch and melody, appreciation and enjoyment of music has been reported to be poor for postlingually deafened CI recipients. Gfeller (2000) reported a decrease in music listening habits from pre- to post-implant for a group of 65 adult CI recipients implanted with a variety of devices. This decrease in music listening for adult CI recipients with a postlingual onset of hearing loss has been supported by subsequent studies (Gfeller, Witt, Stordahl, Mehr, & Woodworth, 2000; Looi & She, 2010; Moran, Rousset, & Looi, 2016). There have been limited studies on the music appreciation of persons implanted with a prelingual onset of hearing loss. A study by Moran et al. (2016) demonstrated equivalent music appreciation between a group of 15 prelingually deafened adult CI recipients compared with 15 postlingually deafened adult CI recipients. In addition, Eisenberg (1982) reported on the music appreciation outcomes of 12 prelingually deaf adult CI recipients. The individuals in this study found music to be enjoyable, and that “in some cases, music has been a major motivating factor behind the acceptance of the implant”. The author proposes that the reason for increased enjoyment in this group compared to the postlingually deaf recipients is that knowledge of music for a prelingually deaf person is simply rhythm and intensity cues via a HA pre-implant. The CI maintains the structural
integrity the prelingually deaf individual is familiar with and provides additional information they could not otherwise obtain.

For a comprehensive review of music perception in cochlear implant users, see McDermott (2004).

2.5.2. Music perception for adult CI users with acoustic hearing

As discussed in Section 2.5.1, the limitations on music perception for adult CI recipients are thought to be linked to poor pitch resolution as a result of limitations in coding. It is understood that as for persons with normal hearing, persons using CIs utilise a combination of place and rate pitch cues to encode pitch however these cues are less successful for CI recipients (McKay, 2004). For instance, place of stimulation cues are encoded for CI recipients via stimulation of relevant electrodes along the electrode array. While this makes use of the tonotopic organisation of the cochlea and auditory system, electrical stimulation of the cochlea results in excitation of populations of neurons which cannot be appropriately focussed as per normal hearing. In addition, rate of stimulation cues appear to be only useful up to approximately 300Hz compared to 2000Hz in normally-hearing persons, and place of stimulation cues are also generally poor due to the inability to stimulate a specific population of auditory neurons with accuracy (McDermott & McKay, 1997; Moore & Carlyon, 2005; Pijl & Schwarz, 1995). With an increasing population of individuals with PD proceeding with CI, there has been interest in whether residual low frequency hearing could be advantageous to pitch perception post-implant.

Studies have demonstrated the benefit of low frequency hearing on tasks of music perception, particularly for pitch perception. Looi, McDermott, McKay, and Hickson (2008) compared a group of adult CI users to a group of adults using HAs who met the inclusion criteria for CI at the time (a bilateral severe-to-profound SNHL at 1000Hz and above) but had functional low frequency hearing. The group using HAs performed significantly better than the CI users for pitch and melody identification tests (CI group 52%, HA group 91%), with no significant difference demonstrated for rhythm perception (CI group 93%, HA group 94%). Multiple tasks were used to assess pitch in the Looi study, using both male and female singers and full, half and quarter octave interval tests. For all the sub-tests, the HA group demonstrated superior scores, and
post-hoc analysis of the results showed a significant effect of group (i.e. CI versus HA) and interval size (i.e. poorer results for smaller intervals) (Looi et al., 2008).

Likewise, Sucher and McDermott (2009) demonstrated the addition of acoustic hearing for CI users, via bimodal stimulation with a HA on the contralateral ear, significantly improved melody recognition and complex sound identification compared to CI alone. In this study, melody recognition was assessed using a closed set test of seven melodies for five adults using a CI. It was found that these adults performed significantly better in the CI + HA (bimodal) condition than they did CI-alone, however there was no significant difference between the bimodal condition and HA alone. These results reflect the importance of low frequency acoustic hearing on music perception (Sucher & McDermott, 2009). A similar result was found by Dorman, Gifford, Spahr & McKarns (2008) for melody recognition, where use of acoustic information (either acoustic only or EAS) was shown to significantly out-perform electric-only stimulation.

Gfeller et al. (2006) compared the song recognition and instrument identification for three groups of individuals – 17 adults with normal hearing, 39 adults with a CI with a standard length electrode, and 4 adults with a CI with EAS and preserved low frequency hearing. This study found that the normal hearing and EAS groups significantly out-performed the standard CI group for both song recognition with and without lyrics, and instrument identification in the low frequency category. There were no significant differences between the normal hearing and EAS groups for the aforementioned subtests (see Figure 2.7 for a reprint of these results). However, for instrument identification subdivided into medium and high frequency categories, the normally hearing group performed significantly better than the EAS group (Gfeller et al., 2006). It must be noted that for the adults using EAS, there was no CI-alone or ipsilateral HA-alone test condition, which would be of interest to fully understand the benefits provided by combined electric and acoustic stimulation.

The results of the studies discussed above highlight the advantage of acoustic hearing on music perception and demonstrates the importance of preserving residual low frequency hearing for those with PD proceeding with a CI.
Figure 2.7: Melody and Instrument recognition results from Gfeller, Olszewski, Turner, Gantz, and Oleson (2006). LE = long electrode (i.e. standard length), Hybrid = Nucleus Hybrid electrode using EAS, NH = normal hearing.
2.6. Cochlear implantation and hearing preservation

Improvements in both CI technology and recipient outcomes have led to changes to candidacy criteria for CIs, as discussed in Section 2.3.1 (Dowell, 2005; Gifford, Dorman, Shallop, et al., 2010; Leigh et al., 2010; Plant, McDermott, van Hoesel, Dawson, & Cowan, 2016). This, in turn increases referrals of persons with significant residual hearing. Persons with residual low frequency acoustic hearing, or PD, have ‘something to lose’ should their hearing be lost as a result of CI surgery and their postoperative outcome for hearing with the CI does not meet expectations (i.e. the individual is potentially ‘worse off’). Audiologists are presented with the clinical dilemma of weighing up the risk of losing the residual acoustic hearing versus the unpredictable amount of benefit to be gained by electrically stimulating the cochlea using a CI. Additionally, implanting a person with significant residual hearing pre-CI potentially allows access to providing both electrical stimulation via the CI and acoustic stimulation with a HA to the same ear (i.e. EAS), a concept introduced by von Ilberg et al. (1999). The following section will discuss EAS and residual hearing preservation with respect to CI technology.

2.6.1. Cochlear Implantation for Partial Deafness

As discussed in Sections 2.1 and 2.2, significant high frequency hearing loss can present a challenge to the individual and their relevant family members and carers. Persons with severely sloping hearing loss represent a significant challenge in terms of management. The high frequency hearing in these adults with PD is too poor to gain significant benefit from HAs yet their low frequency hearing places them outside traditional CI criteria. Many persons with a ski-slope audiometric configuration (as demonstrated in Figure 2.8), described as PD by Skarzynski et al. (2003), have unsatisfactory speech perception despite optimal fitting with hearing-aids and therefore their poor performance on speech perception tests place them within CI candidacy guidelines.

Given this dilemma, the electrode array development has progressed to include devices designed for ‘atraumatic’ CI surgery such as the Nucleus Slim Straight CI422 and CI522 (Cochlear), the MED-EL Flex series electrodes, and the Advanced Bionics HiFocus SlimJ electrode. These allow the surgeon to attempt to preserve the residual hearing with a full-length electrode array and a soft surgery approach (Jayawardena,
Kuthubutheen, & Rajan, 2012; Skarzynski et al., 2012). These devices and techniques have been shown to provide excellent speech perception results in persons with PD (Skarzynski, Lorens, Piotrowska, & Anderson, 2006). Preservation of hearing for an adult with PD permits the consideration of an EAS approach to their CI programming. EAS, where a CI may be used in combination with acoustic hearing either aided or unaided, has been shown to provide significant benefits for suitable persons (Buchner et al., 2009; Gstoettner et al., 2008; Turner, Gantz, & Reiss, 2008; Woodson, Reiss, Turner, Gfeller, & Gantz, 2010). Initial studies of EAS utilised CIs with an electrode array that did not extend as deeply in the cochlea as a standard length array, for example the Nucleus Hybrid-L and MED-EL Flex EAS. These provided the benefits of an atraumatic insertion with minimal damage to apical intracochlear structures (Briggs et al., 2006; Gstoettner et al., 2009; von Ilberg, Baumann, Kiefer, Tillein, & Adunka, 2011). This design of electrode array provides electrical stimulation at the basal end of the cochlea while preserving the apical end of the cochlea to allow acoustic low frequency hearing postoperatively for those where residual acoustic hearing is

Figure 2.8: Example of audiometric configuration for an individual with PD. Pre-op audiogram for patient LG included in present study (see Figure 2.9 for post-operative audiogram).
preserved. Patients with relatively poor acoustic thresholds in the low to mid frequencies, however, may not benefit from this approach and rehabilitation options can be limited. With CI technology continually evolving, CIs indicated for EAS have also evolved to include deeper cochlear insertions. There has been some evidence to suggest that deeper insertions lead to improved speech perception outcomes. Gantz and Turner (2003) examined the outcomes of six persons with PD who were implanted with a research CI device for the purpose of EAS, three using a 6mm electrode array and three using a 10mm array. While acoustic hearing was preserved for all six individuals, those implanted with the 10mm electrode array had superior speech perception outcomes compared to those using the 6mm array. The authors proposed that speech recognition was improved in the 10mm array group due to reduction in the degree of frequency mismatch associated with increasing the insertion depth (Gantz & Turner, 2003). In a simulation of EAS, Dorman, Loizou, Spahr, and Dana (2003) presented signals processed through a CI sound processor to a group of normally-hearing listeners who were simulated to have PD and no hearing beyond 500Hz. Using a variety of simulated electrode array insertion depths their study demonstrated significant speech perception benefit with deeper electrode array ‘insertions’ compared to shallower. The group performed 40% better with a simulated implant depth of 19mm compared to a simulated depth of 11mm (Dorman et al., 2003).

Importantly, the Dorman et al. (2003) study highlighted the issue of loss of hearing combined with a shallow insertion of an electrode array. When the group of normally-hearing listeners were presented with a signal as processed through a CI in combination with a simulation of total loss of hearing, speech understanding for simulated insertion depths of 15mm or less were no better than for the simulated “pre-implant” hearing (i.e. hearing only up to 500Hz). In clinical cases such as these where residual hearing is lost, clinicians and surgeons may consider removal of the short array and subsequent reimplantation with a standard length electrode array. Alternatively, standard length electrode arrays combined with soft surgery techniques are now considered as an option for adults with PD. While some studies have shown that residual hearing can be preserved through soft surgery and careful procedures with a standard length electrode array, the outcomes are variable (Gifford et al., 2013; Gifford, Dorman, Sheffield, Teece & Olund, 2014; Gifford et al., 2015; Gifford et al., 2017; Helbig, Baumann, Helbig, von
The underlying rationale for EAS is to maximise the access to high frequency sounds via the CI while maintaining access to natural low frequency signals. By maintaining natural low frequency hearing, a person has the potential to achieve improvements in localisation and speech perception in noise particularly when combined with residual acoustic hearing in the contralateral ear (Helbig et al., 2008; Incerti, Ching, & Cowan, 2014). In the case of binaural hearing, these tasks are improved as a result of the time difference cues conveyed by low frequency signals, which are transmitted to the auditory neurons via phase-locking (Ching, Incerti, & Plant, 2015; Gifford et al. 2014). The improved frequency resolution associated with preserved low frequency hearing has also been associated with improvements in music perception and appreciation in individuals with EAS (Gfeller et al., 2006; Sucher & McDermott, 2009).
It has been documented in the literature that adults with PD who preserved hearing post-CI and use EAS performed better than their peers with traditional CIs. Lorens, Polak, Piotrowska, and Skarzynski (2008) reported on 11 adults using EAS and a control group of 22 adults with CIs and electric-only hearing using a speech reception threshold (SRT) task to determine the SNR required to obtain 50% speech recognition. This study found that the SRT for 50% speech recognition of monosyllables in noise was significantly better for the EAS group (4.2 dB) compared to the electric-only CI group (14.1 dB). Post hoc examination of the EAS group indicated significantly better scores in the EAS configuration compared to the HA or CI alone (Lorens et al., 2008). These results have been replicated by others including James et al. (2006), where improved speech perception in quiet and noise for adults with PD using EAS compared to CI alone was shown. Helbig et al. (2008) also showed significantly better sentence in noise scores with EAS compared to CI alone in 9 adults with PD.

The majority of implanted persons with PD use a HA on the contralateral ear, so it is important to understand whether the inclusion of low frequency information on the implanted ear contributes to their outcomes. Simpson et al. (2009) examined the addition of acoustic hearing to speech perception in quiet and noise for two adults with partial deafness using CIs. While the EAS outcomes were found to be significantly better compared to CI alone, there was no significant difference between EAS outcomes where the HA component was on the ipsilateral side, contralateral side or both. In a larger study of 11 adult participants looking at SRT for 50% correct, Dunn, Perreau, Gantz, and Tyler (2010) found that performance with bilateral acoustic amplification

Figure 2.10: CI processors designed for use with EAS. Shown above are the Nucleus 7 Hybrid, Nucleus 6 Hybrid and Sonnet EAS. Images sourced from Cochlear Ltd. and MED-EL.
and electric stimulation in the CI ear (i.e. EAS + contralateral HA) significantly exceeded EAS alone and bimodal (CI alone + contralateral HA) by approximately 1 dB. Greater SRT advantages were demonstrated by Gifford, Dorman, and Brown (2010) for a group of 64 adult CI recipients using a spatially separated speech in noise task. In their study, average SRTs were 12.2 dB for unilateral recipients and 9.6 dB for bilateral recipients. In adults with one CI, when tested with the contralateral HA in addition to the CI, the average score improved from 12.2 dB to 10.6 dB. Adults using EAS were also tested in the bimodal condition without the ipsilateral HA, and achieved an SRT of 9.6 dB. When these adults using EAS were provided with access to acoustic stimulation in the ipsilateral ear, the mean speech reception thresholds improved further to 6.2 dB (Gifford, Dorman, & Brown, 2010). Comparing the standard bimodal condition with the EAS + contralateral HA condition, a difference of 4.4 dB SNR was seen, which equated to a 45% improvement in speech perception performance due to the addition of acoustic hearing on the implanted side (Nilsson, Soli, & Sullivan, 1994; Plomp & Mimpen, 1979). Given the large difference demonstrated in the Gifford, Dorman, and Brown (2010) study compared to more subtle benefits demonstrated in others, it is proposed that the benefits of ipsilateral acoustic hearing in the EAS condition becomes more evident under increasingly difficult listening conditions.

2.6.2. Factors Associated with Hearing Preservation

As covered in Section 2.6.1, adults with PD have the potential to gain from CIs using EAS. When an adult with PD receives a CI with preserved low frequency hearing, improvements in speech recognition in noise and better music perception are observed compared to their implanted peers with no residual hearing (Gfeller et al., 2006; Gifford, Dorman, & Brown, 2010; Sucher & McDermott, 2009). As a result of this, much work has gone into developing techniques to minimise trauma during CI surgery in an attempt to preserve the individual’s natural acoustic hearing. The term “soft surgery”, first introduced by Lehnhardt (1993), has been used frequently in the literature to describe atraumatic surgical techniques and device selection designed to minimise insertion trauma to the cochlea and preserve hearing (see Table 2.1 for an overview of potential sources of trauma related to CI surgery). Factors considered in the discussion of atraumatic surgery include surgical approach, insertion technique, use of topical
and/or systemic steroids, and perhaps most importantly the structure and design of the implanted device itself.

It has been suggested that CI insertion depth beyond the first turn (or point of first resistance) is likely to lead to significantly increased risk of cochlear trauma and damage to cochlear structures resulting in a loss of acoustic hearing (Gstoettner et al., 1999). When examining insertion of three Nucleus electrodes and three Combi 40/40+ electrodes into temporal bones, Gstoettner et al. (1999) demonstrated minimal insertion trauma when the devices were advanced to the point of first resistance. When these devices were advanced further, there was evidence to suggest trauma to the cochlea via increased insertion forces and/or physical damage to the electrode array (Gstoettner et al., 1997). Studies demonstrated that, with increased angular depth of insertion, there was a decreased likelihood of preserving usable hearing (James et al., 2005). Suhling et al. (2016) demonstrated increased hearing loss as depth of insertion into the cochlea increased with the use of 20, 24 and 28mm long electrode arrays. Good hearing preservation outcomes were reported in the literature for shorter electrode arrays and arrays specifically designed for reduced insertion trauma (Gantz, Turner, & Gfeller, 2006; Kiefer et al., 2004; Lesinski-Schiedat, Buechner, Schuessler, & Lenarz, 2011; Skarzynski et al., 2014; Van Abel et al., 2015).

Insertion technique has been implicated in hearing preservation during CI surgery. There is clear evidence to demonstrate that a round window approach for electrode insertion is more advantageous to hearing preservation compared to a cochleostomy approach (Piotrowska, Lorens, Jedrzejczak, & Skarzynski, 2010). This finding in relation to the round window approach are in line with results from Adunka et al. (2004) which examined insertion trauma histologically using temporal bones. Their study found that insertions via the round window demonstrated virtually no trauma to the cochleae. The advantages demonstrated with the round window approach result from the reduction of trauma as highlighted in O’Connell, Hunter, et al. (2016). A decrease in drilling required for a round window approach, as compared to cochleostomy, would reduce acute mechanical and non-mechanical trauma (i.e. injury to cochlear structures and/or acoustic trauma) in addition to the sub-acute/delayed trauma (e.g. fibrosis or ossification in relation to the introduction of bone dust into the cochlea, and risk of infection). Piotrowska et al. (2010) examined changes in pure tone acoustic thresholds
from 125Hz to 1000Hz for 550 individuals aged 5 years or older implanted with a variety of implants from three different manufacturers. Their study found that round window insertion was significantly associated with less change in pure tone threshold at all frequencies tested. Additionally, their study found that age at implantation before 19 years was associated with significantly less change in pure tone threshold up to 500Hz (Piotrowska et al., 2010). This has also been highlighted in comparison of hearing preservation outcomes with the Nucleus Hybrid L24 electrode array by surgical approach. In a multi-centre study by Lenarz et al. (2013), it was demonstrated that 92% of participants had low frequency hearing better than 90 dB HL at 6 months post-implant where a round window approach had been used. This is compared with 66% of participants with low frequency hearing better than 90 dB HL in a study by Roland, Gantz, Waltzman & Parkinson (2016) using a cochleostomy approach with the same electrode array. In these studies, inclusion criteria required the participants to have low frequency hearing at or better than 60 dB HL.

Where a cochleostomy approach was used, Briggs, Tykocinski, Stidham, and Roberson (2005) emphasised careful surgical technique and cochleostomy placement was vital for reducing insertion. A cochleostomy performed anterior to the round window rather than inferior was associated with SV electrode array insertion in addition to damage to the delicate cochlear structures such as the spiral ligament or basilar membrane (Briggs et al., 2005). In a further study of round window versus cochleostomy approach using a prototype electrode array designed for hearing preservation, Briggs et al. (2006) commented that while no significant insertion trauma occurred with either the round window or cochleostomy approaches, considerably greater access in addition to skill was required to achieve the correct positioning for a cochleostomy requiring more drilling. The authors also commented that the final array position for those devices implanted via a round window approach was in a more favourable location at the basal end of the cochlea, sitting closer to the modiolus at that location than those implanted by cochleostomy (Briggs et al., 2006). Regardless of approach, research has shown that narrow, flexible arrays particularly with a slim tip have reduced insertion trauma to cochlear structures, and manufactures have produced a variety of electrode arrays in an attempt to provide minimal insertion trauma and an opportunity to preserve natural hearing and cochlear structures (Briggs et al., 2001). These devices include a variety of
array lengths, sizes, and insertion techniques, however results for hearing preservation in the literature have been mixed.

There has been much discussed about the use of steroids as part of a ‘soft surgery’ approach for hearing preservation. The rationale behind this thinking is that steroids are often used in cases of idiopathic sudden SNHL to facilitate return of hearing (Wei, Stathopoulos, & O'Leary, 2013). In an attempt to form some consensus on the effectiveness of steroid use for idiopathic sudden SNHL, Wei et al. (2013) analysed the existing data in an updated Cochrane review of the issue. This study of 267 individuals found contradictory reports from the three randomised controlled trials that met inclusion criteria, highlighting the continued lack of clarity regarding the effectiveness of steroids to affect hearing loss recovery. Nevertheless, steroids such as prednisolone and dexamethasone continue to be used in CI surgery where hearing preservation is the goal. There has been some lack of clarity about steroid delivery, timing and location (i.e. pre-implant, during surgery or post-implant; oral, systemic or topical). Kuthubutheen et al. (2017) randomly assigned 30 persons to either a prednisolone group who took oral steroids for six days pre-implant, a dexamethasone group who received transtympanic steroids one day prior to surgery, or a control group with no treatment. Their study found the group that received the transtympanic steroid dose had significantly better post-implant hearing and demonstrated improvements in pure tone thresholds up to three months post-implant compared to the other groups, which was maintained to the end of the study duration (12 months). Cho, Lee, Choi, Jang, and Lee (2016) also investigated the effect of steroid delivery for 19 individuals versus a control group of ten with no treatment, but in this study the delivery methods for the investigational cohort included both systemic dexamethasone pre-implant coupled with topical administration during CI surgery. Their study found significantly better hearing preservation for persons who received the steroid, with more individuals preserving hearing within 10-15 dB of their pre-implant threshold compared to the control group. Santa Maria, Gluth, Yuan, Atlas, and Blevins (2014) performed a meta-analysis of 24 published studies to uncover factors associated with hearing preservation in CI surgery. In their analysis, postoperative systemic steroids were indicated as a factor associated with better hearing preservation, but topical steroids did not demonstrate any advantage (Santa Maria et al., 2014). While there remains a lack of clarity in this area regarding
effectiveness and best practice for steroid use in hearing preservation post-CI surgery, steroid use may minimise the inner ear trauma post-CI. Further research using randomised controlled trials and large participant numbers is warranted.

### 2.6.3. Hearing Preservation – Success and Measurement

One of the reasons for the varied outcomes in hearing preservation is the inconsistent reporting methods utilised, making it difficult to compare hearing preservation across the array of implant technologies and study groups. Methods that have been used to illustrate change in hearing include calculation of a mean change in hearing at individual frequencies (e.g. mean change at 500 Hz), average low frequency hearing loss, and use of terminology such as ‘complete hearing preservation’ or ‘partial hearing preservation’ based on a variety of different calculation methods. As an example, Gstoettner et al. (2004) reported on 21 individuals with complete or partial hearing preservation at three months post-implant, defining complete hearing preservation as an average change of less than 10 dB HL in pure tone thresholds and partial hearing preservation as any measureable hearing but greater than 10 dB HL change in hearing. In their study, the frequencies used in formulating the average were not mentioned. Kiefer et al. (2004), Balkany et al. (2006), and Helbig, Baumann, Hey, and Helbig (2011) used the same definition for ‘complete hearing preservation’ as seen in the Gstoettner et al. (2004) study, however there was variation as to which frequencies were included in the formulation of average hearing. All of the aforementioned studied used hearing at 250 and 500Hz in their calculations, however Kiefer et al. (2004) and Helbig et al. (2011) included 125Hz in addition to these, and Kiefer et al. (2004) and Balkany et al. (2006) also included 1000Hz. Some studies did not quantify hearing preservation as ‘complete’ or ‘partial’ but simply as preserved or not. Skarzynski et al. (2007) defined preserved hearing as change in pre- to post-operative pure tone thresholds within 10 dB, in order to account for test-retest variability, whereas Fraysse et al. (2006) defined hearing preservation as thresholds preserved within 20 dB of pre-implant levels. Lesinski-Schiedat et al. (2011) defined hearing preservation as less than or equal to 30 dB of change from pre- to post-implant in their study of Hybrid-L versus Slim Straight implants. An alternative method has been the assessment of hearing as ‘functional’ or not. Van Abel et al. (2015) used a low frequency pure tone average from thresholds at 250 and 500Hz to define preservation to 85 dB HL as the cut-off for ‘functional
hearing’. The rationale for choosing 85 dB HL was based on the work of Hornsby and Ricketts (2006) that found individuals with high frequency SNHL (up to 60-80 dB HL) were limited in their ability to make use of amplified high frequency speech sounds.

As a result of this variability in methodology/terminology, it is challenging to comment on realistic expectations for a person’s hearing preservation with respect to percentage change in hearing or average change in dB. Results from numerous studies are presented in Table 2.2 for reference. It is apparent that hearing preservation is possible following CI surgery, however the outcomes remain highly variable. Incerti et al. (2013) conducted a systematic review of studies on preservation of residual acoustic hearing following CI. A total of 14 studies met the criteria for inclusion in this review. Of these, 70-100% of the adult CI recipients were reported to have some hearing preservation to a minimum of six months post-CI. This hearing preservation varied between ‘complete’ and ‘partial’ preservation, as defined in the individual studies (see reports in Incerti et al., 2013). Summarizing the data in Table 2.2, it appears that 70-100% of adult CI recipients demonstrate a post-CI operative hearing threshold change less than 10-15 dB.

In an attempt to provide a standardised method of reporting hearing preservation outcomes, a group of experts in the field came together to form the HEARRING Group. The HEARRING Group proposed a new Hearing Preservation Classification System, sometimes referred to as the HEARRING Group method (Skarzynski et al., 2013). This method was designed to address many of the issues present in existing reporting methods, including being independent of the person’s pre-implant hearing. The HEARRING Group method aimed to be suitable for all CI recipients regardless of pre-implant hearing level and be easy to introduce and understand. The formula is as follows:

$$Relative\ change = \frac{(PTA_{post} - PTA_{pre})}{(PTA_{max} - PTA_{pre})}$$

where PTA_{post} is the pure tone average of all available tested frequencies measured post-CI, and PTA_{pre} is the pure tone average of those same frequencies measured pre-CI. PTA_{max} represents the maximum limits of the audiometer at a given frequency. In order to calculate the relative amount of hearing preservation, this relative change
equation is converted to a percentage using the following equation, where $S$ represents the percent of hearing preserved:

$$S = \left[ 1 - \left( \frac{(PT_{\text{post}} - PT_{\text{pre}})}{(PT_{\text{max}} - PT_{\text{pre}})} \right) \times 100 \right] \text{ (\%)}$$

When hearing preservation data are inputted into this equation, the output percentage represents the degree of change in hearing for an individual with respect to the hearing they had to begin with. The HEARRING Group presented a categorical scale for reporting the $S$ value whereby Complete Hearing Preservation is defined as $S > 75\%$, $S$ within the range 25-75\% is termed Partial Hearing Preservation, and $S < 25\%$ is termed Minimal Hearing Preservation. Where the individual has no measurable hearing post-implant this simply represents a complete loss of hearing (Skarzynski et al., 2013). This method has been well accepted by the field and provides an excellent basis by which to monitor hearing preservation outcomes in groups of individuals, i.e. clinical research and consistent reporting. Monitoring outcomes using this formula provides a means to assess residual acoustic hearing, and also the degree to which hearing preservation may be a representation for the degree of trauma of the CI surgery. Preservation of cochlear structures via atraumatic surgery must be considered the gold standard, for the reasons highlighted in Section 2.6.1. Despite its merits, the HEARRING Group method does not provide an insight into amount of useful or functional hearing preserved as the percentage preservation is heavily related to the individual’s pre-operative hearing. By design, this method is independent from the individual’s initial pre-implant hearing levels. As a result it is difficult to use this method as a pre-implant counselling tool for providing evidence-based recommendations and/or realistic expectations of post-implant hearing levels.
Table 2.2: Overview of hearing preservation research

<table>
<thead>
<tr>
<th>Publication</th>
<th>Participants</th>
<th>Implant/Electrode Type</th>
<th>Definition of Hearing Preservation</th>
<th>Result</th>
</tr>
</thead>
</table>
| Gstoettner et al. (2004)         | 21           | MED-EL Combi 40+                         | Complete HP: ≤ 10 dB change from pre-op hearing  
Partial HP: Post-op hearing >10 dB different to pre-op hearing | 13/21 Complete HP  
5/21 Partial HP  
3/21 No measurable hearing |
| Kiefer et al. (2004)             | 14           | MED-EL Combi 40+                         | Complete HP: ≤ 10 dB change from pre-op hearing  
Partial HP: Post-op hearing 11-20 dB different to pre-op hearing  
125, 250, 500, 1000Hz | 9/14 Complete HP  
3/14 Partial HP  
2/14 No measurable hearing |
| Gantz, Turner, Gfeller, and Lowder (2005) | 21 | Iowa/Nucleus Hybrid  
10mm electrode | Average loss assessed at 125, 250, 500, 1000Hz  
No definition of HP but use the term "successful" preservation | Average change 9.5 dB across the frequencies (range of change 0 - 30 dB)  
Successful preservation reported in 96% of cases  
1/21 lost all measureable hearing at 3 months post-CI |
| Balkany et al. (2006)            | 28           | Nucleus Freedom Contour Advance          | Complete HP: ≤ 10 dB change from pre-op hearing  
Partial HP: Post-op hearing >10 dB different to pre-op hearing | 9/28 Complete HP  
16/28 Partial HP  
3/28 No measurable hearing |
<table>
<thead>
<tr>
<th>Publication</th>
<th>Participants</th>
<th>Implant/Electrode Type</th>
<th>Definition of Hearing Preservation</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fraysse et al. (2006)</td>
<td>27</td>
<td>Nucleus 24 Contour</td>
<td>HP: Post-op hearing ≤ 20dB different to pre-op hearing 125, 250, 500Hz</td>
<td>9/27 HP at 125Hz; 7/27 HP at 250Hz; 5/27 HP at 500Hz; No measurable hearing: 12/27 at 125; 10/27 at 250; 11/27 at 500Hz</td>
</tr>
<tr>
<td>James et al. (2006)</td>
<td>10</td>
<td>Nucleus 24 Contour</td>
<td>Useful hearing, non-vibrotactile thresholds For those with useful hearing, individual thresholds from 125-750Hz ranged from normal to profound levels</td>
<td>7/10 useful HL; 3/10 vibrotactile (&gt;85-110 dB HL at 250-500Hz)</td>
</tr>
<tr>
<td>Skarzynski et al. (2007)</td>
<td>10</td>
<td>MED-EL Combi 40+</td>
<td>HP: ≤ 10 dB change from pre-op hearing</td>
<td>9/10 HP; 1/10 No measurable hearing</td>
</tr>
<tr>
<td>Skarzynski, Lorens, Piotrowska, and Podskarbi-Fayette (2009)</td>
<td>28 (18 adults, 10 children)</td>
<td>MED-EL Combi 40+ or Pulsar</td>
<td>Complete HP: Post-op hearing within 10 dB of pre-op hearing Partial HP: Post-op hearing greater than 10 dB different to pre-op hearing</td>
<td>13/28 Complete HP; 11/28 Partial HP</td>
</tr>
<tr>
<td>Publication</td>
<td>Participants</td>
<td>Implant/Electrode Type</td>
<td>Definition of Hearing Preservation</td>
<td>Result</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------------</td>
<td>----------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Simpson et al. (2009)</td>
<td>5</td>
<td>Nucleus Freedom Contour Advance</td>
<td>Average loss from pre-implant to 24 weeks post implant 125-1000 Hz</td>
<td>5/5 retained measurable hearing Average loss was 27dB</td>
</tr>
<tr>
<td>Helbig et al. (2011)</td>
<td>22</td>
<td>MED-EL FlexSOFT</td>
<td>Complete HP: ≤ 10 dB change from pre-op hearing Partial HP: Post-op hearing &gt;10 dB different to pre-op hearing 125, 250, 500Hz</td>
<td>4/22 Complete HP 13/22 Partial HP 5/22 No measurable hearing</td>
</tr>
<tr>
<td>Lesinski-Schiedat et al. (2011)</td>
<td>122</td>
<td>Nucleus Hybrid-L (n=91); Nucleus Slim Straight CI422 (n=31)</td>
<td>HP: ≤ 30 dB change from pre-op hearing</td>
<td>91/91 HP with Hybrid-L 28/31 HP with CI422</td>
</tr>
<tr>
<td>Skarzynski et al. (2014)</td>
<td>35</td>
<td>Nucleus Slim Straight CI422</td>
<td>HP defined as ≤ 10 dB change or ≤ 30 dB change</td>
<td>13/35 HP ≤ 10 dB 27/35 HP ≤ 30 dB 3/35 No measurable hearing</td>
</tr>
<tr>
<td>Van Abel et al. (2015)</td>
<td>52</td>
<td>Nucleus Slim Straight CI422</td>
<td>Functional hearing using a cut-off of 85 dB HL for low frequency pure tone average (250 and 500Hz)</td>
<td>52/52 had functional hearing pre-op 27/52 had functional hearing at activation 21/44 had functional hearing 6 months post-activation</td>
</tr>
<tr>
<td>Publication</td>
<td>Participants</td>
<td>Implant/Electrode Type</td>
<td>Definition of Hearing Preservation</td>
<td>Result</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>--------------</td>
<td>----------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Ramos Macias, Borkosk Barreiro, Falcon Gonzalez, and Ramos de Miguel (2017)</td>
<td>26</td>
<td>Nucleus Slim Modiolar CI532 (n=10); Nucleus Slim Straight CI522 (n=7); Nucleus Contour Advance CI512 (n=9)</td>
<td>Complete HP: Post-op hearing ≤ 15 dB of pre-op hearing</td>
<td>Complete HP: 7/10 CI532 4/7 CI522 2/9 CI512</td>
</tr>
</tbody>
</table>
|                                                 | 225          | MED-EL Flex 28 (n=52); MED-EL Flex 24 (n=16); MED-EL Standard (n=9); Nucleus Contour Advance (n=54); Nucleus Slim Straight (n =51); Advanced Bionics Mid-Scala (n=35); Advanced Bionics 1J (n=7); Advanced Bionics Helix (n=1) | Hearing at 250Hz ≤ 80 dB HL                                                                       | 38% of ears had hearing preservation as per definition. Better hearing preservation associated with the following:  
  |                                                 |              |                                                          |                                                                                                    | - Better pre-implant hearing  
  |                                                 |              |                                                          |                                                                                                    | - Lateral wall and mid-scala electrodes  
  |                                                 |              |                                                          |                                                                                                    | - Round window or extended round window insertion |
2.7. Clinical questions remaining

Persons considering whether to proceed with a CI must be made aware of the potential benefits and risks of the device prior to surgery and have realistic expectations regarding potential outcomes. Unfortunately, a number of questions still exist regarding the outcomes for adults with PD which complicate pre-CI counselling.

Firstly, while current guidelines for recommending CIs were covered in Section 2.3.1, it is unclear as to whether the same guidelines can be used when making recommendations for adults with PD or whether novel guidelines must be used. One of the major factors related to CI outcomes for adults is duration of deafness, discussed in Section 2.4.1. The population of interest has significant usable hearing, i.e. they are not ‘deaf’ for any duration in this sense. Thus, it is unclear how clinicians and/or surgeons may counsel adults with PD regarding this factor and their potential to benefit from CIs (i.e. Aim 1).

Secondly, while there has been much work done quantifying hearing preservation across a number of devices, neither the work done to date nor the Hearing Preservation Classification System provides counselling guidelines for clinicians and/or surgeons to quantify potential preservation of hearing. Can the degree of hearing preservation be estimated pre-implant? What is the ‘chance’ that a person could preserve functionally useful hearing after the CI procedure (i.e. Aim 2)?

Finally, there is the question of whether electrode array type (i.e. perimodiolar or lateral wall) has an effect on the speech perception outcomes for the population of adults with PD. Given the discussion of placement versus outcomes in Section 2.4.4 in combination with the factors associated with hearing preservation discussed in Section 2.6.2, there is the question of whether risks of hearing preservation outweigh potential benefits to speech perception when choosing electrode array type for this population (i.e. Aim 3).

It is important to provide accurate information about the risks of loss of significant residual hearing versus expected speech perception benefits when counselling adults with PD pre-implant. The present study aims to address some of these questions.
2.8. Review of the research questions

This section will highlight how the clinical questions in Section 2.7 have been addressed in the thesis with reference to the specific study hypotheses:

1. Can the same guidelines as per traditional CI recipients be used when making recommendations for adults with PD or must novel guidelines must be used? In other words, are the potential electric-only speech perception outcomes equivalent between these two populations?
   
   a. This will be addressed in Chapter 4, and relates to Aim 1 and Hypothesis 1.

2. Can the degree of hearing preservation be estimated pre-implant and are there particular factors are associated with hearing preservation in this population?
   
   a. This will be addressed in Chapter 5, and relates to Aim 2 and Hypotheses 2 and 3.

3. Does the type of CI electrode array used have an effect on the speech perception outcomes for adults with PD using a CI?
   
   a. This will be addressed in Chapter 6, and relates to Aim 3 and Hypotheses 4 and 5.
3. Methodology

3.1. Introduction

Review of the relevant literature in Chapter 2 identified a gap in the knowledge base with respect to specific CI recommendation criteria for adults with PD. Whilst there has been substantial research into the outcomes of adults with severe to profound hearing loss pre-implant, there has been little work looking specifically at adults with PD. Before discussing the particulars of the persons involved in this study and experimental design, the reader is reminded of the study aims (see section 1.2.1, page 3) which were designed to help fill this knowledge gap:

1. To assess whether there is a difference in speech perception outcomes for adults with PD using CIs compared to the traditional CI candidates. To address this aim, comparisons will be drawn between persons implanted with a CI that is closer to the modiolus (i.e. a perimodiolar electrode array, specifically Cochlear Nucleus Contour Advance) using electric-only hearing. These findings will guide clinical decision-making for adults with PD with respect to potential to benefit from a CI.

2. To assess the hearing preservation outcomes for adults with PD using a CI and investigate predictive factors relating to degree of change in hearing. To address this aim, hearing preservation outcomes for adults using a TSEA (specifically, the Cochlear Nucleus CI422 Slim Straight) will be studied. These findings will endeavour to provide guidance to clinicians and surgeons regarding realistic expectations for hearing preservation.

3. To assess whether there is a difference in speech perception outcomes of adults with PD using a CI based on the type of electrode array implanted. To address this aim, comparisons will be drawn between persons implanted with a CI with a TSEA and persons implanted with a perimodiolar array who have PD pre-implant. These findings will provide guidance as to whether the type of electrode array chosen has an effect on speech perception outcomes,
and this information could potentially be used to maximise outcomes for adults with PD.

Each of these aims were assessed separately as individual sub-projects and will be reported on in Chapters 4-6. Methodology specific to the sub-projects relating to aims 1, 2 and 3 will be discussed further in Chapters 4, 5 and 6 respectively. The present Chapter presents the methodology for the project as a whole.
3.2. Participants

Participants for this project were comprised of two main groups. Firstly, participants were identified during examination and sorting of an existing RVEEH adult CI patient database. Secondly, 154 participants who used a TSEA were identified for a prospective longitudinal study.

The retrospective analysis was conducted from a database of 640 adults implanted at the Melbourne Cochlear Implant Clinic at RVEEH between September 2005 and July 2011. In order to control for known variables affecting speech perception outcomes for adults using CIs, the following criteria were used to sort participants:

- Postlingual onset of hearing loss (3 years of age or older)
- No history of re-implantation
- English as first language
- Full length electrode array (i.e. no short/hybrid arrays)

Individuals were sorted for inclusion in this study based on their preoperative pure tone audiometry results, as per criteria set in Chapters 4 and 6 to satisfy Aims 1 and 3, and Hypotheses 1 and 4. A total of 54 individuals were included in the sub-project in Chapter 4 and 70 in sub-project in Chapter 6 from this retrospective analysis. All adults included in these sub-projects were implanted with Contour Advance electrode arrays. See Chapters 4 and 6 for an overview of the demographic characteristics of these populations.

The prospective longitudinal study of outcomes with a TSEA was conducted from a total of 154 adults implanted with this device at the Melbourne Cochlear Implant Clinic at RVEEH between December 2010 and May 2015. Adult patients who provided their consent and received a TSEA were assessed pre-operatively, and 3 and 12 months post-implantation. To investigate Aim 2 and Hypotheses 2 and 3 (Chapter 5), the following inclusion criteria were defined:

- Pre- and post-operative pure tone audiometry completed
- No history of comorbid neural or cognitive issues
Using a TSEA

To investigate Aim 3 and Hypotheses 4 and 5 (Chapter 6), the following criteria for inclusion were used to control for known variables affecting speech perception:

- Postlingual onset of hearing loss (3 years of age or older)
- No history of re-implantation
- English as first language
- No history of comorbid neural or cognitive issues

Using a TSEA

Audiometric inclusion criteria were also used to ensure both groups of individuals assessed with respect to Aim 3 had comparable levels of functional acoustic hearing pre-implant (see Chapter 6 for details). Using these inclusion criteria, a total of 139 individuals using a TSEA were included in sub-project 2 and 63 in sub-project 3. All adults using a TSEA were implanted with Nucleus CI422 Slim Straight electrode arrays. See Chapters 5 and 6 for an overview of the demographic characteristics of these study populations.
3.3. Experimental methods

The following section details the experimental method, speech perception test battery and equipment utilised in this study.

All adults identified in the retrospective analysis attended the RVEEH for pre-operative assessment, post-operative assessment and CI programming. Data for each adult’s speech perception outcomes were obtained through analysis of the clinic’s patient outcomes database. Hearing and speech perception tests were conducted in a sound treated booth (see Section 11 (Appendix A) for general RVEEH clinical protocol) and were administered SCORED by experienced CI audiologists.

The speech perception test battery included recorded open set sentence and word tests. Two City University of New York (CUNY) (Boothroyd, Hanin, & Hnath, 1985) sentences were presented, scored for the number of correctly identified words out of a total of approximately 102 keywords per sentence list, and the average of these scores was used. Recorded CUNY sentences were presented in two conditions: in quiet and with 8 talker babble as a competing background noise with an SNR of +10 dB. A female speaker’s voice was used in both conditions. One list of recorded open set monosyllabic consonant-nucleus-consonant (CNC) words (Peterson & Lehiste, 1962) was presented in quiet. Lists of 50 words, using a male speaker’s voice, were scored for the number of correctly identified words and phonemes, using a male speaker. For both sentence and word testing, the individual was required to verbally repeat what they had heard (be it a sentence or word/sound), which was then scored by the audiologist.

All recorded speech materials used a native Australian English speaker, and were presented audition alone via a loudspeaker at 65 dB SPL at zero degrees azimuth. As per RVEEH clinic protocols, appropriate masking was introduced to the contralateral ear wherever it was required (i.e. in the instance of significant asymmetry between ears and there was potential for the test materials to be detected by the non-test ear). The masking protocol in place during the period the recipients were tested utilised a portable Sony digital media player (masker) to provide speech masking through an insert phone, while the recipient listened to test materials from a loudspeaker via their HA (pre-operatively) or CI sound processor (post-operatively). The speech masking noise
consisted of broadband noise weighted according to the international long-term average speech spectrum (ILTASS) at a level calibrated to 75 dB SPL.

The speech perception test battery was conducted in the preoperative phase, and at three and twelve months post-implant. The preoperative speech perception data was obtained during CI candidacy assessment with optimised HAs, verified in the clinic prior to assessment. The NAL-NL1 and NAL-RP fitting algorithms were used in the verification process, at the discretion of the audiologist based on the configuration of the individual’s pure tone audiogram (Byrne & Dillon, 1986; Dillon, 1999). Pre-operative testing was completed in the left, right and binaural conditions (where applicable). Post-operative testing was completed at three and twelve months post- CI activation, using the individual’s CI sound processor and contralateral optimised HA in the monaural (CI alone) and binaural (CI + HA) conditions (where applicable). Pre-operatively and at 3 months post-implant, unaided pure tone audiometry was performed in addition to a speech perception test battery as per RVEEH clinical protocol for those individuals identified in the retrospective analysis. For the prospectively assessed TSEA group, unaided pure tone audiometry was performed in addition to speech perception testing at each time point.
3.4. Surgery and Post-operative Radiological Analysis

All recipients received their CI through the RVEEH CI program.

All adults identified in the retrospective analyses relating to Aims 1 and 3 (Chapters 4 and 6) were all recipients of Contour Advance electrode arrays, being either Nucleus Freedom or Nucleus 5 CI512 devices, manufactured by Cochlear Limited (Sydney, Australia). These devices are functionally identical, with cosmetic differences in the receiver-stimulator component (refer to Cochlear Limited for details). The perimodiolar Contour Advance electrode array is designed to fit close to the modiolus when advanced off the stylet during insertion. The array has a soft tip at the apical end to minimise insertion trauma and 22 half-banded platinum stimulating electrodes across 15mm. Insertion was via an extended round window or separate cochleostomy approach for all Contour Advance electrodes.

As mentioned previously, the TSEA used in this analysis was the Nucleus CI422 Slim Straight, manufactured by Cochlear Limited (Sydney, Australia). This straight electrode array was designed to track along the lateral wall of the cochlea without causing trauma during insertion. The array has a raised soft tip at the apical end and a smooth outer surface that minimises contact with intracochlear structures. The array utilises 22 half-banded platinum stimulating electrodes across 20mm and is designed to be inserted up to 25mm or to the point of first resistance (Lesinski-Schiedat et al., 2011). Atraumatic surgical techniques were used in all cases including a round window approach and administration of low dose intravenous Dexamethasone (8mg). In addition to this, 49 persons who received the TSEA and gave consent were involved in a double-blinded clinical trial whereby they received high dose systemic steroid treatment or placebo at the time of surgery (see Chapter 5 for further details).

Post-operative cochlear view x-rays were used to determine full electrode insertion in all cases. For the TSEA recipients, the angular depth of insertion of the electrode array was assessed by expert analysis of the post-operative x-ray for 100 out of the 139 recipients who had available imaging (72%). The analysis was completed by one of two experienced CI surgeons. The angle of electrode insertion was determined relative to the round window - mid modiolar line on the cochlear view x-ray (Xu, Xu, Cohen, & Clark, 2000).
3.5. Statistical Analysis

Statistical Analysis was conducted using Minitab statistical software versions 16 and 17 (Minitab, 2012, 2014).

For both sub-projects involving speech perception (Chapters 4 and 6), the open-set sentence and word scores in quiet and competing background noise data were assessed using a Principal Components Analysis. These analyses determined that up to 90% of the variance in the data was well explained by one component that was effectively an average of the three scores obtained. Given this result, a Total Speech Perception Score (TSPS) was formulated by calculating an average of a recipient’s score on each test in order to obtain a single metric that could be used in our analysis to provide a reliable statistical measure of performance.

Appropriate parametric and nonparametric tests were used based on the distribution of the data being investigated.

To assess the group mean data, either analysis of variance (ANOVA) or Mood’s median test were used depending on normal or non-normal distribution of the data. To examine differences between two population medians where data were not normally distributed, the Mann-Whitney test was used in place of a 2-sample t-test.

In order to investigate relationships between two variables, either Pearson correlation or Spearman rank correlation were used depending on data distribution.

Regression analyses were used to examine the impact of various factors on the post-operative speech perception outcomes.

A significance level (α) of 0.05 was used for all statistical tests.

3.6. Institutional Approval

Research relevant to this thesis was conducted under the approval of the RVEEH Human Research Ethics Committee, project numbers 04/564 and 15/1207H.
4. Outcomes for patients with sloping hearing loss implanted with standard cochlear implants

In order to assess whether the same guidelines as per traditional CI recipients be used when making recommendations for adults with PD (Aim 1, Hypothesis 1), the following chapter examines the speech perception outcomes of two groups of adult CI recipients differing with respect to their pre-implant audiometric configurations. The content of this chapter has been published in the Journal of Hearing Science:


For the purpose of continuity in the PhD thesis, some abbreviations and phrasing have been edited from the original where applicable (e.g. ‘sloping loss’ to ‘partial deafness’ or PD). The reference list pertaining to this paper has been omitted from this chapter and is included in the complete reference list in Chapter 10. Acknowledgments pertaining to this study have been omitted from this chapter and are included at the beginning of the PhD thesis. A reprint of the original article is provided for reference in
Appendix B – Publication Reprint (Chapter 4).
4.1. Abstract

Background and Aims

This study examined the speech perception outcomes for postlingually deafened adults using cochlear implants who had PD pre-operatively in whom there was no attempt at electroacoustic stimulation. The aim was to determine whether patients with PD who received a standard length cochlear implant electrode would demonstrate significant benefit, and compare the degree of benefit to a matched group of cochlear implant users with preoperative profound hearing loss.

Method

A retrospective analysis of pre and post implant speech perception scores of 27 adults with PD and a matched group of 27 adults with profound hearing loss was conducted. Matching was based on age at implant and duration of loss. All were implanted with Nucleus Freedom (CA) or Nucleus 5 implants.

Results

Postoperative open-set speech perception testing demonstrated significant improvement compared to pre-implant for both groups. Speech perception outcomes were better in the PD group however there was no significant difference demonstrated in degree of improvement pre- to post operatively in either the implant alone or binaural condition between the groups.

Conclusion

This study demonstrates that postlingually deafened adults with PD have the potential to gain significant benefit from cochlear implants and achieve equivalent improvement in speech perception to implant recipients with profound loss. The results achieved in this group without attempted hearing preservation, supports the use of newer standard length electrodes for both hearing preservation and optimal electric stimulation in patients with PD.
4.2. Introduction

High frequency sensorineural hearing loss, or ‘partial deafness’ (PD) is a common configuration of audimetric results in adults and can be caused by a number of etiologies including ageing (presbycusis), noise exposure, ototoxicity and genetic factors. This type of hearing loss typically reduces the audibility of spectral cues of speech, in particular place of articulation cues for high frequency consonants, with subsequent negative effects on the clarity of speech (Miller & Nicely, 1955; Turner, 2006). PD, in which the hearing loss is mild to moderate or better in the low frequencies, and severe to profound at 1 kHz and above, can present a significant challenge for audiological rehabilitation. Conventional amplification may not always provide adequate benefit to patients with high frequency hearing loss, as issues such as feedback, recruitment, distortion or cochlear dead regions can limit the effective programming of a HA. Cochlear dead regions have been defined as regions in the cochlea where inner hair cells are non-functional and are prevalent in individuals with sensorineural hearing loss (Moore, 2001; Vinay & Moore, 2007). For clients with findings of large or multiple dead regions, there are reported implications on the choice of HA or amplification strategy (Moore, 2004). In addition, increasing amplification in high frequency regions where the hearing loss exceeds 55 dB HL has been found to offer little to no improvement in speech perception performance, and can sometimes lead to a decrease in scores (Ching et al., 1998; Hogan & Turner, 1998; Turner & Cummings, 1999).

Frequency compression and frequency transposition HAs, which compress or transpose previously inaudible frequencies into less damaged regions of the cochlea, have been proposed as a possible solution for these individuals. Results in the literature on experimental outcomes have been mixed, with no clear consensus available as yet on the benefits of frequency compression or transposition aids in individuals with PD (Glista et al., 2009; Kuk et al., 2009; Simpson et al., 2006; Simpson et al., 2005). The literature suggests that frequency compression or frequency transposition HAs may not be the ideal solution for individuals with a more severely sloping audiometric configuration. While Simpson et al. (2005), Glista et al. (2009) and Kuk et al. (2009) have demonstrated improvements in speech recognition in groups of participants with
moderately sloping hearing losses, a study by Simpson et al. (2006) looking specifically at listeners with severely sloping audiograms, demonstrated no measurable benefit with a frequency compression device in comparison to conventional amplification. It should be noted that the participants in this later study all had hearing levels in the profound range above 1000Hz.

EAS, where a CI is used in combination with acoustic hearing, has been shown to provide significant benefits for suitable individuals (Buchner et al., 2009; Gstoettner et al., 2008; Turner et al., 2008; Woodson et al., 2010). Initial studies of EAS utilised a CI with an electrode array which, when inserted, does not extend as deeply in the cochlea as a standard length array. This has the benefits of an atraumatic insertion with minimal damage to apical intracochlear structures (Briggs et al., 2006; Gstoettner et al., 2009; von Ilberg et al., 2011). This design of electrode array provides electrical stimulation of the basal end of the cochlea while preserving the apical end of the cochlea to allow acoustic low frequency hearing postoperatively for those where residual acoustic hearing is preserved. However, patients with relatively poor acoustic thresholds in the low to mid frequencies may not benefit from this approach and rehabilitation options can be limited. With cochlear implant technology continually evolving, CIs for EAS have also evolved to include deeper cochlear insertions. While some studies have shown that residual hearing can be preserved through soft surgery and careful procedures with a standard length electrode array, the outcomes are variable (Helbig et al., 2008; Incerti et al., 2013; Kiefer et al., 2005; Simpson et al., 2009).

Patients with severely sloping hearing loss tend to fall within a substantial ‘grey area’ in terms of management. The high frequency hearing in these patients is too poor to gain significant benefit from HAs and their low frequency hearing is too good to fit within standard CI criteria; however the short electrode approach may not give the best outcome given the progressive nature of many of these types of hearing losses. In addition to this, many patients with a ski-slope audiometric configuration have poor speech perception despite optimal HA fitting and so become standard candidates for CI based on speech perception ability. CI technology has evolved to include devices such as the CI422 (Cochlear) and Flex28 (MED-EL) which allow for the clinician and surgeon to attempt to preserve the residual hearing with a full-length electrode array and
a soft surgery approach, which shows promise for patients falling into this group (Jayawardena et al., 2012; Skarzynski et al., 2012).

Improvements in both CI technology and recipient outcomes have led to expansion in the candidacy criteria for CI (Dowell, 2005; Gifford, Dorman, Shallop, et al., 2010; Leigh et al., 2010). This in turn brings increased referral of patients with significant residual hearing. Patients with residual acoustic hearing have more to lose if their hearing is lost following CI surgery and their postoperative outcome for hearing with the CI does not meet expectations. Audiologists are presented with the clinical dilemma of ‘weighing up’ the risk of losing the residual acoustic hearing versus the unpredictable amount of benefit to be gained by electrically stimulating the cochlea using a CI. A recent systematic review examining studies that investigated the preservation of residual acoustic hearing has demonstrated a significant speech perception benefit postoperatively using electric only stimulation over their preoperative scores (Incerti et al., 2013). The authors suggest that this provides evidence to support attempting an electroacoustic device approach, as the recipients show benefit even where there is complete hearing loss.

The purpose of the present study is to examine the outcomes for a group of postlingually deafened adults with significant preoperative residual hearing, or PD (PD group), whose preoperative speech perception places them as candidates for a CI, however were not considered candidates for a hearing preservation approach using a short electrode. The results of the PD group, whose hearing was not preserved through CI surgery, will be compared to both their own preoperative results and to a reference group of CI recipients with preoperative profound hearing loss. The aim of the paper is to assess the degree of benefit received by electrically stimulating the cochlea of recipients with preoperative PD, in comparison to the traditional CI patient with profound bilateral hearing loss.
4.3. Material and Methods

To examine the impact of preoperative PD on outcomes in adult CI recipients implanted with standard electrode arrays, a retrospective analysis was conducted from a database of 640 adults implanted at the Melbourne Cochlear Implant Clinic at the RVEEH between September 2005 and July 2011. This research was conducted under the approval of the RVEEH Human Research Ethics Committee (approval number 04/564).

4.3.1. Subjects

Subjects were selected for inclusion in this study based on their preoperative pure tone audiometry results. Recipients were considered to have PD when the audiometric thresholds of the ear to be implanted fell within the following range:

- 250 Hz and 500 Hz pure tone thresholds of 60 dB HL or better
- 1 kHz pure tone threshold of 75 dB HL or greater
- 2-8kHz pure tone thresholds of 90 dB HL or greater

These audiometric criteria were used in order to ensure the subject group had residual low frequency hearing but no significant high frequency hearing. The criteria for 1 kHz was used given the clinical criteria at the time for attempting a hearing preservation technique using a short electrode, which required a 1 kHz pure tone threshold of 70 dB HL or better. It must be noted that while these subjects were selected for a standard-length contour electrode, with the range of devices available today they would likely be selected for a full-length array which could potentially preserve the low frequency hearing.

Subjects were excluded from the analysis if they were considered to have a prelingual hearing loss, if they underwent re-implantation, if English was not their first language, or if they were fitted with a short electrode device for EAS. Only recipients with unilateral cochlear implants were included in the analysis. A total of 27 recipients fit the criteria.

A matched group of 27 recipients with pre-operative hearing in the profound range was selected for comparison. This Profound Loss group was matched with the PD group for both duration of deafness and age at implant. Each recipient in this matched group met
the same inclusion criteria for the study as the PD group, only differing in their audiometric thresholds. More specifically for the Profound Loss group, the ear to be implanted was required to have thresholds greater than or equal to 90 dB HL from 250Hz to 4000Hz.

The demographics of both groups are described in Table 4.1. Audiometric thresholds of both groups are shown in Figure 4.1 and Figure 4.2.

4.3.2. Test Materials
An analysis of the pre and post implant speech perception scores of the PD group and the Profound Loss group was conducted.

The speech perception test battery included open set sentence and word testing using recorded material. CUNY open set sentences were used, whereby lists of 12 sentences were scored for the number of correctly identified words out of a total of approximately 102 keywords per sentence list. For each test, two sentence lists were presented and the average of the two scores was taken. CUNY sentence testing was conducted in quiet and in 8 talker babble background noise with a signal to noise ratio of +10dB. In both the quiet and the noise test protocols, a female speaker was used. Open set monosyllabic word testing was conducted using CNC words, with lists of 50 words scored for the number of correctly identified words and phonemes, using a male speaker.

Recorded speech materials were used for all tests using a native Australian English speaker, presented audition alone at 65 dB SPL. Appropriate masking was introduced to the contralateral ear where required. The masking procedure utilises a portable Sony digital media player (masker) to provide speech masking through insert phones, while the recipient listens to test materials from a loudspeaker via their HA or cochlear implant sound processor. The masker continuously plays a .wav file of broadband noise weighted according to the ILTASS at a level calibrated to 75 dB SPL.

Preoperative speech perception data was obtained during implant candidacy assessment with optimised HAs. Each patient’s own HAs were verified in the clinic using real ear measures and compared to the target prescription. The NAL-NL1 and NAL-RP fitting algorithms were used to determine gain targets, with the choice of algorithm dependent on the configuration of the patient’s audiogram (Byrne & Dillon, 1986; Dillon, 1999). Where a patient’s HAs were not optimised for reasons other than documented loudness
tolerance issues, they returned to their HA provider for review of their aids prior to formal speech perception testing. Postoperative data was obtained at three and twelve months post CI activation, using the patient’s CI sound processor and contralateral optimised HA in the monaural (CI alone) and binaural (CI + HA) conditions. All speech perception results were obtained at the Melbourne Cochlear Implant Clinic.

To provide a more informative evaluation than assessing each test in the speech perception battery individually, an overall speech perception score was calculated by including each participants result for each test in the analysis.

### 4.3.3. Surgery and Devices

The subjects in this study underwent surgery between September 2005 and July 2011. All patients received Contour Advance electrode arrays, being either Nucleus Freedom or Nucleus 5 CI512 devices. These devices are functionally identical, with slight cosmetic differences (refer to Cochlear Limited for further details). In the PD group, twenty-one patients were fitted with the Nucleus Freedom cochlear implant, and six were fitted with the Nucleus 5 CI512 cochlear implant. In the Profound Loss group, twenty-two patients were fitted with the Nucleus Freedom cochlear implant, and five were fitted with the Nucleus 5 CI512 cochlear implant. All participants used the ACE sound coding strategy. Regarding stimulation rate, 20 recipients (74.1%) from the PD group and 18 (66.7%) from the Profound Loss group used the default of 900Hz. The remaining recipients from each group used a variety of stimulation rates from 250Hz to 2400Hz dependent on the recipient’s personal preference.

### 4.3.4. Statistics

Statistical analysis was conducted using Minitab statistical software version 16.

Paired t-tests were used in order to examine the difference between the population’s pre- and post-operative speech perception scores, given the samples were related and approached a normal distribution.

Additional data analysis was completed using nonparametric tests, as the data were not normally distributed. To assess the equality of group medians, Mood’s median test was used in place of an ANOVA. To examine the difference between two population medians, the Mann-Whitney test was used in place of a 2-sample t-test. In order to
investigate whether there was a relationship between two variables, Spearmann rank correlation was used.

An α level of 0.05 was used for all statistical tests.

Table 4.1: Demographic data of the PD and Profound Loss matched groups

<table>
<thead>
<tr>
<th></th>
<th>Partial Deafness group (n=27)</th>
<th>Profound Loss group (n=27)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duration of Deafness (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>12.54</td>
<td>12.94</td>
</tr>
<tr>
<td>SD</td>
<td>8.94</td>
<td>9.82</td>
</tr>
<tr>
<td>Median</td>
<td>12.00</td>
<td>10.00</td>
</tr>
<tr>
<td>Range</td>
<td>1 – 34</td>
<td>1 – 38</td>
</tr>
<tr>
<td><strong>Age at Implant (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>65.74</td>
<td>65.17</td>
</tr>
<tr>
<td>SD</td>
<td>13.84</td>
<td>12.68</td>
</tr>
<tr>
<td>Median</td>
<td>65.84</td>
<td>63.44</td>
</tr>
<tr>
<td>Range</td>
<td>35.23 – 89.27</td>
<td>39.80 – 88.68</td>
</tr>
<tr>
<td><strong>4FA (dB) – ear to be implanted</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>96.48</td>
<td>117.50</td>
</tr>
<tr>
<td>SD</td>
<td>5.90</td>
<td>7.26</td>
</tr>
<tr>
<td>Median</td>
<td>96.25</td>
<td>120.00</td>
</tr>
<tr>
<td>Range</td>
<td>81.25 – 107.50</td>
<td>102.50 – 125.00</td>
</tr>
<tr>
<td><strong>4FA (dB) – contralateral ear</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>89.77</td>
<td>103.29</td>
</tr>
<tr>
<td>SD</td>
<td>9.70</td>
<td>17.74</td>
</tr>
<tr>
<td>Median</td>
<td>91.25</td>
<td>105.00</td>
</tr>
<tr>
<td>Range</td>
<td>72.50 – 110.00</td>
<td>57.50 – 125.00</td>
</tr>
<tr>
<td><strong>4FA (dB) – post-op hearing (implanted ear)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>119.56 (n=17)</td>
<td>123.57 (n=7)</td>
</tr>
<tr>
<td>SD</td>
<td>6.22</td>
<td>1.68</td>
</tr>
<tr>
<td>Median</td>
<td>122.50</td>
<td>123.75</td>
</tr>
<tr>
<td>Range</td>
<td>107.50 – 125.00</td>
<td>121.25 – 125.00</td>
</tr>
</tbody>
</table>
Figure 4.1: Hearing levels for each participant in the PD group. The group average is shown with black squares and dotted line.

Figure 4.2: Hearing levels for each participant in the Profound Loss group. The group average is shown with black squares and dotted line.
4.4. Results

The results of this study demonstrate that the PD group had significantly better pre-implant speech perception scores compared with the Profound Loss group, and better post-implant scores looking at the implanted ear alone (Figure 4.3), however in terms of pre- to post-operative improvement either for implanted ear alone or the bimodal condition, there were no significant differences shown between the groups (Figure 4.4). These results are discussed in further detail below.

4.4.1. Demographics

The groups demonstrated a high level of similarity with respect to duration of loss and age at implant. There were no significant differences found between the PD and Profound Loss matched groups for either duration of loss or age at implant (p=0.586 and 0.414 respectively). As expected, due to the selection of the groups based on audiometric criteria, a significant difference was found between the groups in the four-frequency average (4FA) (dB) for both the ear to be implanted (p<0.001) and the contralateral ear (p<0.001). Refer to Table 4.1 for details of the median values for each comparison.

An analysis of the available data of the post implant unaided hearing thresholds for the implanted ear was conducted. Of the PD group, 17 of the recipients had their post implant hearing assessed (62.96%), while only 7 of the recipients from the Profound Loss group had their post implant hearing assessed (25.93%). Mann-Whitney analysis of the group medians demonstrated no significant difference between the level of post implant four-frequency average (dB) in the PD and Profound Loss groups (PD median 122.50 dB, Profound Loss median 123.75 dB, p=0.155).

4.4.2. Monaural Analysis

Paired t-test analysis showed the PD and the Profound Loss groups both demonstrated significantly higher speech perception scores measured at three months post implant compared to their pre-implant scores when looking at the implanted ear alone (PD: \(T=14.54, p<0.001\); Profound Loss: \(T=15.91, p<0.001\)).
The PD group demonstrated significantly better pre-implant speech perception scores compared to the Profound Loss group in the monaural condition for their ear to be implanted (PD median=13.0%, Profound Loss median=0%; p<0.001).

At three months post-implant there was no significant difference in the speech perception scores between the groups in the CI alone condition, although it was noted that the PD group did trend towards higher scores (PD median=63.5%, Profound Loss median=57.5%; p=0.119).

The post-operative scores were compared to the pre-operative scores to examine whether either group received more benefit from the cochlear implant at the three month post-implant point. There were no significant differences between the groups for overall improvement in speech perception in the monaural condition (PD median improvement 45.0%, Profound Loss median improvement 57.0%; p=0.342).

Speech perception scores were also analysed at the 12 month post-implant point. At twelve months post-implant there was no significant difference in the speech perception scores between the groups in the CI alone condition, although as at three months it was noted that the PD group did trend towards higher scores (PD median=72.0%, Profound Loss median=66.5%; p=0.157).

The twelve month post-operative scores were compared to the pre-operative scores to examine whether either group received more benefit from the cochlear implant at the later point. A significant difference was shown between the groups for overall improvement in speech perception in the monaural condition whereby the Profound Loss group demonstrated greater improvement at twelve months (PD median improvement 44.0%, Profound Loss median improvement 64.5%; p=0.047).

Given the retrospective nature of this project, it must be noted as a limitation to the data at the 12 month postoperative point that only 44-67% of the PD recipients completed the various speech perception tests and had data collected, compared with 70.4% of Profound Loss recipients who completed the speech perception battery. This limits the group matching and any conclusions that can be drawn at the 12 month point.
4.4.3. Binaural Analysis

Paired t-test analysis showed the PD and the Profound Loss groups both demonstrated significantly higher speech perception scores measured at three months post implant compared to their pre-implant scores in the binaural condition (PD: T=8.26, p<0.001; Profound Loss: T=6.27, p<0.001).

The PD group demonstrated significantly better pre-implant speech perception scores compared to the Profound Loss group in the binaural condition using their optimised HAs (PD median=30.0, Profound Loss median=2.0; p=0.008).

Examining the post-implant results for the binaural (CI+HA) condition, it was found that there was no significant difference in the speech perception scores between the groups measured at three months post-op (PD median=67.0%, Profound Loss median=76.0%; p=0.378).

The post-operative CI+HA scores were compared to the pre-operative HA+HA scores to examine whether either group received more benefit from the cochlear implant at the three month post-implant point. There were no significant differences between the groups for overall improvement in speech perception in the binaural condition (PD median improvement 30.0%, Profound Loss median improvement 24.0%; p=0.413). There were no data collected in the CI+HA condition at twelve months post implant.

4.4.4. Correlation Analysis

Correlation analyses were performed to assess whether the speech perception outcomes of the PD and Profound Loss groups were associated with established predictive factors. Details of these correlation analyses are provided in
Table 4.2 and
Table 4.3. Significant weak negative correlations were found for the PD group between age at implant and both CI alone and CI+HA speech perception at 3 months post-implant. Duration of deafness was also found to have a significant weak negative correlation with CI alone speech perception in the PD group only. A significant correlation was found between pre-op 4FA (dB) in the ear to be implanted and negative correlations were found between age at implant and duration of deafness for both the PD and the Profound Loss groups.
Figure 4.3: Comparison of the pre-implant and 3-month post-implant speech perception scores for the PD and Profound Loss (PrL) groups. The left panel shows the pre- and post-implant monaural scores; the right panel shows the corresponding binaural scores.
Table 4.2: Correlation analysis for PD group

<table>
<thead>
<tr>
<th>PD Group</th>
<th>Duration of Deafness</th>
<th>Age at Implant</th>
<th>4FA (dB) – ear to be implanted</th>
<th>4FA – contralateral ear</th>
<th>CI alone speech perception (3m post)</th>
<th>CI+HA speech perception (3m post)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of Deafness</td>
<td></td>
<td></td>
<td>-0.342</td>
<td></td>
<td>0.159</td>
<td>-0.254</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>p&lt;0.001</td>
<td></td>
<td>p=0.101</td>
<td>p=0.011</td>
</tr>
<tr>
<td>Age at Implant</td>
<td>-0.342</td>
<td></td>
<td>0.084</td>
<td>0.001</td>
<td>-0.234</td>
<td>-0.273</td>
</tr>
<tr>
<td></td>
<td>p&lt;0.001</td>
<td></td>
<td>p=0.387</td>
<td>p=0.992</td>
<td>p=0.021</td>
<td>p=0.025</td>
</tr>
<tr>
<td>4FA (dB) – ear to be implanted</td>
<td>0.159</td>
<td>0.084</td>
<td>0.462</td>
<td>0.079</td>
<td>0.102</td>
<td></td>
</tr>
<tr>
<td></td>
<td>p=0.101</td>
<td>p=0.387</td>
<td>p&lt;0.001</td>
<td>p=0.438</td>
<td>p=0.413</td>
<td></td>
</tr>
<tr>
<td>4FA – contralateral ear</td>
<td>0.251</td>
<td>0.001</td>
<td>0.462</td>
<td>-0.169</td>
<td>-0.263</td>
<td></td>
</tr>
<tr>
<td></td>
<td>p=0.009</td>
<td>p=0.992</td>
<td>p&lt;0.001</td>
<td>p=0.097</td>
<td>p=0.032</td>
<td></td>
</tr>
<tr>
<td>CI alone speech perception (3m post)</td>
<td>-0.254</td>
<td>-0.234</td>
<td>0.079</td>
<td>-0.169</td>
<td>0.883</td>
<td></td>
</tr>
<tr>
<td></td>
<td>p=0.011</td>
<td>p=0.021</td>
<td>p=0.438</td>
<td>p=0.097</td>
<td>p&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>CI+HA speech perception (3m post)</td>
<td>-0.130</td>
<td>-0.273</td>
<td>0.102</td>
<td>-0.263</td>
<td>0.883</td>
<td></td>
</tr>
<tr>
<td></td>
<td>p=0.295</td>
<td>p=0.025</td>
<td>p=0.413</td>
<td>p=0.032</td>
<td>p&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>
Table 4.3: Correlation analysis for the Profound Loss group

<table>
<thead>
<tr>
<th>Profound Loss Group</th>
<th>Duration of Deafness</th>
<th>Age at Implant</th>
<th>4FA (dB) – ear to be implanted</th>
<th>4FA – contralateral ear</th>
<th>CI alone speech perception (3m post)</th>
<th>CI+HA speech perception (3m post)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of Deafness</td>
<td></td>
<td>-0.239 p=0.013</td>
<td>0.511 p&lt;0.001</td>
<td>-0.319 p=0.001</td>
<td>0.020 p=0.840</td>
<td>0.234 p=0.106</td>
</tr>
<tr>
<td>Age at Implant</td>
<td>-0.239 p=0.013</td>
<td>-0.256 p=0.007</td>
<td>0.249 p=0.009</td>
<td>-0.145 p=0.149</td>
<td>0.107 p=0.465</td>
<td></td>
</tr>
<tr>
<td>4FA (dB) – ear to be implanted</td>
<td>0.511 p&lt;0.001</td>
<td>-0.256 p=0.007</td>
<td>-0.181 p=0.061</td>
<td>0.083 0.413 p=0.010</td>
<td>0.363</td>
<td></td>
</tr>
<tr>
<td>4FA – contralateral ear</td>
<td>-0.319 p=0.001</td>
<td>0.249 p=0.009</td>
<td>-0.181 p=0.061</td>
<td>0.023 p=0.822</td>
<td>-0.106 p=0.467</td>
<td></td>
</tr>
<tr>
<td>CI alone speech perception (3m post)</td>
<td>0.020 p=0.840</td>
<td>-0.145 p=0.149</td>
<td>0.083 0.413 p=0.822</td>
<td>0.652 p&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CI+HA speech perception (3m post)</td>
<td>0.234 p=0.106</td>
<td>0.107 p=0.465</td>
<td>0.363 p=0.010</td>
<td>-0.106 p=0.467</td>
<td>0.652 p&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>
Figure 4.4: Comparison of the percentage speech perception improvement for the PD and Profound Loss (PrL) groups (measured by difference in scores at 3 months post-implant compared to pre-implant). The left panel shows the monaural improvement; the right panel shows the binaural improvement.
4.5. Discussion

The over-arching aims of this study were to examine the outcomes for postlingually deafened adults with PD who were implanted with standard length electrode arrays without attempt at hearing preservation and hybrid stimulation, and to compare these results to a matched group of adults with profound hearing loss who had been clear candidates for CI. The underlying concept of this analysis was to examine the speech perception benefits available to recipients with pre-operative residual hearing, or PD, in the situation where all residual hearing was lost. The result of such an analysis provide CI clinicians information with which to counsel patients who risk their pre-operative low frequency hearing by proceeding with implantation in today’s clinical setting. The results demonstrated that cochlear implantation can provide significant benefit to adults with pre-operative PD, and the PD group can obtain equivalent levels of benefit to their implanted peers with profound hearing loss.

The results of this study are supportive of findings from Incerti et al. (2013) which demonstrated that recipients achieved significantly better postoperative speech perception scores compared to preoperative using only the electric component of their EAS system. In the present study, hearing preservation techniques were not used and the recipients in the PD group did not use an EAS configuration, however performance on speech perception tests was equivalent to their peers in the Profound Loss group, and the PD group did indeed demonstrate significantly better scores postoperatively compared to their preoperative scores.

A major issue facing clinicians and patients today is the risk of losing natural residual hearing following cochlear implantation with a hearing preservation technique, and whether the patient will be ‘worse off’ in that instance. In a systematic review of 187 publications on EAS using both Nucleus and MED-EL devices and assessing a variety of outcomes including hearing preservation, Talbot and Hartley (2008) found that 24% of recipients experienced greater than 20 dB hearing loss across all frequencies. The results of this study suggest that a PD patient with poor preoperative speech perception is likely to have an equivalent level of improvement to a more typical CI patient, even if they lose all residual hearing. Should the patient retain their natural hearing after the CI
procedure, we can expect their performance to be superior based on the reported benefits of EAS.

Previous studies have demonstrated that duration of deafness, age at implant, and preoperative speech perception are factors that have a significant effect on the outcomes for adults using cochlear implants (Blamey et al., 1996; Blamey et al., 2013; Dowell, 2012; Dowell et al., 2004). In the present study, significant weak negative correlations were found between the speech perception outcomes of the PD group and age at implant in that older patients performed slightly poorer. The Profound Loss group demonstrated significantly better binaural speech perception with a higher preoperative 4FA in the implanted ear. In both groups, a significant weak negative correlation was found between age at implant and duration of deafness, indicating that the individuals in the group implanted younger had been deaf longer and waited longer for their implant.

Additionally, a weak negative correlation was found in the PD group between speech perception and duration of deafness, although this is contrary to what previous studies have found. There may be a number of reasons for this. Firstly, the number of participants in the PD group in this study was relatively small at 27 compared to the large group analyses noted previously (Blamey et al., 1996; Blamey et al., 2013). A follow up study with increased subject numbers may clarify this result. In addition, the question of ‘duration of deafness’ is problematic in the PD group given they were technically using some natural low frequency hearing up to the point of cochlear implantation. As ‘duration of deafness’ is ill-defined in this group, this therefore may have also contributed to an unusual result in correlation. Finally, previous studies have noted that there is a relatively large amount of variance in outcomes that is not accounted for by the known predictive factors or preoperative assessments (Dowell et al., 2004), and this remains evident in this population of recipients with significant preoperative residual hearing.

Patients with PD are presenting more regularly to cochlear implant centres, and bring with them additional challenges in making recommendation. Given their residual hearing, patients with PD may present with speech perception abilities that render them ‘borderline’ candidates under traditional guidelines.
Particular attention must be paid to the level of residual hearing this group of PD patients had prior to cochlear implantation. As discussed previously, despite this group having significant low tone hearing they were selected for standard Contour electrode arrays as their preoperative speech perception was relatively poor. Additionally, given hearing configuration, the available electrode choice and clinical criterion for short electrode insertion at the time, no attempt was made to provide the PD group with EAS. It should be noted that in today’s clinical setting use of newer electrode arrays specifically designed for preservation of residual acoustic hearing (eg Nucleus CI422, MED-EL Flex28) may allow patients with PD better potential to preserve and make use of their natural low frequency hearing and take advantage of EAS. Skarzynski et al. (2011) have demonstrated high levels of hearing preservation in patients with preoperative residual hearing when using full-length electrode arrays with deep insertion and surgical techniques designed to minimise electrode insertion trauma. The evolution of devices and surgical techniques provides an opportunity for more recipients to benefit from acoustic stimulation in combination with their CI. Turner et al. (2008) highlighted the benefits of integrating electrical and acoustic hearing in patients implanted with the Iowa/Nucleus Hybrid device, whereby the participants with the electroacoustic hearing had improved speech recognition in competing noise, compared to participants using traditional CIs. The authors attributed this difference to the preservation of low frequency hearing in the participants using the electroacoustic device. In these cases, the authors postulated that participants with preserved natural low frequency hearing would in turn have preserved outer hair cell tuning curves, leading to increased frequency resolution (Turner et al., 2008). In contrast, a recent publication by Cosetti et al. (2013) demonstrated that while hearing could be preserved using conventional Contour implants, there was no correlation between hearing preservation and performance on speech perception tasks. The benefits of low frequency hearing preservation have been found in areas other than speech perception as improved frequency resolution has also been found to improve music perception and appreciation in implant recipients with electroacoustic hearing (Gfeller et al., 2006; Sucher & McDermott, 2009). Incerti et al. (2013) reviewed hearing and speech perception outcomes and fitting techniques across patients implanted with standard perimodiolar electrode arrays, standard to medium length straight arrays and electro acoustic arrays.
This study highlighted the variety of devices available for use today in patients with pre-operative low frequency hearing, and the excellent hearing preservation that has been demonstrated in the literature with available electrode arrays.
4.6. Conclusions

The results of this study demonstrate that postlingually deafened adults with partial deafness have the potential to gain significant benefit from electrical stimulation and can achieve equivalent levels of improvement to typical candidates with profound hearing loss. The results presented in this paper provide evidence to support the preoperative clinical counselling of patients with residual hearing. Patients with PD can be counselled that, should they lose their residual natural hearing, they are still likely to gain a significant benefit from their CI. Should the patient retain their low frequency residual hearing, research would suggest their outcome could only be further improved in terms of sound quality, naturalness, music perception etc. The results suggest that clinics should consider recommending CI for patients with PD where conventional amplification fails to offer sufficient speech perception benefit, and the patient is motivated to seek other options. When considering the proven benefits of EAS, the results of this study support the combination of a hearing preservation approach using a full length electrode in patients with sloping hearing loss. Further research with larger numbers is required to assess the outcomes for adults with PD who receive CIs designed for hearing preservation.
5. Hearing preservation outcomes for 139 cochlear implant recipients using a thin straight electrode array

In order to assess whether the hearing preservation can be estimated pre-implant and whether there are any factors associated with hearing preservation (Aim 2, Hypotheses 2 and 3), the following chapter examines the hearing preservation outcomes of a group of adult CI recipients implanted with a Nucleus CI422 Slim Straight CI (TSEA). The content of this chapter has been published in Otology & Neurotology:


For the purpose of continuity in the PhD thesis, some abbreviations and phrasing have been edited from the original where applicable. The reference list pertaining to this paper has been omitted from this chapter and is included in the complete reference list in Chapter 10. Acknowledgments pertaining to this study have been omitted from this chapter and are included at the beginning of the PhD thesis. A reprint of the original article is provided for reference in
Appendix C – Publication Reprint (Chapter 5).
5.1. Abstract

Background and Aims

To assess the hearing preservation outcomes in a large group of adult CI recipients implanted with a TSEA using atraumatic surgical techniques. Factors affecting hearing preservation will be investigated.

Method

Prospective cohort study undertaken at the RVEEH in Melbourne, Australia from December 2010 to May 2015. Setting - Tertiary academic hospital. Patients - One hundred thirty-nine adults undergoing CI. Main outcome measure - Primary outcome measure of interest was pre- and post-operative pure-tone audiometry.

Results

Median low-frequency hearing change for the whole group of 139 recipients was -22.5 dB HL at the 3 months post-op point. Eighty-six participants had functional pre-operative low-frequency hearing (≤70 dB HL average at 250 and 500 Hz). Of these, 90.7% retained measurable hearing at 3 months post-implant. 39.5% of this original 86 participants retained functional hearing at 3 months post-implant. At 12 months post-implant, those who retained functional hearing at 3 months had no significant change in hearing. The group who lost functional hearing continued to have a significant deterioration in low-frequency hearing. Degree of hearing loss pre-implant was identified as a predictor for the preservation of hearing post-operatively.

Conclusion

Preservation of hearing is possible following atraumatic cochlear implant surgery with a thin straight electrode array. The amount of hearing preserved seems to be variable, and factors related to this variability are not yet known. The results of the present study suggest pre-operative low-frequency hearing at or better than 45 dB HL may be related to preservation of functional hearing.
5.2. Introduction

CIs have become the intervention of choice for patients presenting with severe to profound hearing loss, with some patients achieving excellent open-set speech recognition and improved communication abilities (Dowell, 2005; Gifford, Dorman, Shallop, et al., 2010; Leigh et al., 2010). Over the past decade, individuals with significant low frequency hearing and little to no high frequency hearing have emerged as a patient group indicated for CI (Buchner et al., 2009; Turner et al., 2008; Woodson et al., 2010). Where these individuals receive an implant and have preserved low frequency hearing, there is improved speech recognition in noise and better music perception when compared to their implanted peers with no residual hearing (Gfeller et al., 2006; Sucher & McDermott, 2009). As a result of this, much work has gone into developing techniques to minimise trauma during CI surgery in an attempt to preserve the patient’s natural hearing.

Factors considered in the discussion of atraumatic surgery include surgical approach, insertion technique, use of topical and/or systemic steroids, and perhaps most importantly the structure and design of the implanted device itself. It has been suggested that a CI insertion depth beyond the first turn (or point of first resistance) is likely to lead to significantly increased risk of cochlear trauma and damage to cochlear structures resulting in a loss of acoustic hearing (Gstoettner et al., 1999). Manufacturers have produced a variety of electrode arrays in an attempt to provide minimal insertion trauma and an opportunity to preserve natural hearing and cochlear structures, however results for hearing preservation in the literature have been mixed.

One of the reasons for the varied outcomes in hearing preservation is the inconsistent reporting methods utilised, making it difficult to compare hearing preservation across the array of implant technologies and study groups. Methods that have been used to illustrate change in hearing include calculation of a mean change in hearing at 500 Hz, average low frequency hearing loss, and use of terminology such as ‘complete hearing preservation’ based on a variety of different calculation methods. In 2013, the HEARRING Group attempted to provide a standardised method of quantifying percentage of hearing preservation which provided some clarification as to what defined ‘complete hearing preservation’ where this method of calculation was used (Skarzynski
et al., 2013). The HEARRING Group method does not, however, provide an insight into amount of useful hearing preserved as the percentage preservation is heavily related to the individual’s pre-operative hearing. Additionally, this percentage preservation may not be easily calculated in a clinical setting using the audiogram itself, though it has clear merits in a research database setting for consistent recording.

It is important for research in this area of hearing preservation post-CI to follow a patient cohort for a number of months. Research has shown that atraumatic surgery plays an important, though not all-encompassing, role in hearing preservation. Post-implant factors also play a part in loss of hearing, as patients who have preserved some natural hearing often go on to have a rapid deterioration of hearing within the months following CI surgery (Santa Maria, Domville-Lewis, Sucher, Chester-Browne, & Atlas, 2013; Van Abel et al., 2015). There is therefore a need to understand the risks of loss of hearing, including the pattern of progression, in order to effectively counsel recipients pre-operatively.

The aim of this research was to assess the hearing preservation outcomes in a large group of adult CI recipients using a TSEA. More specifically this study aimed to assess which factors, whether controllable or non-controllable, have an effect on the post-operative hearing. An understanding of these factors would likely aid in pre-operative patient counselling and expectation management.

The present study will present the hearing preservation data in a number of ways, with a view to providing information that is relevant for clinical counselling of patients pre-implant. Many techniques have been used for assessing hearing preservation in the literature. An issue highlighted in the literature is that certain techniques used will lead to a bias in the group hearing loss statistics (James et al., 2005; Skarzynski et al., 2002; Skarzynski et al., 2012). In addition to using the HEARRING Group method to assess percentage of hearing preservation across the group, we will also present the raw data relating to change in hearing for the group. For this analysis, we have utilised the approach of representing non-measurable hearing thresholds as an arbitrary figure of 125 dB, used in a variety of previous studies (Balkany et al., 2006; Dalbert et al., 2015; Kiefer et al., 2004). While it is acknowledged that this approach may underestimate the
group metrics, the approach represents the individuals with non-measurable hearing thresholds and does not skew the distribution unduly.

Finally we will analyse the group in relation to preservation of ‘functional’ hearing. It is generally accepted in both clinical experience and in the literature that conventional amplification may not always provide adequate benefit to patients with significant hearing loss. It has been found that for those with hearing loss in the severe regions, intelligibility of the speech signal may be reduced despite appropriate amplification. It is thought that this is due to damage in the cochlea not limited to the outer hair cells but also affecting the inner hair cells (Ching et al., 1998; Hogan & Turner, 1998). As one of the major goals of a TSEA and atraumatic surgical technique in cochlear implantation are to retain and make use of functional low frequency hearing, the present study will use the conservative value of 70 dB HL in its definition of ‘functional’ low frequency hearing.
5.3. Materials and Methods

A prospective longitudinal study of hearing outcomes was undertaken at the RVEEH, where institutional HREC approval was obtained under project number 15/1207H. Adult patients who were consented for and received a TSEA were observed pre-operatively, and 3 and 12 months post-implantation. At each time point, unaided audiometric testing was performed in addition to a speech perception test battery as per RVEEH clinical protocol.

5.3.1. Participants

The study was performed from December 2010 to May 2015, during which time 154 adults were implanted with a TSEA in accordance with RVEEH CI candidacy guidelines (Leigh et al., 2016). Of those, 139 recipients had pure tone audiometry completed at 3 months post-implant to enable analysis (note: of these, 74 recipients had pure tone audiometry measures at 12 months post-implant and 65 did not). The 15 recipients from the original 154 who were not included in the analysis were either lost to follow up (due to implant non-use and/or being transferred to another CI service), had been previously determined to have auditory neuropathy spectrum disorder, or did not attend for their evaluation session. Of the 139 recipients, 49 were involved in a double-blinded clinical trial assessing the effect of a large dose of steroid administered intra-operatively. As this trial is ongoing, the authors are currently blinded to which recipients were given the steroid and as such will account for this by including study involvement in the factor analysis (see Figure 5.1).

Post-operatively, each recipient received the standard RVEEH clinical protocol and was programmed using behavioural techniques by experienced audiologists. EAS devices were used where audiologically appropriate and where the recipient was interested to try this style of fitting.

5.3.2. Analysis of pre- and post-operative hearing

For whole-group analyses, we have utilised the approach of representing non-measurable hearing thresholds as an arbitrary figure of 125 dB. We have used median values (and median change) in order to provide valid measures of hearing preservation (James et al., 2005). In our application of the HEARRING Group method, we used pure
tone thresholds from 250-4000 Hz where the maximum testing level was considered to be 125 dB HL. Finally, we used a technique whereby the low frequency pure tone median (LFPTM) was determined from each participant’s median hearing levels at 250 and 500 Hz. Given the patient population, this approach may be more representative of degree of hearing and change in hearing. The LFPTM was used in our assessment of preservation of functional hearing, with a LFPTM of 70 dB HL or better defined as ‘functional hearing’. Those with functional hearing pre-operatively were divided into two groups based on presence of functional hearing at 3 months post-implant. Group 1 were those who had functional hearing pre-operatively and preserved it, where Group 2 were those who had functional hearing and lost it (refer to Figure 5.2). Non-measurable post-implant hearing thresholds were accounted for in the statistics when looking at ‘loss of measurable hearing’. As there was no valid way to quantify the degree of change accurately without bias, those who lost all measurable hearing were excluded from the analysis of change in hearing.

5.3.3. Surgery and Post-operative Radiological Analysis

All recipients received a Nucleus Slim Straight CI422 through the RVEEH service. Atraumatic surgical techniques were used in all cases using a round window approach. The true round window membrane was exposed by drilling the overhang of the round window niche. The membrane itself was punctured with a hypodermic needle and the electrode slowly inserted without lubricant. Steroid administration was variable, as recipients either received either intravenous Dexamethasone (8mg) or they were enrolled in a clinical trial that involved an additional high dose intravenous steroid. Surgery was performed by one of ten RVEEH CI surgeons with variable levels of experience.

The final position of the electrode array was assessed by analysis of post-operative x-rays for 100 recipients who had available x-rays out of the population of 139 (72%). The analysis was completed by one of two experienced CI surgeons. The angle of electrode insertion was determined relative to the Round Window - Mid Modiolar line on cochlear view plain x-ray.
5.3.4. Data collection

Information was collected on a series of patient specific factors (see Table 5.1) in order to assess their effect on the preservation of hearing. Demographic data was collected as the recipients were implanted with the TSEA, with additional clinical data acquired at the 3 and 12 month post-implant points.

Statistical analysis was conducted using Minitab statistical software version 17. Appropriate parametric and non-parametric tests were used based on the distribution of the data being investigated, as noted in the Results section. An α level of 0.05 was used for all statistical tests.
Figure 5.1: Flowchart of Participants in the study to 3 months post-implant.
5.4. Results

5.4.1. Participants
Assessing the demographics of the group of 139, 68 (48.9%) were female and 71 (51.1%) were male. Mean age at implant was 62.3 years (SD=15.7) with a mean duration of deafness in the implanted ear of 14.9 years (SD=11.3). The average number of days between surgery and activation was 17.2 days (SD=3.5) with a mean angular depth of insertion of 420.5 degrees (SD=46.7). Finally, 31 recipients (20.1%) of the TSEA were 2nd side CI recipients.

In our assessment of preservation of functional hearing and factors affecting change in hearing, a number of participants were excluded to enable accurate analysis. 14 participants with a prelingual hearing loss were excluded, and an additional 39 recipients were excluded as they were not considered to have functional low frequency hearing pre-implant. In this way, the prelingually deaf recipients and those without functional hearing were excluded to attempt to create a more uniform group to study. This left a study group of 86 participants.
Figure 5.3: The pre- and post-implant LFPTM for 78 TSEA recipients with functional pre-implant low frequency hearing. The diagonal line represents the ideal scenario where post-implant hearing is the same as pre-implant.

5.4.2. Change in hearing – whole-group analysis

Assessment of hearing preservation was conducted across the whole group of 139 TSEA recipients for the 3 months post-implant time point. Using the HEARRING Group criteria, mean hearing preservation was 58.4%. According to the criteria, 36.7% of recipients had Complete Hearing Preservation (HP), 46.8% had Partial HP, 6.5% had Minimal HP, and 10.1% had Loss of Hearing/no HP. Median change in LFPTM from pre-implant to 3 months post-op was found to be -22.5 dB HL, and ranged between +12.5 dB HL to -87.5 dB HL. Note that one recipient demonstrated threshold improvement post-operatively, with the reason for this being unclear. Median pre- and post-operative audiometric thresholds in addition to median change at each individual frequency are displayed in Figure 5.2.

The data were further analysed for the 74 recipients with hearing measured to the 12 month post-op point. The average hearing preservation was 44.4% by 12 months post-op, according to the HEARRING Group criteria. Breaking this down into the individual categories, it was found that by 12 months 20.3% of recipients had Complete HP,
47.3% had Partial HP, 14.9% had Minimal HP, and 17.6% had no HP. Median change in LFPTM from pre-implant to 12 months post-implant in this smaller group of 74 recipients was found to be -34.1 dB HL, and ranged between 0 dB HL to -105 dB HL change.

5.4.3. Preservation of functional hearing

Assessment of the group with functional pre-operative low frequency hearing was conducted at 3 months post-implant, where the LFPTM at or better than 70 dB HL was considered ‘functional hearing’. Of the 86 TSEA recipients in this group, a total of 8 recipients (9.3%) lost all measurable hearing. Of the remaining group, 78 retained measurable hearing (90.7%) and 31 retained functional hearing (39.5%).

Excluding the 8 participants who lost all measurable hearing post-implant, the group of 78 were further analysed to assess difference between those who lost functional hearing versus those who did not. Group 1 were those who had functional hearing and retained it (n=31), Group 2 were those who had functional hearing and lost it post-implant (n=47). There was no significant difference between the groups for number of days between surgery and activation (Group 1 mean= 17.8 days, Group 2 mean= 16.7 days, p=0.245), age at implant (Group 1 mean= 64.7 years, Group 2 mean= 64.2 years, p=0.864), angular depth of insertion (Group 1 mean= 420.8 degrees, Group 2 mean= 412.2 degrees, p=0.481) or duration of severe to profound loss in the implanted ear (Group 1 mean= 11.5 years, Group 2 mean= 13.2 years, p=0.444). There was an even spread between the groups for those included in the additional blinded steroid study (Group 1 38.7%, Group 2 38.3%). Proportion of males and females differed slightly between the groups (Group 1 38.7% males, 61.3% females; Group 2 55.3% males, 44.7% females). Group 1 had significantly better pre-operative low frequency hearing compared to Group 2 (Group 1 mean= 36.3 dB HL, Group 2 mean= 54.5 dB HL, p<0.001). This is demonstrated in Figure 5.3.

As would be expected from the division into respective groups, Group 1 had significantly better low frequency hearing at 3 months post-implant compared to Group 2 (Group 1 mean low frequency hearing= 51.7 dB HL, Group 2 mean= 89.8 dB HL, p<0.001). There was a significant difference in the low frequency hearing between the groups at 12 months post-implant, where Group 1 continued to retain significantly
better hearing compared to Group 2 (Group 1 mean low frequency hearing= 58.6 dB HL, Group 2 mean= 98.0 dB HL, p<0.001). For both Group 1 and Group 2, significant deterioration in hearing was noted from pre-implant to the 3 month point (p<0.001). Between 3 and 12 months post-implant however, Group 1 participants did not demonstrate a significant deterioration in low frequency hearing (p=0.065). In contrast, there was a significant deterioration seen in the low frequency hearing thresholds for Group 2 between 3 and 12 months post-implant (p=0.004), see Figure 5.4.

5.4.4. Factors contributing to hearing loss

From the 13 analyses conducted against change in LFPTM at 3 months, no patient or surgical factors were shown to have significant relationships. This data is presented in Table 5.1. Angular depth of insertion had no relationship with change in LFPTM at 3 months post implantation (p=0.177). This lack of relationship is demonstrated in Figure 5.5. Of the group of 78, 57 of those had available x-rays for analysis (73%), with 29 of Group 1 and 28 of Group 2 having available imaging. There was no significant difference in the angle of insertion between those who preserved functional hearing and those who lost (Group 1 mean= 406 degrees, SD=51.5; Group 2 mean= 419.9 degrees, SD=38.0; p=0.254). To evaluate consistency in reporting, 10 post-operative x-rays were analysed by both surgeons. As the data was not normally distributed, a Mann-Whitney analysis of medians was used. There was no significant difference between reported angular insertion depth between the two surgeons.
Figure 5.4: Change in LFPTM over time, comparing Group 1 (n=31) and Group 2 (n=47).

Figure 5.5: Scatterplots of angular depth of insertion versus change in LFPTM from pre-implant to 3 months post-op for n=78 adult recipients of a TSEA. No significant relationships were found (p=0.177).
5.5. Discussion

The results of the present study demonstrate that, hearing preservation is possible when using a TSEA. Median low frequency change by three months post-implant was 22.5 dB HL and 34.1 dB HL by 12 months, with some recipients showing no change in low frequency hearing. These outcomes are consistent with results in the literature demonstrating the preservation of functional hearing post-implant (Lesinski-Schiedat et al., 2011; Skarzynski et al., 2014; Van Abel et al., 2015).

The present data set showed a variety of outcomes from complete hearing preservation through to total loss of hearing. However, in those with ‘functionally useful hearing’ pre-implant (i.e. LFPTM of 70 dB HL or better, as determined by the criteria set in the present study), it was identified that degree of hearing loss was a predictor for the preservation of hearing post-operatively. Those with better hearing pre-implant had better low frequency hearing post-implant.

While it is not surprising that better pre-implant hearing is predictive of better post-op hearing, it is important to observe the distribution of the data presented for those with functionally useful pre-operative hearing. When assessing the distribution of pre-operative hearing of both groups in Figure 5.6, looking specifically at Group 1’s 3rd Quartile and Group 2’s 1st Quartile figures, it would appear that low frequency hearing at 45 dB HL or better is an important marker for hearing preservation. Approximately 75% of Group 1 had pre-operative hearing ≤ 45 dB HL, and 75% of Group 2 had pre-op hearing ≥ 45 dB HL. Using this data, CI surgeons and clinicians can be guided in their discussion of hearing preservation for potential recipients with useful pre-operative low frequency hearing. Where the recipient has a pre-operative low frequency median of 45 dB HL or better, counselling would reflect a 75% chance of preserving functionally useful hearing. More importantly for recipients with low frequency hearing of 50 dB HL or poorer, careful counselling should be employed to inform candidates that there may be a 75% chance of losing functional hearing.

The figure of 70 dB HL was used in this study as the differentiator between functional and non-functional low frequency hearing. It is worth noting that this is a metaphorical ‘line in the sand’, and results presented may have been different should another figure have been chosen. Clinically we know that there comes a point that, while measurable,
an individual’s hearing is no longer useful for the purposes of acoustic amplification. The authors acknowledge that there may be disagreement in the field about how much low frequency hearing is considered ‘functional’, however for the purposes of this study we propose the figure of 70 dB HL.

In contrast to literature suggesting a deeper insertion depth is likely to lead to increased loss of residual acoustic hearing (Gstoettner et al., 1999; James et al., 2005), this study demonstrated no correlation between the depth of insertion and loss of hearing. Angular depth of insertion ranged from 270-530° with no relationship to degree of hearing loss evident (see Figure 5.5). Further research at RVEEH using intraoperative electrocochleography (ECochG) suggests depth of insertion may be important, particularly beyond 25mm. A limitation of the present study is the measurement of depth of insertion from x-ray. Our department has subsequently changed to using cone beam CT for assessing electrode position and depth post-operatively.

Recent electrophysiological research has provided evidence to show that all patients who had detectable changes in their intra-operative ECochG response lost all residual acoustic hearing (Dalbert et al., 2015; Radeloff et al., 2012). Campbell and colleagues (Campbell, Kaicer, Briggs, & O'Leary, 2015) have demonstrated the ability to record

Figure 5.6: Comparison of pre-operative hearing between Group 1 and Group 2. A significant difference was found in the pre-operative LFPTM between the groups (p<0.001).
ECochG using the CI itself. These techniques may prove useful in intra-operative monitoring and allow better hearing preservation outcomes in future.

The majority of patients encountered in implant centres have a progressive hearing loss, therefore pre-operative counselling must also touch on the possibility of further hearing loss over time. It is important to consider use of a full-length electrode array given the likelihood of further hearing deterioration over time. Continued audiological monitoring of both the CI ear and the contralateral ear is important, with contralateral ear hearing one factor we were unable to assess in the present study. Long-term follow-up is necessary, particularly for patients using electroacoustic stimulation, as change to hearing may necessitate changes to amplification settings, cross-over frequencies and their general EAS set-up in future.

Table 5.1: Assessment of change in low frequency hearing versus patient-specific and surgical factors in 78 TSEA recipients. Asterisk on 'Laterality' represents the factor is controllable to an extent - there may be ability to control for side however this will not always be the case.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Pearson r</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Controllable Factors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insertion angle (degrees)</td>
<td>0.181</td>
<td>0.177</td>
</tr>
<tr>
<td>Time between Sx and IA (days)</td>
<td>0.100</td>
<td>0.384</td>
</tr>
<tr>
<td>Surgical factors (high dose steroid clinical trial)</td>
<td>n/a</td>
<td>0.425</td>
</tr>
<tr>
<td>Laterality*</td>
<td>n/a</td>
<td>0.083</td>
</tr>
<tr>
<td>Surgical factors (surgeon)</td>
<td>n/a</td>
<td>0.073</td>
</tr>
<tr>
<td><strong>Non-Controllable Factors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aetiology</td>
<td>n/a</td>
<td>0.312</td>
</tr>
<tr>
<td>Gender</td>
<td>n/a</td>
<td>0.672</td>
</tr>
<tr>
<td>Duration of loss (CI ear)</td>
<td>-0.143</td>
<td>0.215</td>
</tr>
<tr>
<td>Duration of loss (total)</td>
<td>-0.118</td>
<td>0.307</td>
</tr>
<tr>
<td>Pre-operative 500 Hz threshold</td>
<td>-0.091</td>
<td>0.427</td>
</tr>
<tr>
<td>Pre-operative LFPTM</td>
<td>-0.089</td>
<td>0.440</td>
</tr>
<tr>
<td>Pre-operative monosyllabic word score (%)</td>
<td>0.143</td>
<td>0.235</td>
</tr>
<tr>
<td>Age at CI (years)</td>
<td>-0.164</td>
<td>0.152</td>
</tr>
</tbody>
</table>
5.6. Conclusion

In a study of 139 recipients of a TSEA, good hearing preservation was demonstrated up to 12 months post-operatively. There is a large amount of variability in the preservation of hearing for adults with a TSEA and the causes for this variability are not known. It is likely there are patient-specific factors at play that we are either unaware of or unable to measure at present. Degree of hearing loss prior to implantation has been indicated as a potential predictor for the preservation of hearing, in that those patients with low frequency hearing of 45 dB HL or better appear to have a 75% chance of preserving significant hearing post-op.

Further study is warranted in this area, with both adult and paediatric CI recipients, which may allow researchers to identify specific factors related to the preservation of hearing. Additionally, while outside the scope of the present study, future study of the functional outcomes of CI recipients with preserved hearing is warranted with a view to further understanding the benefits of EAS in this group.
6. Speech perception for adult cochlear implant recipients using a lateral wall or perimodiolar array

In order to assess whether the style of electrode array used has an effect on the speech perception outcomes for adults with PD using CI (Aim 3, Hypotheses 4 and 5), the following chapter examines the speech perception outcomes for two groups of adult CI recipients with pre-implant PD who differ in the type of electrode array used. The content of this chapter has been accepted for publication by Otology & Neurotology:


For the purpose of continuity in the PhD thesis, some abbreviations and phrasing have been been edited from the original where applicable. The reference list pertaining to this paper has paper has been omitted from this chapter and is included in the complete reference list in in Chapter 10. Acknowledgments pertaining to this study have been omitted from this chapter and are included at the beginning of the PhD thesis. A reprint of the initial publication proofs is provided for reference in
Appendix D – Publication Proofs Reprint (Chapter 6).
6.1. Abstract

Background and Aim

To assess the speech perception outcomes of adult CI recipients with partial deafness, examining differences between perimodiolar and lateral wall electrode placement in order to provide clinical guidance for clinicians and surgeons.

Method

A prospective cohort study was undertaken identifying all adults who received a TSEA at the RVEEH from 2010-2015 and who had a pre-implant low frequency pure tone median ≤70 dB HL (n=63). A retrospective review was completed of the RVEEH database to identify a comparison group who had been implanted with a perimodiolar electrode array, comprising adults implanted between 2004 and 2011 (PM Group) with pre-implant hearing equivalent to the TSEA group (n=70). The TSEA Group were further divided into subgroups in which n=19 used EAS (TSEA-EAS) and n=44 who used electric-only hearing (TSEA-Standard).

Results

There was no significant difference in median speech perception outcomes between the TSEA and PM Groups (TSEA 61.7%, PM 67.3%, p=0.954). A significant difference was found between the TSEA-EAS and TSEA-Standard sub-groups for median speech perception outcome (TSEA-EAS median 73.5%, TSEA-Standard median 58.3%, p=0.043).

Conclusion

Significant speech perception benefit following CI was achieved with both the perimodiolar and lateral wall electrode arrays and no significant difference was found between outcomes with those array types. Those that received a TSEA, had preserved hearing, and utilised an EAS sound processor performed better than their peers with a TSEA and electric-only hearing.
6.2. Introduction

Developments in internal and external components of the CI have led to improvements in speech perception outcomes and the gradual expansion of candidacy criteria to include those with more residual hearing (Dowell, 2005; Gifford, Dorman, Shallop, et al., 2010). Many patients seeking advice regarding their own CI candidacy may have higher expectations of speech perception benefit than in the past. As with any medical intervention, a thorough evaluation of the relative risks and benefits is essential. It is the clinician’s role to assess the needs of their patient and recommend a device that provides the greatest speech perception benefit whilst balancing the potential risk of loss of hearing. This benefit-risk trade-off must also incorporate the patient’s own preferences in the decision-making process, as the perception of risk may be greater for some than others (Hauber, Fairchild, & Johnson, 2013).

Research suggests that the greatest hearing preservation occurs where there has been the least trauma to the cochlea at the time of implantation. Several studies have demonstrated that with increased angular depth of electrode insertion there is a decreased likelihood of preserving usable hearing (James et al., 2005; O'Connell, Cakir, et al., 2016). Suhling and colleagues demonstrated increased hearing loss as depth of insertion into the cochlea increased (2016). The rate of hearing preservation was poorer where the electrode array had been advanced beyond the point of first resistance (Gstoettner et al., 1999). Moran and colleagues (2017) found that angular depth of insertion was not related to degree of hearing loss for adult CI recipients, however a key limitation in that study was that imaging techniques were restricted to plain x-ray. Improved hearing preservation outcomes have been reported in the literature for shorter electrode arrays and for arrays specifically designed for reduced insertion trauma (Gantz et al., 2006; Kiefer et al., 2004; Lesinski-Schiedat et al., 2011; Moran et al., 2017; Skarzynski et al., 2014; Van Abel et al., 2015). Regardless of the device chosen or surgical procedure, there remains the possibility that CI recipients lose all hearing during or after the procedure, thus it is important to provide accurate information about this risk in addition to expectations regarding speech perception benefit during counselling.
Certain demographic and surgical/device-related variables have been identified as having a significant effect on speech perception benefit for adults with an acquired hearing loss who receive CIs. Increasing age at implantation is generally accepted to have a negative effect on speech perception performance (Blamey et al., 1996; Friedland et al., 2010; Holden et al., 2013; Holden et al., 2016; Rubinstein et al., 1999). There appears to be a stronger negative effect in the very elderly population who receive a CI, though there is likely some confounding factor to this effect due to known changes in auditory and cognitive processing in this age group (Gates et al., 2008; Holden et al., 2016; Wong et al., 2016). Duration of deafness has traditionally been seen to have a negative effect on speech perception outcomes, thought to be a result of deteriorating central auditory processing skills with increasing years of auditory deprivation (Blamey et al., 1996; Blamey et al., 2013; Dowell, 2005; Holden et al., 2013). In Blamey and colleagues’ update to their 1996 study, while duration of deafness was a significant factor it had a smaller effect size than in their original study (2013). Further reflecting the potential changes in CI candidates, Holden and colleagues (2016) did not find a significant correlation between duration of deafness and speech perception outcomes, which the authors proposed was related to the group’s use of HAs pre-CI, mitigating the effects of auditory deprivation. Additionally, higher levels of pre-implant speech perception appear to have a positive effect on post-implant speech performance (Holden et al., 2013; Rubinstein et al., 1999).

Position of the electrode array within the cochlea appears to be important, in that ST location has been shown to provide superior outcomes compared to SV location (Aschendorff et al., 2007; Wanna et al., 2014). Finley and colleagues (2008) discussed the possibility of “cross-turn stimulation”, for an electrode array in SV, whereby activation of a single electrode site has the possibility of stimulating two populations of spiral ganglion cells in different cochlear turns, leading to pitch confusions and therefore diminished speech perception. If the electrode array trajectory translocates from ST to SV, this will lead to trauma, including fixation of the basilar membrane at the point of penetration; loss of the surviving hair cells; or potentially loss of spiral ganglion cells, and reduced benefits (Roland, 2005; Skinner et al., 2007).

The proximity of the electrode array to the modiolus has also been investigated in regards to speech perception outcomes. CI electrode arrays that are curved and designed
to be positioned adjacent to the modiolus (i.e. perimodiolar) are closer to the target neural receptors than straight arrays that sit against the lateral wall. Perimodiolar arrays have been reported to have lower current requirements than lateral wall arrays, and potentially reduced channel interaction leading to better speech perception (K. A. Gordon & Papsin, 2013; Saunders et al., 2002). However, there have been limited studies directly comparing perception outcomes with perimodiolar arrays versus lateral wall arrays. In a retrospective study of 465 adult CI recipients, Dowell (2012) reported that those using a curved perimodiolar electrode array had significantly better speech perception outcomes as compared to adults implanted with straight lateral wall arrays. Similarly, in a study of 114 adults using a variety of CIs, Holden and colleagues (2013) found that positioning of the electrode array closer to the modiolus was significantly correlated with better speech perception outcomes.

The aim of the present study was to assess the speech perception outcomes of adult CI recipients with significant pre-implant low frequency hearing or PD, with a view to providing clinical guidance for realistic expectation of benefit for the present CI candidate population. An additional aim was to examine differences in speech perception outcomes between perimodiolar and lateral wall electrode placement, by comparing populations using Nucleus Contour Advance electrode arrays (hereafter described as perimodiolar) and Nucleus Slim Straight electrode arrays (hereafter described as a TSEA). To examine the benefits hearing preservation may offer, speech perception outcomes were also analysed for a sub-group of recipients using lateral wall electrode arrays with and without EAS.
6.3. Materials and Methods

This prospective cohort study identified 154 adults who received a TSEA between December 2010 and May 2015 at the RVEEH CI Clinic in Melbourne, Australia. The standard assessment protocol involved unaided audiometric testing and an aided speech perception test battery pre-operatively, and at 3 and 12 months post-implant. These data were collected prospectively and entered with demographic details into a database. In order to compare speech perception outcomes by device type, a retrospective analysis of the RVEEH database also identified 636 adults who received a perimodiolar electrode array at RVEEH CI Clinic between 2004 and 2011 and who also completed the standard audiometric and speech perception protocol.

6.3.1. Participants

Participants were included in the study if their unaided audiometric testing indicated functional and aidable low frequency hearing, or PD: those with a LFPTM equal to or better than 70 dB HL. For participants with bilateral CIs, test data from the first side was included in the analysis. Those with prelingual onset of hearing loss, re-implanted patients, non-English speakers, and those with any comorbid neural or cognitive issues were excluded.

Data from 63 participants with a TSEA (TSEA Group) and 70 participants with a perimodiolar electrode array (PM Group) were included in this study.

Post-operatively, each recipient was programmed using behavioural techniques by experienced audiologists. EAS was used only with the TSEA Group, where clinically appropriate. For all post-operative assessments, participants used the sound processor provided at the time of initial activation which had been programmed as per standard clinical protocols. The PM Group used Freedom and Nucleus 5 (CP810) sound processors (54% (n=38) and 46% (n=32) respectively). The TSEA Group used Nucleus 5 (CP810) and Nucleus 6 (CP910 or CP920) sound processors if using a standard device (49% (n=31) Nucleus 5, 21% (n=13) Nucleus 6). Thirty percent (n=19) of the TSEA group used an EAS set-up, using either Freedom Hybrid (n=4), Nucleus 6 Hybrid (n=14), or a CP810 with an optimised ITE HA (n=1). All recipients were programmed using the ACE sound coding strategy and used Adaptive Dynamic Range Optimization (ADRO) regardless of the sound processor used (James et al., 2002; Vandali et al.,
Recipients were programmed at initial activation using the default software settings.

6.3.2. Materials

Recorded open-set word and sentence materials were used for all tests using a native Australian English speaker, via audition alone at 65 dB SPL at an azimuth of zero degrees. For tests in noise, the noise was presented from the same loudspeaker. Open-set monosyllabic word testing was conducted using CNC words spoken by a male speaker, with lists of 50 words scored for the number of correctly identified words and phonemes (Peterson & Lehiste, 1962). Open-set sentence-in-noise testing was conducted using the CUNY sentences, in which lists of 12 sentences were scored for the number of correct words from a total of approximately 102 keywords per list (Boothroyd et al., 1985). For each test, two lists were presented and the average of the two scores was taken. CUNY sentence testing was conducted in 8 talker babble background noise with an SNR of +10 dB, using a female speaker. Appropriate masking was introduced to the contralateral ear where required.

Preoperative speech perception data was obtained during implant candidacy assessment with optimised HAs. For the purpose of this assessment, only monaural scores from the ear to be implanted were included in the analysis. Post-operatively, where the recipient used ipsilateral EAS in their CI ear, this condition was used in the CI speech perception analysis (i.e. their ‘everyday’ configuration).

6.3.3. Surgery and Post-operative Radiological Analysis

Surgery was performed by one of ten RVEEH CI surgeons with variable levels of experience. All recipients in the PM Group received Contour Advance electrode arrays, manufactured by Cochlear Limited (Sydney, Australia). These devices were either Nucleus Freedom or Nucleus CI512 implants (74% (n=52) and 26% (n=18) respectively). For all the Contour Advance electrodes, insertion was through an extended round window or separate cochleostomy approach. For the TSEA Group, all participants received the Nucleus Slim Straight CI422 implant, manufactured by Cochlear Limited. In the majority of cases the electrode was inserted through an incision in the round window membrane. In the proximal basal turn, the TSEA is held close to the modiolus by the inferior edge of the round window and then assumes a
lateral wall position. The electrode arrays for both groups utilise 22 half-banded platinum stimulating electrodes.

For the TSEA Group only, the position of the electrode array was assessed by analysis of post-operative cochlear view x-rays in 45 of the 63 recipients (71%) who had x-rays available. The analysis was completed by one of two experienced CI surgeons. The angle of electrode insertion was determined relative to the round window - mid modiolar line on cochlear view plain x-ray.

6.3.4. Data management

Data pertaining to known variables likely to affect post-implant speech perception were collated (see Table 6.1). For the TSEA Group, demographic data was collected at the point of implant recommendation, with additional clinical data acquired at the 3 and 12 month post-implant points. For the PM Group, all data was collected retrospectively from the clinic database.

Speech perception data were assessed using a Principal Components Analysis. This showed 90.5% of the variance in the data was well explained by one component – a weighted average of the three scores. Given this, a TSPS was formulated by calculating an average of a recipient’s open set word, phoneme and sentence in noise score in order to obtain a single metric that could be used in our analysis to provide the most reliable statistical measure of performance. Scores are also presented for pre- to post-operative improvement by calculating the percentage point difference between the pre-operative score and the best post-operative score.

Statistical analysis was conducted using Minitab statistical software version 17. Data analysis was completed using nonparametric tests, as the data were not normally distributed. To assess the equality of group medians, Mood’s median test was used in place of an analysis of variance. Regression analyses were used to examine the impact of various factors on the post-operative speech perception outcomes for both groups. An α level of 0.05 was used for all statistical tests.
6.4. Results

6.4.1. TSEA and PM Group comparison

Mood’s median test indicated no significant differences between the groups in terms of the age at implantation (TSEA Group 66.7yrs, PM Group 71.1yrs; p=0.139), duration of severe to profound deafness (TSEA Group 10.0yrs, PM Group 10.0yrs; p=0.366), or post-operative speech perception scores (TSEA Group 61.7%, PM Group 67.3%; p=0.954). There was a significant difference found between the groups in terms of their median pre-operative hearing levels (TSEA Group LFPTM 50.0 dB HL, PM Group LFPTM 57.5 dB HL; p<0.004, see Figure 6.1). The TSEA Group also showed significantly better median acoustic hearing thresholds post-operatively (TSEA Group LFPTM 80.0 dB HL, PM Group LFPTM 106.3 dB HL; p<0.001). The TSEA Group had significantly better pre-operative speech perception than the PM Group (TSEA Group TSPS 21.7%, PM Group 10.8%; p=0.004, see Table 6.1)

As the TSEA and PM Groups differed with respect to factors associated with pre-implant hearing ability (i.e. LFPTM and TSPS), post-hoc examination of the degree of improvement were also completed in an effort to assist pre-implant counselling discussions. While there was no difference in overall functional hearing outcome as noted above, a significant difference was observed between the TSEA and PM Groups for the degree of improvement for TSPS, with the PM Group showing greater improvement (TSEA Group 38.2 percentage point improvement, PM Group 46.8 percentage point improvement; p=0.029).

6.4.2. Factors affecting speech perception outcomes

Multi-factor regression analysis was used to assess which factors may have had an influence over the post-operative speech perception outcomes. Factors included in the statistical model were age at implant, duration of deafness, pre-implant LFPTM, pre-implant TSPS and electrode position type (TSEA or perimodiolar). The outcome variable used in the model was post-implant TSPS.

Factors shown to significantly influence the variance of the post-implant TSPS were age at implant (F=34.64, p<0.001) and duration of ipsilateral deafness (F=4.00, p=0.048). This model accounted for 26.75% of the variance (R^2 adj) in post-implant TSPS. None of pre-operative LFPTM, pre-operative TSPS, nor electrode array used were
significantly associated with speech perception results (F=0.28, p=0.600; F=3.43, p=0.067; F=1.28, p=0.260 respectively).

Table 6.1: Demographic comparisons for the TSEA Group and the Perimodiolar Group. The post-implant speech perception scores represent the average score for each test at either 3 or 12 months post-op using the most recent test scores for each individual. Note: Some participants did not complete sentence in noise testing, as a result for Sentences in Noise and therefore TSPS have lower participant numbers in the analysis (Pre-implant TSEA n=53, Perimodiolar n=62; Post-implant TSEA n=58, Perimodiolar n=67).

<table>
<thead>
<tr>
<th></th>
<th>TSEA Group (n=63)</th>
<th>Perimodiolar Group (n=70)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age at Implant (years)</strong></td>
<td>65.6</td>
<td>69.1</td>
<td>p=0.115</td>
</tr>
<tr>
<td><strong>Duration of deafness (years)</strong></td>
<td>13.0</td>
<td>11.1</td>
<td>p=0.251</td>
</tr>
<tr>
<td><strong>Pre-implant LFPTM (dB)</strong></td>
<td>47.4</td>
<td>56.5</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td><strong>Post-implant LFPTM (dB)</strong></td>
<td>79.6</td>
<td>102.9</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td><strong>Pre-implant speech perception (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Words</td>
<td>11.5</td>
<td>6.2</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Phonemes</td>
<td>36.1</td>
<td>26.1</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Sentences in noise</td>
<td>16.1</td>
<td>10.8</td>
<td>p=0.119</td>
</tr>
<tr>
<td>TSPS</td>
<td>20.6</td>
<td>13.8</td>
<td>p=0.002</td>
</tr>
<tr>
<td><strong>Post-implant speech perception (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Words</td>
<td>50.9</td>
<td>52.0</td>
<td>p=0.774</td>
</tr>
<tr>
<td>Phonemes</td>
<td>72.6</td>
<td>72.2</td>
<td>p=0.901</td>
</tr>
<tr>
<td>Sentences in noise</td>
<td>62.7</td>
<td>60.4</td>
<td>p=0.628</td>
</tr>
<tr>
<td>TSPS</td>
<td>63.1</td>
<td>62.5</td>
<td>p=0.877</td>
</tr>
</tbody>
</table>

6.4.3. TSEA Group analysis

In order to investigate the potential impact of use of EAS and/or angular depth of insertion on post-operative speech perception, separate analysis of data for the TSEA Group was conducted.
The TSEA Group was divided into two sub-groups based on the sound processing used. The TSEA-EAS Group (n=19) included those using a sound processor with EAS, and TSEA-Standard Group (n=44) included those using a sound processor in the standard electric-only configuration. There was no significant different in pre-operative median TSPS (TSEA-EAS median score 24.0%, TSEA-Standard median score 15.8%, p=0.107). Mood’s Median Test indicated that the post-operative TSPS was significantly better for the TSEA-EAS Group (TSEA-EAS median score 73.5%, TSEA-Standard median score 58.3%, p=0.043). Pre-implant LFPTM was significantly better in the TSEA-EAS group compared to the TSEA-Standard group (TSEA-EAS Group median LFPTM 35.0 dB HL, TSEA-Standard group 55.0 dB HL, p=0.006). The difference in LFPTM was also present at the 3 and 12 month post-operative points, with the TSEA-EAS group showing better hearing thresholds than the TSEA-Standard group (3m: TSEA-EAS Group LFPTM 50.0 dB HL, TSEA-Standard Group mean 90.0 dB HL, p<0.001; 12m: TSEA-EAS Group LFPTM 55.0 dB HL, TSEA-Standard Group mean 100.0 dB HL, p=0.027). Refer to Table 6.2 for details of these comparisons.

The TSEA-EAS Group was also compared to the PM Group to assess any differences in speech perception outcomes. Whilst there was a significant difference between the groups for median TSPS pre-implant (TSEA-EAS Group 26.7%, PM Group 11.7%, p=0.004), no significant difference was found for post-implant TSPS (TSEA-EAS Group 73.5%, PM Group 67.3%, p=0.175) or TSPS improvement scores (TSEA-EAS Group 38.0 percentage point improvement, PM Group 46.8 percentage point improvement, p=0.073)

To assess how much variance in the TSEA Group’s post-operative speech perception score was influenced by the angular depth of insertion of the electrode array, a regression analysis was completed. The angular depth of insertion varied between 350.0 and 530.0 degrees in the TSEA group, with the average being 417.2 degrees. Angular depth of insertion was not significantly associated with post-operative TSPS (p=0.482, R^2 adjusted 0%).
Figure 6.1: Comparison of pre- and post-operative hearing for the TSEA Group (6.1a) and PM Group (6.1b). Group average hearing levels shown in dB HL pre-operatively and 3 months post-implant, error bars indicating 95% confidence interval of the mean.
Table 6.2: Comparison of the TSEA Group sub-groups based on type of sound processor used. The post-implant speech perception scores represent the average score for each test at either 3 or 12 months post-op using the most recent test scores for each individual. Note: Some participants did not complete sentence in noise testing, as a result for Sentences in Noise and therefore TSPS have lower participant numbers in the analysis (Pre-implant TSEA-EAS n=15, TSEA-Standard n=38; Post-implant TSEA-EAS n=17, TSEA-Standard n=41).

<table>
<thead>
<tr>
<th></th>
<th>TSEA-EAS (n=19)</th>
<th>TSEA-Standard (n=44)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at Implant (years)</td>
<td>66.8</td>
<td>65.1</td>
<td>0.570</td>
</tr>
<tr>
<td>Duration of deafness (ipsilateral) (years)</td>
<td>11.7</td>
<td>13.5</td>
<td>0.507</td>
</tr>
<tr>
<td>Pre-implant LFPTM (dB)</td>
<td>37.5</td>
<td>51.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Post-implant LFPTM (dB)</td>
<td>56.1</td>
<td>89.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pre-implant speech perception (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Words</td>
<td>13.1</td>
<td>10.9</td>
<td>0.322</td>
</tr>
<tr>
<td>Phonemes</td>
<td>39.5</td>
<td>34.7</td>
<td>0.205</td>
</tr>
<tr>
<td>Sentences in noise</td>
<td>20.3</td>
<td>14.4</td>
<td>0.297</td>
</tr>
<tr>
<td>TSPS</td>
<td>23.1</td>
<td>19.5</td>
<td>0.322</td>
</tr>
<tr>
<td>Post-implant speech perception (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Words</td>
<td>52.3</td>
<td>50.3</td>
<td>0.757</td>
</tr>
<tr>
<td>Phonemes</td>
<td>71.2</td>
<td>73.2</td>
<td>0.680</td>
</tr>
<tr>
<td>Sentences in noise</td>
<td>68.0</td>
<td>60.5</td>
<td>0.353</td>
</tr>
<tr>
<td>TSPS</td>
<td>66.2</td>
<td>61.8</td>
<td>0.453</td>
</tr>
</tbody>
</table>
6.5. Discussion

Changes to CI candidacy in terms of pre-operative residual hearing thresholds are evident worldwide. This changing CI candidate pool is reflected in the present study. Despite following an audiometric inclusion criterion, the prospectively-recruited TSEA Group had significantly better pre-implant LFPTM than the PM Group who received their CI between 2004 and 2011. As identified by Blamey and colleagues (2013) this suggests that people are not waiting as long to access hearing technology.

No significant difference was seen between the TSEA and PM Groups for speech perception outcomes. Both groups received significant benefit from the CI, further evidence supporting the use of CI as a treatment option for individuals with PD (Buchner et al., 2009; Incerti et al., 2013; Moran, Dowell, Umansky, Briggs, & Corbett, 2014). The factors affecting speech perception outcomes in this cohort were consistent with previous studies including age at implant and duration of deafness. Recent literature suggests decreasing importance of ‘duration of deafness’ as a factor in CI studies given that candidates have much more hearing pre-CI than in the past. Individuals seeking CIs in the present day are typically making some use of HAs and residual low frequency hearing (Holden et al., 2016). The present study indicated a significant negative effect of duration of deafness, which post-hoc analysis showed was related to the sentence perception in noise task only. This may be due to the effect of auditory deprivation on higher level central auditory processing and the effect is therefore more pronounced for a sentence in noise task. Neither pre-implant speech perception nor LFPTM were found to be associated with post-implant TSPS in this study.

The TSEA Group maintained significantly better post-operative hearing thresholds than the PM Group. In a systematic review of 27 studies, Incerti and colleagues (2013) examined detailed hearing preservation data. They found that while hearing preservation was possible for a variety of electrodes including those with a perimodiolar design, it was improved with shorter or thinner electrodes specifically designed for hearing preservation, compared with conventional perimodiolar electrodes or straight electrodes used with varying insertion depths. Wanna and colleagues (2014) studied a series of 116 cases and found that lateral wall arrays were more likely to stay in ST than
perimodiolar arrays (89% vs. 58%). This result is supported by a recent systematic review by Hoskison and colleagues (2017) who found a 17.6% rate of insertion trauma from 653 implantations, 71.8% of which related to electrode array translocation. This was shown to be more common for curved rather than straight electrodes (Hoskison et al., 2017). Given the increased complexity in achieving ideal perimodiolar electrode insertion, it is possible that surgeon skill and/or device experience may contribute to variability. Recent review of experience with perimodiolar electrode positioning at the RVEEH demonstrated an 18% rate of scalar translocation and 9% SV insertion for Contour Advance electrodes that were intended for ST insertion. These findings were associated with a significant reduction in speech perception scores, approximately 15% poorer than those where the array lies wholly in ST (Shaul, Dragovic, Stringer, O'Leary, & Briggs, in press). Given these results, we must consider the group of implanting surgeons in the present study as a potential source of variability which may in turn have affected the average outcomes for the PM group. While the surgical group had the varying levels of experience, all ten surgeons were fellowship-trained CI surgeons and full electrode insertion was achieved in all cases as confirmed by x-ray. In a previous study by our group assessing hearing preservation for 139 TSEA recipients and the same ten CI surgeons, there was no significant correlation found between surgeon and change in low frequency hearing pre- to post-implant (Moran et al., 2017).

The results of the current study differ from previous studies that have reported better speech perception outcomes using perimodiolar arrays (Dowell, 2012; Holden et al., 2013). It is important to note that the present study differs from those in the literature in that it assesses outcomes for a particular group of implant recipients (i.e. pre-implant functional hearing as per the audiological inclusion criterion), and as a result these outcomes may not be representative of all CI recipients. Given the recent results by Shaul and colleagues (in press) discussed above, it is worth considering whether the rate of electrode arrays being positioned in SV or translocated may be similar for the perimodiolar group in the present study. While cone beam CT imaging was not available for the population in the present study, it would be of interest to compare the speech perception outcomes with the TSEA to perimodiolar devices with complete ST placement. In light of the evidence suggesting perimodiolar devices may yield improved speech perception outcomes, but with higher rates of trauma, there appears to be a need
for a perimodiolar electrode array with a more consistent ST placement. McJunkin and
colleagues (2018) recently published experience with a new slim modiolar device
(Nucleus Slim Modiolar CI532) with 74% complete ST insertions in a study of 117. Another study of the same device yielded 100% complete ST insertions for a series of 45 implantations (2017). Recent findings from RVEEH also demonstrate 100% ST placement in a study of CI532 implantations (Shaul et al., in press). These figures are higher than previously published results with older perimodiolar devices, which is promising for future CI recipients. Considering the risk-benefit trade-off of hearing preservation and speech perception, an electrode array with a predictable and consistent ST placement coupled with atraumatic surgical technique may provide the ideal balance. Further studies on the hearing preservation rates of such devices are needed.

As is the nature of studies using retrospective clinical data, a key limitation is that certain data points may be unavailable or not recorded. The sub-analysis looking at EAS fittings and imaging results conducted with the TSEA Group would have been useful with the entire cohort, however the necessary data was not available. An additional limitation of the present study was that only the TSEA Group was recruited and assessed prospectively, and as a result there was some variation in sound processing technology used. As would be expected from newer generations of sound processors, improvements were introduced in the CP900 generation of sound processors used by some of the TSEA Group which were not available to the PM Group at the time of their assessment. Improved microphone directionality and the introduction of a single channel noise reduction algorithm have been shown to provide improved speech perception outcomes in adults and children, which may have impacted the results seen in the present study when comparing groups (Hersbach, Arora, Mauger, & Dawson, 2012; Mauger, Warren, Knight, Goorevich, & Nel, 2014; Plasmans et al., 2016).

The benefits of EAS fittings are well reported in the literature. There is agreement within the field that if low frequency hearing can be preserved and successfully integrated with an EAS sound processor fitting, it is possible to have improved outcomes in domains relying on low frequency/timing cues. In the present study, it was observed that those with preserved hearing utilising an EAS device (TSEA-EAS) performed significantly better than their counterparts with electric-only hearing (TSEA-Standard), with a median TPS that was 15.2% greater. This difference was not
observed when the TSEA-EAS Group was compared to the PM Group, however the TSEA-EAS Group did demonstrate superior outcomes (TSEA-EAS median 73.5%, PM Group 67.3%, p=0.175). More sensitive test methodology and a larger EAS population may provide more insights in future.

Finally, it is important to address the question of power when assessing clinical data such as this. As no significant difference was found between the TSEA and PM Groups for TSPS, it is important to address whether the study was adequately powered to do so. Post hoc analyses were completed to assess the margin of error based on the standard deviation observed in the TSPS data. Conservatively taking the larger standard deviation of the two groups for TSPS (21.19), it was found that we would require a sample size of 111 to detect a difference within +/- 4%. Given the total population included in this assessment was 125, it would appear this study was sufficiently powered to detect a clinically significant difference if it was present for this population. Additionally, to verify the result seen in the TSEA sub-group analysis and assess the ability to truly detect a 15.2% difference, a margin of error analysis was conducted based on the TSEA TSPS standard deviation (17.95). Based on this information, it was calculated that with a sample size of 52 it would be possible to detect a difference within +/- 5%. Previous studies have accepted a difference of 10% as being a clinically significant (Dowell, 2012; Gilden, Lewis, Grant, & Crosson, 2015; Neben, Buechner, Schuessler, & Lenarz, 2018). It can therefore be concluded that the analysis of the TSEA group is appropriately powered and we can accept this as a clinically significant difference.
6.6. Conclusion

In this group of 133 adult CI recipients with pre-implant low frequency hearing, significant benefit to overall speech perception was achieved with either perimodiolar or lateral wall electrode array positioning. Electrode array type was not shown to have a significant relationship with speech perception outcomes. In those that received a TSEA, the angular depth of electrode insertion was not related to speech perception outcomes. Those who received a TSEA and utilised an EAS sound processor performed better than their peers with a TSEA and electric-only hearing.

Irrespective of the CI device used, in order to provide realistic expectations to this group, audiologists and surgeons must counsel appropriately on the factors at hand (i.e. duration of loss, age at implant) in relation to the individual’s chance of improvement. In light of the relative equivalence in speech perception outcomes found, for patients with no significant residual hearing to risk it would be reasonable to recommend either a TSEA or a perimodiolar device where the surgeon has a high degree of skill and confidence with the procedures. Where it is desirable that functional low frequency hearing be preserved, the device chosen and surgical techniques used should be in the interest of preserving and using this residual hearing given the significant benefit demonstrated in the present study.
7. General Discussion and Conclusions

7.1. Introduction

Cochlear implantation has become the standard of care for adults and children with severe to profound hearing loss. It is well established in the literature that modern CI systems provide recipients with improved access to sound and better open-set speech perception than HAs when they are indicated (i.e. based on audiological criteria and speech discrimination scores). Significant benefits to communication and speech discrimination have been reported for both adults and children (Blamey et al., 2013; Dettman et al., 2016; Dettman et al., 2007; Finley et al., 2008; Leigh et al., 2013; Skinner et al., 2002). Previously individuals were required to have profound-to-total bilateral SNHL to be considered for a CI, however criteria have expanded to include those with greater levels of residual hearing, due in part to documented speech perception benefits. Audiological guidelines for recommending CIs at the RVEEH presently include moderate-to-profound SNHL in the ear to be implanted, with equal to or less than 55% recognition of phonemes on an open-set audition alone monosyllabic word test (Leigh et al., 2016).

Pre-operative counselling for adults considering CIs is typically based on data from ‘traditional’ recipients with severe-to-profound or poorer audiometric thresholds pre-implant. Taking the RVEEH CI clinic guidelines, an adult who scores equal to or less than 55% phonemes on a monosyllabic word test in the ear to be implanted using their optimised HA would have a 75% chance of achieving better scores with a CI. The question remains as to whether this criterion is applicable to adults presenting with PD who have significant acoustic hearing that could be impacted by CI surgery. The guidelines for recommending CIs do not presently address potential differences in counselling for adults with PD regarding their potential to preserve or lose acoustic hearing, and there have been varying reports in the literature. This apparent variability in hearing preservation outcomes in addition to the consideration of risks to hearing versus benefits of speech perception has posed a significant challenge for clinicians in their ability to provide comprehensive evidence-based counselling.
The purpose of this project was to examine the hearing preservation and speech perception outcomes of a group of adults using CIs with pre-implant PD, reflective of the current population of CI candidates. The aim was to produce data to support evidence-based recommendations for adults with PD and to address some of the challenges in pre-implant counselling for this population.
7.2. Speech Perception

In the present study, speech perception for adults with PD using a CI was initially assessed by comparing to the traditional CI recipient with profound SNHL loss pre-implant, in order to address Aim 1 and Hypothesis 1 (discussed in Chapter 4). In addition, the outcomes for adults with PD using a CI were compared by electrode array design, in order to address Aim 3 and Hypotheses 4 and 5 (discussed in Chapter 6).

Reviewing the outcomes of the study presented in Chapter 4, it was found that both the group with PD pre-implant and the group with profound loss demonstrated significant benefit over their pre-implant scores as measured at 3 months post-implant. At both 3 and 12 months post-implant, there was no significant difference found for CI-alone speech perception between the groups (12 month TSPS: PD group median 72.0%, Profound group median 66.5%, p=0.157). It is important to note that for the group of adults with PD discussed in Chapter 4, all persons in this study used Contour Advance electrode arrays and no attempt was made at preserving acoustic hearing. As a result, while the groups had markedly different pre-implant hearing, both groups used only electrical hearing post-implant.

Reviewing the outcomes of the study presented in Chapter 6, it was found that there was no significant difference between the median TSPS for adults with PD using a CI with a TSEA or a perimodiolar electrode array (TSEA 61.7%, PM 67.3%, p=0.954). Some individuals within the TSEA group had preserved hearing and used EAS sound processors (the TSEA-EAS sub-group). The individuals in this sub-group were found to perform significantly better than their peers with electric-only hearing (median TSPS for TSEA-EAS 73.5% and TSEA-Standard 58.3%, p=0.043). These results are comparable to data presented in Skarzynski et al. (2014) for recipients of the CI422 TSEA using the Freedom Hybrid sound processor. In this study, recipients were divided into groups based on pre-implant hearing at 500Hz (n=11 with 500Hz threshold ≤50 dB HL, n=13 at 50-80 dB HL, n=11 ≥80 dB HL). While all three groups showed significant improvement in speech perception from pre- to 12 month post-implant, the groups with hearing better than 80 dB HL (i.e. those that had potential to gain from EAS) performed significantly better than the group whose hearing threshold was ≥80 dB HL at 500Hz pre-implant. This result was most pronounced for speech in noise testing, where the
groups with hearing better than 80 dB HL performed approximately 15% better than their peers with profound loss pre-implant.

Overall, the results of these studies suggested that adults with PD achieve similar speech perception outcomes to the traditional CI recipient and may be better if hearing is preserved allowing them to use EAS. Electrode array type was not found to be a significant factor in outcomes for this population of adults with PD. However, in a small subset of adults with PD where hearing was preserved allowing the person to use EAS, this provided significant benefit over electric-only stimulation for those with a TSEA. Given that lateral wall devices (e.g. TSEA) have the potential to better preserve acoustic hearing compared to perimodiolar devices (Incerti et al., 2013), choice of device type may in fact be a significant factor for speech perception outcomes in adults with PD when using all modes of auditory input available.

The results of the speech perception analyses completed in Chapters 4 and 6 provide some evidence to guide counselling regarding the risk versus benefit question for adults with PD proceeding with a CI. The question of risk versus benefit is a significant issue in the CI field today with persons considering a CI raising queries in relation to the risk of losing their natural residual hearing, and whether they may be ‘worse off’ in that instance. As Chapter 4 examined the speech perception outcomes of adults with PD where no attempt was made at hearing preservation, the data from this paper allows the opportunity to consider the ‘worst case scenario’, i.e. evidence regarding outcomes where all residual hearing was lost. The results demonstrated that CIs can provide significant benefit to adults with PD who had lost all functional acoustic hearing; adults with PD in this study obtained equivalent levels of speech perception to their implanted peers who had profound hearing loss pre-implant. The results of this study support the findings of Incerti et al. (2013) who demonstrated that CI recipients achieved significantly better post-operative speech perception scores (compared to pre-operative) using only the electric component of their EAS system. The authors suggest that this provides evidence to support a hearing preservation approach, with the relative ‘risk’ of hearing loss being minimised, as the recipients show benefit even where there is complete loss of residual hearing. The Incerti review also demonstrated that speech perception scores were consistently higher where EAS was used over electric-only stimulation.
The data from Chapter 6 demonstrated further benefits for those with preserved hearing using EAS compared to CI alone. This would suggest that electric-only speech perception outcomes are comparable, and roughly predictable, for postlingually deafened adult CI recipients, whether they have PD or a more profound loss pre-implant (Chapter 4). Should the individual retain their natural hearing after the CI procedure, we can expect their performance to be improved by using EAS. This information provides CI clinicians and surgeons with evidence to tackle the ‘benefits’ part of the equation, and the ‘risks’ to natural acoustic hearing will be discussed in Section 7.3.

Finally, both of the studies discussed in Chapters 4 and 6 assessed factors associated with speech perception outcomes. For all the PD groups, both in Chapter 4 and 6, age at implant and ipsilateral duration of deafness were shown to have a significant effect on the post-implant speech perception score. For the group with profound loss, no relationships were found between known predictive factors (e.g. age at implant, duration of deafness) and post-operative speech perception. It is difficult to comment on why the profound loss group did not demonstrate these relationships given the two groups in that study were matched pair-wise on duration of deafness and age at implant and did not demonstrate a significant difference in their post-operative speech perception. It is possible that significant effects were not demonstrated due to a lack of statistical power arising from the relatively low participant numbers in the group.

The factors affecting speech perception outcomes in the adults with PD using CI, age at implant and duration of deafness, demonstrated effects that were consistent with previous studies of CI recipients (Blamey et al., 1996; Blamey et al., 2013; Dowell, 2005). Recent literature suggests a decreasing importance of ‘duration of deafness’ as a factor in CI studies given that candidates have much more hearing pre-CI than in the past. As a result of greater access to and awareness of assistive hearing technology, individuals are typically receiving CIs earlier in the time course of their deafness than in the past. Therefore, when looking at the factors contributing to speech perception outcomes with a CI, duration has become less important (Blamey et al., 2013; Holden et al., 2013). Individuals seeking CIs in the present day are typically making some use of HAs and residual low frequency hearing.
The question of ‘duration of deafness’ is problematic in a population of adults with PD, given that by definition they were technically using some natural low frequency hearing up to the point of receiving their CI. In addition, should hearing preservation techniques be successful during surgery, they may continue to make use of natural acoustic hearing post-implant. While the results presented in Chapter 6 indicated a significant negative effect of duration of deafness on TSPS, post-hoc analysis revealed that this was related to the sentence perception in noise task only. This may be due to the effect of auditory deprivation on higher level central auditory processing and the effect is therefore more pronounced for a sentence in noise task. It is worth considering that many of these adults with PD have auditory deprivation for high frequency input. The present PhD study has not attempted to quantify this and its potential effects, however this may have contributed to this outcome. These results, combined with a changing population of adults seeking CIs, may point to a need to shift our thinking on how ‘duration of deafness’ is discussed with regard to post-implant expectations.
7.3. Hearing Preservation

In the present study, hearing preservation for adults with PD pre-implant was assessed in a number of ways. Firstly, measurement of the amount of hearing preserved (i.e. change to pure tone thresholds, in dB HL) and use of the HEARRING group method was employed to provide data for comparison to other studies. It is important to note, as discussed in Section 2.6.3, that this method should be discouraged as a way of describing outcomes for an individual. The HEARRING group method reflects the degree of change in pure tone thresholds and not the functional outcome (i.e. whether ‘functional hearing’ is preserved or not). Secondly, there was a need to understand if the degree of hearing preservation was related to specific surgical or patient-related factors. Finally, measurement of the preservation of ‘functional hearing’ was employed to provide meaningful information for clinical use. The outcomes of these analyses address Aim 2 and Hypotheses 2 and 3 (discussed in Chapter 5).

The amount of hearing preservation measured in this study (i.e. median low frequency change for the group being -22.5 dB HL) is comparable to other studies with similar devices and populations. Van Abel et al. (2015) published results for 52 CI422 recipients and demonstrated an average low frequency (250 and 500Hz) change in hearing of -25.5 dB HL from pre-implant to 6 months post-implant. Skarzynski et al. (2014) demonstrated an average low frequency change of -15 dB HL at 12 months post-implant for 35 individuals using the CI422, however it is important to note that this measurement also involved a low frequency threshold at 125Hz in addition to 250 and 500Hz. In a study of 31 CI422 recipients, Lesinski-Schiedat et al. (2011) reported an average change in hearing for 250 and 500Hz from pre-implant to activation day of -17.5 dB HL. This study also reported on 91 recipients of the Hybrid-L, whose electrode array does not extend as deeply into the cochlea as the CI422 and found an average change in hearing for 250 and 500Hz from pre-implant to activation day of -12.5 dB HL. This finding of better hearing preservation with a shorter electrode array is in line with data from Gantz et al. (2005), who reported average change in hearing of -9.5 dB HL across frequencies of 125, 250, 500 and 1000Hz for 13 adults using the Iowa/Nucleus 10mm electrode array. The Iowa/Nucleus 10mm electrode array has a shallower insertion than the Hybrid-L electrode array.
While the papers discussed above may indicate that a shallower depth of insertion is related to increased hearing preservation, this was not a finding of the present study. The present study assessed depth of insertion as ‘angular depth of insertion’, as judged by positioning of the electrode array within the cochlea. Although there was a range of insertion depths from 270 to 530 degrees, the variation in insertion is limited by the use of one electrode array type. Comparing hearing preservation and angular depth of insertion across multiple devices or electrode arrays may provide further information.

An additional factor that has been reported to be related to degree of hearing preservation is duration of deafness (Van Abel et al., 2015). While a very weak negative correlation between duration of deafness and hearing preservation was observed in the present study, this relationship was not found to be significant. A key difference between the present study and that of Van Abel et al. (2015), which may have contributed to the difference in findings, was the range of duration of deafness in the study populations. In the present study, the mean duration of deafness was 15.0 years with a range between 0 and 35 years of deafness. This is compared with a mean duration of deafness of 9.8 years with a range between 0 and 50 years in the Van Abel study. While the difference in mean values is likely insignificant, it is possible that the increased upper range of duration in the Van Abel study contributed to the significant relationship for their group.

The present study addressed the issue of hearing preservation in a different way by considering whether the hearing was ‘functional’ or ‘non-functional’ from the point of view of usefulness with amplification. As is highlighted in Chapter 5, this was defined in the study to be low frequency hearing at or better than 70 dB HL. This definition of functional hearing proposes an audiometric limit on what would be considered useful residual low frequency thresholds, a definition which was constructed both from the literature on what level of hearing constitutes useful hearing from the point of view of speech perception benefit with amplification (see sections 2.1, 2.2 and Chapter 5 for review) and from clinical experience. A study by Van Abel et al. (2015) also assessed hearing preservation outcomes as functional or non-functional for adults using the CI422 electrode array, however in that study functional hearing was defined as having average thresholds at 250 and 500Hz at or better than 85 dB HL. The results in the Van Abel et al. study found 47% of recipients had functional hearing at 6 months post-
implant compared with 39.5% in the present study at 3 months post-implant. It is likely that the more generous inclusion criteria for ‘functional hearing’ led to the difference in outcomes for these two studies. It is acknowledged that there may be disagreement in the field regarding how much low frequency hearing is considered ‘functional’. The present thesis maintains that low frequency hearing thresholds in excess of 70 dB HL (where a person has sloping hearing loss) are not likely to be beneficial for speech perception with amplification based on data reported in the literature, and would be considered ‘non-functional’ (Ching et al., 1998; Hogan & Turner, 1998; Hornsby & Ricketts, 2006; Moore, 2001). A recent paper proposing minimum standards for reporting CI outcomes for adults has highlighted the need for appropriate reporting of pre- and post-operative acoustic thresholds in ongoing literature (Adunka, Gantz, Dunn, Gurgel & Buchman, 2018). The goal of this paper was to provide some standardisation in reporting (i.e. thresholds tested, time period reported, device/s used) in order to enable meta-analyses on outcomes including functional hearing preservation going forward. This paper suggested functional hearing be defined as a pure tone average of <80 dB HL at 125, 250 and 500 Hz (Adunka et al., 2018).

Whatever guidelines are used, it is important to remember that one of the primary goals for soft surgery, with a TSEA or other electrode array, is the preservation of hearing at a level that can be useful to the individual CI recipient i.e. for use with EAS. The results in Chapter 6 have demonstrated the clinically significant speech perception advantage of EAS compared with electric-only hearing for individuals using a TSEA. Functional hearing preservation to enable the person to use EAS must therefore be the goal for persons with PD proceeding with a CI. In this way, we may consider functional or non-functional hearing as successful or unsuccessful hearing preservation. These definitions may not hold true for the individual recipient themselves, however. If we consider a case where an individual has an LFPTM of 20 dB HL pre-implant which deteriorates to 60 dB HL post-implant, while this may be considered functional and successful hearing preservation it still represents a significant loss to the individual. Subjectively, while they may be able to use EAS and have excellent outcomes, an individual in this case may not find this degree of preservation to be a ‘success’. It is crucial to present realistic expectations regarding potential to preserve hearing in a meaningful way prior to
implant to enable informed decision-making, with the concept of functional and non-functional hearing being easily understood.

The results of the present study offer guidance for providing evidence-based recommendations on the chances of preserving functional hearing (see Chapter 5 and section 7.4). Where an adult with PD has a pre-implant LFPTM ≤ 45 dB HL, the data suggest that the person can be counselled that they have a 75% chance of preserving functional hearing post-op and therefore a 25% chance of losing functional hearing. Where the pre-implant LFPTM ≥ 50 dB HL, the data suggest the person has a 75% chance of losing functional hearing post-op and a 25% of preserving functional hearing.

It is important to note that these guidelines are based on outcomes from the present study, assessing adults with a postlingual hearing loss using a Nucleus Slim Straight electrode array up to 12 months post-implant. It is possible that these guidelines may not extend to individuals with a prelingual hearing loss, those using different electrode arrays and that preservation may be poorer where an individual is followed for an extended period of time (i.e. > 12 months post-implant).

A number of other studies have presented outcomes that may also be used for such counselling. Adult CI recipients have been found to have preserved hearing within 30 dB HL of pre-implant thresholds in 76.9-90.3% of cases (Lesinski-Schiedat et al., 2011; Skarzynski et al., 2014; Van Abel et al., 2015). This is compared with more variable results for preservation within 10 dB HL, where 18.2-64.2% of cases were found to preserve hearing within this range (Balkany et al., 2006; Gstoettner et al., 2004; Helbig et al., 2011; Kiefer et al., 2004; Skarzynski et al., 2014; Skarzynski et al., 2009). In a review of 187 publications assessing hearing preservation, Talbot and Hartley (2008) reported 76% of recipients preserved hearing within 20 dB HL of pre-implant thresholds. Adults with PD can be informed of their chance to preserve functional hearing based on their low frequency hearing level, in addition to guidance that in approximately 75% of recipients, low frequency hearing thresholds are preserved within 20 dB HL of pre-implant levels. With this information, in addition to guidance on realistic expectations on the chance to improve their speech perception, adults with PD should be empowered to make an informed decision on the risks and benefits a CI may offer.
7.4. Clinical Implications

The findings from the present PhD thesis have several implications for clinicians working with adults with PD in CI clinics.

Firstly, it is suggested that adults with PD should be recommended for a CI based on pre-implant speech perception guidelines similar to those used for adults with severe-to-profound losses (i.e. the ‘traditional’ CI candidate). ‘Good’ low frequency thresholds should not be considered a barrier to recommending CI where the speech perception with optimised HAs meets the criteria for candidacy (in the absence of any other clinically relevant co-morbidities).

Second, realistic expectations for hearing preservation post-CI should be provided to adults with PD to enable informed decision-making. Based on the findings of the present study, the following information can be provided on the likelihood of preserving functional, aidable hearing post-CI:

- Where pre-implant LFPTM is at 45 dB HL or better, the individual has a 75% chance of preserving functional hearing post-op
- Where pre-implant LFPTM is at 50 dB HL or poorer, the individual has a 75% chance of losing functional hearing post-op

Individuals must also be aware that regardless of their degree of hearing preservation post-implant, they may encounter some further deterioration of their acoustic hearing over time.

Finally, it was observed that adults with PD did not demonstrate a difference in speech perception outcomes based on electrode array type. However, those for whom functional hearing was preserved and who used EAS sound processing demonstrated significantly better outcomes than those using electric only hearing. The implications from these results are that where an adult has significant residual low frequency hearing pre-implant, the device chosen and surgical techniques used should be in the interest of preserving and using this residual hearing (i.e. via EAS). Clinicians should therefore be actively encouraging CI recipients to use an EAS fitting in order to maximise the benefit with their CI.
7.5. Study Limitations

There were a number of limitations identified in the present study, some of which were largely unavoidable in this particular clinical setting and some which could be improved upon in future studies. Firstly, to address the limitations put in place by the clinical setting, there were a variety of ENT surgeons and CI audiologists involved in the management of the CI recipients as this project was undertaken in a large CI centre. While consistent protocols were followed for both surgical and clinical interventions, this provides an inherent source of variability. Additionally, the data set contained a number of missing data points as noted in the Results sections of Chapters 4-6. As results were obtained in clinical appointments, this required individuals to attend their appointments. Where testing appointments were missed, recipients were encouraged to attend a rescheduled session however these were not always attended and/or other issues arose in these subsequent sessions that took priority over assessment which was at the discretion of the clinician. These issues prevented a full data set of results being available for analysis.

An additional limitation related to the particular clinical setting in which this study was undertaken was the CI devices used. Throughout the period this study was undertaken, the Melbourne Cochlear Implant Clinic at the RVEEH used only Nucleus electrodes therefore limiting the types of devices which could be assessed. As shown in Table 2.2, there are a number of electrodes from different manufacturers that have demonstrated good outcomes with respect to hearing preservation. It was not possible to compare outcomes in the present study, however this would be of interest going forward.

The Melbourne Cochlear Implant Clinic at the RVEEH has historically had, and continues to have, a strong research focus. All adults implanted through this centre are invited to participate in clinical research, with the clinic involved in multiple projects at any one time. As is noted in Chapter 5, 49 of the 139 TSEA recipients were involved in a double-blinded clinical trial assessing the effect of a large dose of steroid administered intra-operatively (refer to Figure 5.1). Due to the nature of the trial, it was not possible to have information as to which recipients were given the steroid versus placebo. While there was an attempt to account for this in the factor analysis for hearing preservation outcomes, it remains unclear as to what impact this use of steroids may have on the
outcomes as there is generally a lack of clarity in the field regarding the effectiveness of steroids (Cho et al., 2016; Kuthubutheen et al., 2017; Santa Maria et al., 2014). Nevertheless, this must be noted as a potential source of variability in outcomes.

As discussed in Chapter 3, this study contained a combination of both prospective and retrospective data analysis. As a result of this, the adults studied were using a variety of sound processing technologies. Those using the perimodiolar electrode arrays, who were in the retrospective analysis, were using a Freedom or Nucleus 5 sound processor whereas those using a TSEA were typically using a Nucleus 5 or Nucleus 6 sound processor. Improvements were introduced in Nucleus 6 sound processors that were not available to the PM Group at the time of their assessment, including improved microphone directionality and single channel noise reduction (Hersbach et al., 2012; Mauger et al., 2014; Plasmans et al., 2016). Ideally future studies in this area would study groups using uniform sound processing technologies to eliminate this as a potential source of variability.

A key limitation in the methodology and analysis is that post-operative imaging was done by plain cochlear view x-ray and not by cone beam CT. With the development of cone beam CT imaging and its use in post-operative CI studies, researchers have greater knowledge than in the past of where an electrode array is placed in the cochlea (i.e. ST, SV or translocated). While in the present study, x-rays were analysed for angular depth of insertion and could be used to identify any extra-cochlear electrodes, cone beam CT has only subsequently been incorporated in the RVEEH post-operative clinical protocol. As highlighted in section 2.4.4, placement of the electrode array within the cochlea has a significant relationship with speech perception outcomes, with electrode arrays wholly located in ST shown to be related to improved performance (Aschendorff et al., 2017; O’Connell, Hunter, et al., 2016; Wanna et al., 2014). While cone beam CT was not available for the group of adults assessed in the present study, it is worth considering whether insertion issues such as SV placement or electrode array translocation, particularly for the perimodiolar group, may have had an impact on results. In a study by Holden et al. (2013) where only those with electrode arrays located wholly in ST were included, it was found that adults using a CI with an electrode array positioned more closely to the modiolus had better speech perception outcomes than those with an electrode array positioned further from the modiolus. A more recent study by
Chakravorti et al. (2019) found similar results for precurved electrode arrays, in that scalar position and proximity to the modiolus was significantly associated with speech perception outcomes. These results differ from what was found in the present study, as per Chapter 6, although as noted there was no exclusion of recipients based on array positioning in the present study nor were the Holden et al. (2013) or Chakravorti et al. (2019) studies assessing adults with PD in particular. Both of these factors may have contributed to the difference in outcomes between these studies.

Finally, any conclusions drawn regarding speech perception outcomes can only be applied to adults with PD of a postlingual origin. Adults with a prelingual onset of deafness were excluded from the speech perception analysis, as is commonplace in the field for such comparisons, given the established relationship between onset of hearing loss and speech perception outcomes (Dowell et al., 2004; Holden et al., 2013; Leigh et al., 2016).
7.6. Future Directions

While the results presented highlight some advantages of preserving and utilising low frequency hearing with an EAS system, there is more to be examined in the area of adults with PD receiving CIs. It would be of interest to examine other domains where listeners with EAS may show advantages over their electric-only peers to provide further evidence of the benefits (e.g. speech perception in noise and music perception/appreciation). This would potentially enable the relevant CI recipients to make an informed decision about whether to attempt an EAS fitting and/or whether to persevere with it. Music perception and appreciation for CI users with preserved hearing has been examined in the past, though it would be of interest to provide an updated analysis with modern sound processing and larger participant numbers. In addition, where a recipient has bilateral PD, it would be of interest to examine localisation and more challenging speech in noise tasks given what we know about low frequency hearing in relation to interaural timing cues.

Duration of deafness was found to be associated with speech perception outcomes in this study, albeit the relationship was weak as has been the trend in recent years (Blamey et al., 2013; Holden et al., 2016). Although not possible in the present study due to the RVEEH speech perception test battery at the time, it would be of interest to examine the SRT outcomes for groups of adults with PD using a CI. This would enable further investigation of the effect of duration of deafness on speech perception outcomes, and potentially provide some insight as to how auditory deprivation may be affecting this population.

Finally, as has been highlighted throughout the present thesis, it would be of interest to replicate this speech perception analysis on a group of adults with PD where cone beam CT has been used for post-operative imaging. This would enable further understanding of the outcomes for this population based on electrode array type where the variability associated with incorrect placement can be accounted for.
7.7. Summary

The present study has reported the hearing preservation and speech perception outcomes for a large group of adults with PD using CI. This section will provide a summary of the outcomes.

Speech perception outcomes using a CI with electric-only stimulation appear to be unrelated to the amount of pre-implant hearing a recipient has, as in the present study there was no significant difference between those with a profound loss pre-implant and those with PD. Given these results, it is possible that where all relevant factors have been accounted for (i.e. duration of deafness, age at implant, aetiology, anatomy), it is the device that essentially provides and/or limits the speech perception outcomes when using electric hearing alone.

Insertion depth did not appear to have an effect on hearing preservation outcomes in the present study, in contrast with Hypothesis 2. It is important to note that while there was a wide range of insertion depth reported for recipients examined, there is a limit to how far this hypothesis could be tested as the same electrode array was used in all cases, as discussed in Section 7.3. There have also been excellent hearing preservation outcomes reported for electrode arrays with more shallow insertion depths than the TSEA studied (Gantz et al., 2005; Lesinski-Schiedat et al., 2011; Suhling et al., 2016). While no relationship was found in the present study, it could be argued that the relationship between insertion depth and hearing preservation has not been effectively and conclusively examined here.

As noted above, while the CI alone speech perception outcomes of adults with PD appear to be determined by/limited to what the CI can do in relation to sound coding and technical capabilities (i.e. numbers of electrode contacts, size, current spread etc.), the hearing preservation outcomes appear to be related to the individual who receives the device. The present study found comparable hearing preservation outcomes for the group as a whole compared to those in the literature (i.e. average change -22.5 dB HL for 250 and 500Hz) and reported on guidelines for counselling on likelihood of retaining functional acoustic hearing post-implant. Based on the data, adults with PD with low frequency hearing at or better than 45 dB HL pre-implant have a 75% chance of preserving functional hearing (i.e. at or better than 70 dB HL, as per the study.
definition) post-CI. The individuals in the study that preserved hearing at functionally aidable levels also showed no significant deterioration by 12 months post-implant, suggesting that the amount of hearing preserved may have some relationship to the quality and integrity of the individual’s hearing organ.

Finally, while two previous larger studies (Dowell, 2012; Holden et al., 2013) noted improved speech perception outcomes with an array closer to the modiolus, the present study did not find a difference, in contrast to Hypothesis 4. This reiterates the notion discussed above that speech perception outcomes are likely highly related to the CI itself, the method of electrically reproducing sound and stimulating auditory nerves. It is possible that due to subject numbers, there may be an effect that was not significant in this study. It is worth mentioning that if there had been a larger cohort of TSEA-EAS participants in the study presented in Chapter 6, there may have been significantly better TSPS outcomes demonstrated for the TSEA group as a whole compared to the PM group given the results for the small sub-group using EAS (particularly for sentences in noise). Additionally, the present study examined only a specific group (adults with PD), whereas the aforementioned studies do not make this distinction. Of note, the Holden paper provided data from a group of adults whose CI electrode array was determined to have ST placement. While the present study did not examine scalar positioning, it has been well reported in the literature that electrodes located wholly in the ST are associated with better speech perception outcomes (Aschendorff et al., 2007; Finley et al., 2008; O’Connell, Cakir, et al., 2016; Skinner et al., 2007). As we learn more about electrode positioning and its relationship to outcomes, there is indication that we need to look further to conclusively answer these questions which highlights the need for further study in this area.

In summary, results from the present study do support:

- Hypothesis 1: Adults with PD who receive a CI with a perimodiolar electrode array will demonstrate equivalent post-operative speech perception performance to those adults with a profound hearing loss pre-implant (i.e. traditional CI recipient) also using a perimodiolar array, where only electric hearing is used.
- Hypothesis 3: For adults with PD using a TSEA, those with better pre-implant low frequency hearing will demonstrate better preservation of functional low frequency hearing post-implant (i.e. lower pure tone thresholds).

- Hypothesis 5: For adults with PD using a TSEA, better post-operative speech perception outcomes will be demonstrated for persons with preserved hearing using EAS.

Results from the present study do not support:

- Hypothesis 2: For adults with PD using a TSEA (CI422), poorer hearing preservation outcomes will be demonstrated as angular depth of insertion of the electrode array increases.

- Hypothesis 4: When pre-operative hearing is controlled to include only those with functional hearing pre-implant, adults with PD using a perimodiolar electrode array will demonstrate better post-operative speech perception outcomes than adults with PD using a TSEA.
8. Conclusions

This thesis explored the hearing preservation and speech perception outcomes for a group of adults with PD using CIs.

In summary, it was found that adults with PD can be considered for CI in accordance with existing CI candidacy guidelines, provided the individuals have realistic expectations in relation to the risk of residual hearing loss. The degree of hearing preservation observed in the study was variable, and specific causes for the variability remain unknown. The study outcomes suggested that the presence of low frequency hearing at or better than 45 dB HL is associated with a 75% chance of preserving useful acoustic hearing post-implant. Finally, there was no significant relationship found in the study between speech perception outcomes for adults with PD and electrode array type. Individuals that preserved hearing and utilised EAS demonstrated superior outcomes to their peers with electric-only hearing.

The main implication from this study is that where an adult has the potential to preserve useful acoustic hearing, every effort should be made to do so via atraumatic surgery and appropriate CI device selection. Where functional acoustic hearing is preserved, it would be recommended to fit a sound processor compatible with EAS in order to maximise the speech perception and communication outcomes.
9. **List of Associated Publications and Presentations**


**Departmental Seminar** - December 2012

**Departmental Seminar** - February 2014


**RHD Colloquium presentation** - October 2014


**Departmental Seminar - October 2018**

10. References


11. Appendix A – RVEEH Cochlear Implant Evaluation Protocol for Adults
OUTCOMES FOR PATIENTS WITH SLOPING HEARING LOSS GIVEN STANDARD COCHLEAR IMPLANTS

Michelle Moran1,2, Richard C. Dowell1,2, Arielle Umansky3, Robert J.S. Briggs1,3, Susannah Corbett1

1 Department of Audiology and Speech Pathology, University of Melbourne, Melbourne, Victoria, Australia
2 HEARing Cooperative Research Centre, Melbourne, Victoria, Australia
3 Cochlear Implant Clinic, Royal Victorian Eye and Ear Hospital, Melbourne, Victoria, Australia

Corresponding author: Michelle Moran, Department of Audiology and Speech Pathology, University of Melbourne, 555 Swanston Street, Parkville, Victoria 3010, Australia. Fax: +613 9347 9756. Phone: +613 9655 7996, c-mail: mmoran@unimelb.edu.au

Abstract

Background: This study examined the speech perception outcomes for postlingually deafened adults using cochlear implants who preoperatively had steeply sloping hearing loss and in whom there was no attempt at electroacoustic stimulation. The aims were firstly to determine whether patients with sloping loss (SL) who received a standard length cochlear implant electrode would show significant benefit and secondly to compare the degree of benefit to a matched group of cochlear implant users with preoperative profound hearing loss.

Material and methods: A retrospective analysis of pre- and post-implant speech perception scores of 27 adults with sloping hearing loss and a matched group of 27 adults with profound hearing loss was conducted. Matching was based on age at implant and duration of loss. All were implanted with a Nucleus Freedom (CA) or a Nucleus 5 implant.

Results: Postoperative open-set speech perception testing demonstrated significant improvement compared to pre implant for both groups. Speech perception outcomes were better in the VI group; however, there was no significant difference between the groups in the degree of improvement pre- to post-operatively under either the condition of implant alone or binurally.

Conclusions: This study demonstrates that postlingually deafened adults with sloping hearing loss have the potential to gain significant benefit from cochlear implants, and achieve equivalent improvement in speech perception to implant recipients with profound loss. The results achieved in this group, without any attempt at hearing preservation, support the use of newer standard-length electrodes for both hearing preservation and optimal electric stimulation in patients with sloping hearing loss.

Keywords: cochlear implant • adults • hearing loss (high frequency)

RESULTADOS DE LA APLICACIÓN DE LOS IMPLANTES COCHLEARES ESTÁNDAR EN PACIENTES CON LA PERDIDA AUDITIVA CON LA CAÍDA EN LAS FRECUENCIAS

Resumen

Introducción: El presente estudio valoró los resultados del reconocimiento del habla en adultos con la pérdida auditiva postlingual, en las que antes de la inserción del implante coclear se pudo observar una pérdida auditiva con caída en las frecuencias agudas y en las que no se ha intentado aplicar la estimulación electroacústica. El primer objetivo ha sido el de comprobar, si la implantación del electrodo de la longitud estándar, es claramente beneficioso para los pacientes con la pérdida auditiva con caída en las frecuencias agudas (SL). Se ha comparado, además, el grado de ventajas con el grupo de usuarios del implante coclear, en los que antes de la implantación se reconoció una pérdida auditiva severa.

Material y métodos: Se ha realizado un análisis retrospectivo de los resultados del reconocimiento del habla antes y después de la implantación, en 27 adultos con la pérdida auditiva con caída en las frecuencias agudas, y en otro grupo, también de 27 adultos, con la pérdida audítea severa. En la selección de los participantes de la prueba se ha tenido en cuenta un idéntico momento de la implantación y la duración de la pérdida auditiva. En la prueba han participado los usuarios del implante Nucleus Freedom (CA) o de Nucleus 5.

Resultados: Las pruebas postoperatorias del reconocimiento del habla han demostrado una mejoría significativa en comparación con los resultados de antes de la operación en ambos grupos. Los resultados de las pruebas han sido mejores en el grupo...
SL, sin embargo no hubo diferencia significativa en el grado de mejora antes y después de la implantación en ambos grupos con la inserción del implante en uno o en ambos oídos.

**Conclusiones:** El estudio demuestra que para los adultos con la pérdida auditiva postlingual, con la caída en las frecuencias agudas, los implantes cocleares pueden ser beneficiosos; estas personas pueden lograr una mejoría similar en la comprensión del habla a la de las personas con una pérdida severa. Los resultados obtenidos en ambos grupos, sin tratar de preservar la audición existente, son prueba para apoyar los beneficios que derivan del uso de los electrodos más modernos con una longitud estandarizada tanto en la preservación de la audición residual como en la estimulación acústica óptima de los pacientes con caída en las frecuencias agudas.

**Palabras clave:** implantes cocleares • adultos • pérdida auditiva (en altas frecuencias)

## РЕЗУЛЬТАТЫ ИСПОЛЬЗОВАНИЯ СТАНДАРТНЫХ УЛИТКОВЫХ ИМПЛАНТАТОВ У ПАЦИЕНТОВ С НИЗСОЧАЩЕЙ ТУТОУШНОСТЬЮ

### Введение

В настоящей работе оцениваются результаты распознавания речи у взрослых людей с постлингвальной глухотой, у которых перед операцией консервативной имплантации наблюдалась критическая тутоухость, поскольку не было показаний применить электроакустическую стимуляцию. Первой целью являлось определение, испытывали ли наличие электроудара стандартной длины заметное повышение у пациентов с низкой тутоухостью (SL). Кроме того, сравнивали степень пользы с группой пользователей улиткового имплантата, у которых перед операцией обнаружена глубокая тутоухость.

**Материал и методы:** Проведено ретроспективный анализ результатов распознавания речи перед и после имплантации у 27 взрослых людей с низкой тутоухостью в двух группах: 27 взрослых людей с глубокой тутоухостью. При отборе участников имели значение возраст во время имплантации и время продолжительности тутоухости. В исследованиях была отмечена возможность использования имплантата Nucleus Freedom (CA) или Nucleus 5.

**Результаты:** Послереоперационные тесты распознавания речи показали значительное улучшение в сравнении с предоперационными результатами в обеих группах. Результаты тестов были лучше в группе SL, однако не было значимой разницы и степени улучшения перед и после имплантации в обеих группах при использовании имплантата в одном или обоих ушах.

**Заключение:** Настоящая работа показывает, что взрослые люди с постлингвальной глухотой, с низкой тутоухостью, не получают значительное улучшение при использовании имплантата, а также улучшение в одном или обоих ушах.

**Ключевые слова:** улитковые имплантаты • взрослые люди • тутоухость (для всех частот)

## WYNIKI ZASTOSOWANIA STANDARDOWYCH IMPLANTÓW ŚLIAMAKOWYCH U PACJENTÓW Z OPAĐAJĄCYM NIEDOSŁUCHEM

**Streszczenie**

Wprowadzenie: Niniejsza praca ocenia wyniki rozpoznawania mowy u osób dorosłych z głuchotą postlingwialną, u których przed zabiegiem implantacji ślimakowej zastosowano wskrzeszający niedosłuch i nie poddano zastosowań stymulacji elektroakustycznej. Pierwszym celem było stwierdzenie czasu wyciszania elektrody o standardowej długości jest wystarczająco krótkie u pacjentów z opadającym niedosłuchem (SL). Ponadto, porównano stężeń korzyści z grupy użytkowników implantu ślimakowego, u których przed zbiorem stworzono głęboki niedosłuch.

**Material i metody:** Przeprowadzono analizę retrospektywną wyników rozpoznawania mowy przed i po implantacji u 27 osób dorosłych z opadającym niedosłuchem oraz u drugiej grupy 27 osób dorosłych z głębokim niedosłuchem. Przy doborze uczestników liczyły wiek podczas implantacji oraz czas trwania niedosłuchu. W badaniu udział wzięli autorzy/ownicy implantu Nucleus Freedom (CA) lub Nucleus 5.
Background

High frequency or “sloping” sensorineural hearing loss is a common configuration of audiometric results in adults and can be caused by a number of etiologies including aging (presbycusis), noise exposure, ototoxicity, and genetic factors. This type of hearing loss typically reduces the audibility of spectral cues of speech, in particular places of articulation cues for high frequency consonants, with subsequent negative effects on the clarity of speech [1,2]. Sloping hearing loss (SL), in which the hearing loss is mild to moderate in the low frequencies and severe to profound at 1 kHz and above, can present a significant challenge for audiological rehabilitation. Conventional amplification may not always provide adequate benefit to patients with high frequency hearing loss, as issues such as feedback, recruitment, distortion, or cochlear dead regions can limit the effective programming of a hearing aid. Cochlear dead regions have been defined as regions in the cochlea where inner hair cells are non-functional and are prevalent in individuals with sensorineural hearing loss [3,4]. For clients with large or multiple dead regions, there are implications for the choice of hearing aid or amplification strategy [5]. In addition, increasing amplification in high frequency regions where the hearing loss exceeds 55-60 dB HL has been found to offer little or no improvement in speech perception performance, and can sometimes lead to a decrease in scores [5-8].

Frequency compression and frequency transposition hearing aids, which compress or transpose previously inaudible frequencies into less damaged regions of the cochlea, have been proposed as a possible solution for these individuals. Results in the literature on experimental outcomes have been mixed, with no clear consensus as yet on the benefits of frequency compression or transposition aids in individuals with SL [9-12]. The literature suggests that frequency compression or frequency transposition hearing aids may not be the ideal solution for individuals with a more severely sloping audiometric configuration. While Simpson et al. [10], Gista et al. [9], and Katz et al. [12] have demonstrated improvements in speech recognition in groups with moderately sloping hearing loss, a study by Simpson et al. [11], looking specifically at listeners with severely sloping audiograms, demonstrated no measurable benefit with a frequency compression device in comparison to conventional amplification. It should be noted that the participants in this later study all had hearing levels above 1000 Hz in the profound range.

Electroacoustic stimulation (EAS), where a cochlear implant is used in combination with acoustic hearing, has been shown to provide significant benefits for suitable individuals [13-16]. Initial studies of EAS used a CI with an electrode array which, when inserted, does not extend as deeply into the cochlea as a standard length array. This has the benefits of an atrumatic insertion with minimal damage to apical intracochlear structures [17-19]. This design of electrode array provides electrical stimulation of the basal end of the cochlea while preserving the apical end to allow acoustic low frequency hearing post-operatively. However, patients with relatively poor acoustic thresholds in the low to mid frequencies may not benefit from this approach and rehabilitation options can be limited. With cochlear implant technology continually evolving, CIs for EAS have also evolved to include deeper cochlear insertions. While some studies have shown that residual hearing can be preserved through soft surgery and careful procedures with a standard length electrode array, the outcomes are variable [20-23].

Patients with severely sloping hearing loss tend to fall within a substantial grey area in terms of management. The high frequency hearing in these patients is too poor to gain significant benefit from hearing aids and their low frequency hearing is too good to fit within standard cochlear implantation criteria; however the short electrode approach may not give the best outcome given the progressive nature of many of these types of hearing losses. In addition, many patients with a ski-slope audiometric configuration have poor speech perception despite optimal hearing aid fitting and so become standard candidates for cochlear implantation based on speech perception ability. CI technology has evolved to include devices such as the CI822 (Cochlear) and HiRes (Med El) which allow for the clinician and surgeon to attempt to preserve the residual hearing with a full length electrode array and a soft surgery approach which shows promise for patients falling into this group [24,25].

Improvements in both CI technology and recipient outcomes have led to expansion in the candidacy criteria for cochlear implantation [26-28]. This in turn brings increased referral of patients with significant residual hearing. Patients with residual acoustic hearing have more to lose if their hearing is lost following CI surgery and their post-operative outcome for hearing with the CI does not meet expectations. Audiologists are presented with the clinical dilemma of weighing up the risk of losing the residual acoustic hearing versus the unpredictable amount of benefit to be gained by electrically stimulating the cochlea.
Table 1. Demographic data of the SL and FL matched groups

<table>
<thead>
<tr>
<th></th>
<th>Sloping Loss group (n=27)</th>
<th>Profound Loss group (n=27)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duration of deafness (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>12.54</td>
<td>12.94</td>
</tr>
<tr>
<td>SD</td>
<td>8.94</td>
<td>9.82</td>
</tr>
<tr>
<td>Median</td>
<td>12.00</td>
<td>10.00</td>
</tr>
<tr>
<td>Range</td>
<td>1–54</td>
<td>1–58</td>
</tr>
<tr>
<td><strong>Age at implant (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>65.74</td>
<td>65.17</td>
</tr>
<tr>
<td>SD</td>
<td>13.64</td>
<td>12.68</td>
</tr>
<tr>
<td>Median</td>
<td>65.84</td>
<td>63.44</td>
</tr>
<tr>
<td>Range</td>
<td>35.23–89.27</td>
<td>39.30–88.68</td>
</tr>
<tr>
<td><strong>41A (dB) – ear to be implanted</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>96.48</td>
<td>117.50</td>
</tr>
<tr>
<td>SD</td>
<td>5.90</td>
<td>7.26</td>
</tr>
<tr>
<td>Median</td>
<td>96.25</td>
<td>120.00</td>
</tr>
<tr>
<td>Range</td>
<td>81.26–107.50</td>
<td>102.60–125.00</td>
</tr>
<tr>
<td><strong>41A (dB) – contralateral ear</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>89.77</td>
<td>103.29</td>
</tr>
<tr>
<td>SD</td>
<td>9.70</td>
<td>17.74</td>
</tr>
<tr>
<td>Median</td>
<td>91.25</td>
<td>105.00</td>
</tr>
<tr>
<td>Range</td>
<td>72.50–110.00</td>
<td>57.50–125.00</td>
</tr>
<tr>
<td><strong>41A (dB) – post-op hearing (implanted ear)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>119.56. (n=17)</td>
<td>123.37. (n=7)</td>
</tr>
<tr>
<td>SD</td>
<td>8.22</td>
<td>1.98</td>
</tr>
<tr>
<td>Median</td>
<td>122.50</td>
<td>133.75</td>
</tr>
<tr>
<td>Range</td>
<td>107.50–135.00</td>
<td>121.20–135.00</td>
</tr>
</tbody>
</table>

using a CI. A recent systematic review examining studies that have investigated the preservation of residual acoustic hearing has demonstrated a significant speech perception benefit post-operatively using electric-only stimulation over their pre-operative score [22]. The authors suggest that this provides evidence in support of attempting an electroacoustic device approach, as the recipients show benefit even where there is complete hearing loss.

The purpose of the present study is to examine the outcomes for a group of postlingually deafened adults with significant pre-operative residual hearing in the sloping loss configuration (SL group) whose pre-operative speech perception places them as candidates for a cochlear implant, however these subjects were not considered candidates for a hearing preservation approach using a short electrode. The results of the SL group, whose hearing was not preserved through CI surgery, will be compared to both their own pre-operative results and to a reference group of CI recipients with pre-operative profound hearing loss. The aim of the paper is to assess the degree of benefit received by electrically stimulating the cochlea of recipients with pre-operative sloping hearing loss, in comparison to the traditional CI patient with profound bilateral hearing loss.

Material and methods

To examine the impact of pre-operative SL on outcomes in adult cochlear implant recipients implanted with standard electrode arrays, a retrospective analysis was conducted from a database of 640 adults implanted at the Melbourne Cochlear Implant Clinic at the Royal Victorian Eye and Ear Hospital between September 2005 and July 2011. This research was conducted under the approval of the Royal Victorian Eye and Ear Hospital Human Research Ethics Committee (approval number 04656).

Subjects

Subjects were selected for inclusion in this study based on their pre-operative pure tone audiometry results. Recipients were considered to have an SL when the audiometric thresholds of the ear to be implanted fell within the following range:

- 250 Hz and 500 Hz pure tone thresholds of 60 dB HL or better
- 1 kHz pure tone threshold of 75 dB HL or greater
- 2–4 kHz pure tone thresholds of 90 dB HL or greater.

These audiometric criteria were used in order to ensure the subject group had residual low frequency hearing but
no significant high frequency hearing. The criteria for 1 kHz was used given the clinical criteria at the time for attempting a hearing preservation technique using a short electrode, which required a 1 kHz pure tone threshold of 70 dB HL or better. It must be noted that while these subjects were selected for a standard length Contour electrode, with the range of devices available today they would likely be selected for a full length array which could potentially preserve the low frequency hearing.

Subjects were excluded from the analysis if they were considered to have a prelingual hearing loss, if they underwent reimplantation, if English was not their first language, or if they were fitted with a short electrode device for NASS. Only recipients with unilateral cochlear implants were included in the analysis. A total of 27 recipients fitted the criteria.

A matched group of 27 recipients with pre-operative hearing in the profound range was selected for comparison. This profound loss (PL) group was matched with the SL group for both duration of deafness and age at implant. Each recipient in this matched group met the same inclusion criteria for the study as the SL group, only differing in their audiometric thresholds. More specifically, for the PL group the ear to be implanted was required to have thresholds greater than or equal to 90 dB from 250 Hz to 4000 Hz.

The demographics of both groups are set out in Table 1. Audiometric thresholds of both groups are shown in Figures 1 and 2.

Test materials

An analysis of the pre- and post-implant speech perception scores of the SL group and the PL group was conducted.
The speech perception test battery included open set sentence and word testing using recorded material. City University of New York (CUNY) open set sentences were used, in which lists of 12 sentences were scored for the number of correctly identified words out of a total of approximately 102 keywords per sentence list. For each test, two sentence lists were presented and the average of the two scores was taken. CUNY sentence testing was conducted in quiet and in 8-talker babble background noise with a signal to noise ratio of +10 dB. In both the quiet and the noise test protocols, a female speaker was used. Open set monosyllabic word testing was conducted using consonant-vowel-consonant (CVC) words, with lists of 50 words scored for the number of correctly identified words and phonemes, using a male speaker.

Recorded speech materials were used for all tests using a native Australian English speaker, presented sound track alone at 65-dB SPL. Appropriate masking was introduced to the contralateral ear where required. The masking procedure utilized a portable Sony digital media player (masker) to provide speech masking through insert phones, while the recipient listened to test materials from a loudspeaker via their hearing aid or cochlear implant sound processor. The masker continuously plays a saw file of broadband noise weighted according to the international long-term average speech spectrum (ILTSAS) at a level calibrated to 75 dB SPL.

Pre-operative speech perception data was obtained during implant candidacy assessment with optimised hearing aids. Each patient’s own hearing aids were verified in the clinic using real ear measures and compared to the target prescription. The NAL-NL1 and NAL-RP fitting algorithms were used to determine gain targets, with the choice of algorithm dependent on the configuration of the patients audiogram [29,30]. Where a patient’s hearing aids were not optimised for reasons other than documented loudness tolerance issues, they returned to their hearing aid provider for review of their aids prior to formal speech perception testing. Post-operative data was obtained at 3 and 12 months post CI activation, using the patient’s CI sound processor and contralateral optimised hearing aid in the monaural (CI alone) and binaural (CI + HA) conditions. All speech perception results were obtained at the Melbourne Cochlear Implant Clinic.

To provide a more informative evaluation than assessing each test in the speech perception battery individually, an overall speech perception score was calculated by including each participant’s result for each test in the analysis.
Surgery and devices

The subjects in this study underwent surgery between September 2005 and July 2011. All patients received Contour Advance electrode arrays, being either Nucleus Freedom or Nucleus CI512 devices. These devices are functionally identical, with slight cosmetic differences (refer to Cochlear Limited for details). In the SL group, 21 patients were fitted with the Nucleus Freedom cochlear implant, and 6 were fitted with the Nucleus CI512 cochlear implant. In the PL group, 22 patients were fitted with the Nucleus Freedom, and 5 were fitted with the Nucleus CI512. All participants used the Advanced Combination Encoder (ACE) sound coding strategy. Regarding stimulation rate, 10 recipients (41%) from the SL group and 8 (66.7%) from the PL group used the default of 930 Hz. The remaining recipients from each group used a variety of stimulation rates from 250 Hz to 2400 Hz dependent on the recipient’s personal preference.

Statistics

Statistical analysis was conducted using Matlab statistical software version 16.

Paired t-tests were used in order to examine the difference between the populations pre- and post-operative speech perception scores, given that the samples were related and approached a normal distribution.

Additional data analysis was completed using nonparametric tests, as the data were not normally distributed. To assess the equality of group medians, Mood’s median test was used in place of an analysis of variance. To examine the difference between two population medians, the Mann-Whitney test was used in place of a 2-sample t-test. In order to investigate whether there was a relationship between two variables, Spearman rank correlation was used. An α level of 0.05 was used for all statistical tests.

Results

The results of this study demonstrate that the SL group had significantly better pre-implant speech perception scores compared with the PL group, and better post-implant scores looking at the implanted ear alone (Figure 3); however, in terms of pre- to post-operative improvement either for implanted ear alone or the bimodal condition, there were no significant differences shown between the groups (Figure 4). These results are discussed in further detail below.

Demographics

The groups demonstrated a high level of similarity with respect to duration of loss and age at implant. There were no significant differences found between the SL and PL match groups for either duration of loss or age at implant (p=0.586 and 0.414 respectively). As expected, due to the selection of the groups based on audiometric criteria, a significant difference was found between the groups in the four-frequency average (4dB) for both the ear to be implanted (p<0.001) and the contralateral ear (p<0.001). Refer to Table 1 for details of the median values for each comparison.

An analysis of the available data of the post-implant unaided hearing thresholds for the implanted ear was conducted. Of the SL group, 17 of the recipients had their post-implant hearing assessed (63%), while only 7 of the recipients from the PL group had their post-implant hearing assessed (28%).

Monaural analysis

Paired t-test analysis showed the SL and the PL groups both demonstrated significantly higher speech perception scores measured at 3 months post-implant compared to their pre-implant scores when looking at the implanted ear alone (SL: T=14.54, p<0.001, PL: T=15.91, p<0.001).

The SL group demonstrated significantly better pre-implant speech perception scores compared to the PL group in the monaural condition for their ear to be implanted (SL median=53.2%, PL median=9%, p<0.001).

At 3 months post-implant there was no significant difference in the monaural speech perception scores between the groups in the CI alone condition, although it was noted that the SL group did tend towards higher scores (SL median=63.5%, PL median=57.5%, p=0.119).

The post-operative scores were compared to the pre-operative scores to examine whether either group received more benefit from the cochlear implant at the 3-month post-implant point. There was no significant difference between the groups for overall improvement in speech perception in the monaural condition (SL median improvement 45.9%, PL median improvement 57.0%, p=0.362).

Speech perception scores were also analysed at the 12-month post-implant point. At 12 months post-implant there was no significant difference in the speech perception scores between the groups in the CI alone condition, although it was again noted that the SL group did tend towards higher scores (SL median=72.9%, PL median=65.5%, p=0.157).

The 12 month post-operative scores were compared to the pre-operative scores to examine whether either group received more benefit from the cochlear implant at the latter point. A significant difference was shown between the groups for overall improvement in speech perception in the monaural condition so that the PL group demonstrated greater improvement at 12 months (SL median improvement 44.9%, PL median improvement 64.5%, p=0.007).

Given the retrospective nature of this project, it must be noted that, as a limitation to the data at the 12 month post-operative point, only 44-67% of the SL recipients completed the speech perception battery. This limits the group matching and any conclusions that can be drawn at the 12-month point.
Table 2. Correlation analysis for SL group

<table>
<thead>
<tr>
<th>SL group</th>
<th>Duration of deafness</th>
<th>Age at implant</th>
<th>4FA (dB) – ear to be implanted</th>
<th>4FA – contralateral ear</th>
<th>CI alone speech perception (3 m post)</th>
<th>CI-HA speech perception (3 m post)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of deafness</td>
<td>-0.342</td>
<td>p&lt;0.001</td>
<td>0.119</td>
<td>p=0.101</td>
<td>0.241</td>
<td>p=0.009</td>
</tr>
<tr>
<td>Age at implant</td>
<td>-0.254</td>
<td>p=0.01</td>
<td>0.064</td>
<td>p=0.387</td>
<td>0.001</td>
<td>p=0.992</td>
</tr>
<tr>
<td>4FA (dB) – ear to be implanted</td>
<td>0.159</td>
<td>p=0.201</td>
<td>0.054</td>
<td>p=0.587</td>
<td>0.462</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>4FA – contralateral ear</td>
<td>0.159</td>
<td>p=0.009</td>
<td>0.001</td>
<td>p=0.992</td>
<td>0.462</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>CI alone speech perception (3 m post)</td>
<td>-0.139</td>
<td>p=0.295</td>
<td>0.273</td>
<td>p=0.025</td>
<td>0.102</td>
<td>p=0.413</td>
</tr>
</tbody>
</table>

Table 3. Correlation analysis for PL group

<table>
<thead>
<tr>
<th>PL group</th>
<th>Duration of deafness</th>
<th>Age at implant</th>
<th>4FA (dB) – ear to be implanted</th>
<th>4FA – contralateral ear</th>
<th>CI alone speech perception (3 m post)</th>
<th>CI-HA speech perception (3 m post)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of deafness</td>
<td>-0.239</td>
<td>p=0.013</td>
<td>0.511</td>
<td>p&lt;0.001</td>
<td>-0.310</td>
<td>p=0.001</td>
</tr>
<tr>
<td>Age at implant</td>
<td>-0.256</td>
<td>p=0.001</td>
<td>-0.256</td>
<td>p=0.007</td>
<td>0.349</td>
<td>p=0.009</td>
</tr>
<tr>
<td>4FA (dB) – ear to be implanted</td>
<td>0.111</td>
<td>p=0.001</td>
<td>-0.256</td>
<td>p=0.007</td>
<td>0.349</td>
<td>p=0.009</td>
</tr>
<tr>
<td>4FA – contralateral ear</td>
<td>-0.319</td>
<td>p=0.001</td>
<td>0.249</td>
<td>p=0.009</td>
<td>-0.181</td>
<td>p=0.061</td>
</tr>
<tr>
<td>CI alone speech perception (3 m post)</td>
<td>0.010</td>
<td>p=0.146</td>
<td>-0.145</td>
<td>p=0.149</td>
<td>0.083</td>
<td>p=0.413</td>
</tr>
<tr>
<td>CI-HA speech perception (3 m post)</td>
<td>0.234</td>
<td>p=0.106</td>
<td>0.107</td>
<td>p=0.465</td>
<td>0.363</td>
<td>p=0.010</td>
</tr>
</tbody>
</table>

Binaural analysis

Paired t-test analysis showed that the SL and the PL groups both demonstrated significantly higher speech perception scores measured at 3 months post-implant compared to their pre-implant scores in the binaural condition (SL: T=8.26, p<0.001; PL: T=6.27, p<0.001).

The SL group demonstrated significantly better pre-implant speech perception scores compared to the PL group in the binaural condition using their optimized hearing aids (SL median=30.0, PL median=26.0, p=0.008).

Examinining the post implant results for the binaural (CI+HA) condition, it was found that there was no significant difference in the speech perception scores between the groups measured at 3 months post-op (SL median=67.0%, PL median=76.0%, p=0.378).

The post-operative CI+HA scores were compared to the pre-operative HA-only scores to examine whether either group received more benefit from the cochlear implant at the 3-month post-implant point. There were no significant differences between the groups for overall improvement in speech perception in the binaural condition (SL median improvement 30.0%, PL median improvement 24.0%, p=0.413).

There were no data collected in the CI+HA condition at 12 months post-implant.

Correlation analysis

Correlation analyses were performed to assess whether the speech perception outcomes of the SL and PL groups were associated with established predictive factors. Details of these correlation analyses are provided in Tables 2 and 3. Significant weak negative correlations were found for the SL group between age at implant and both CI alone...
and CI-HA speech perception at 3 months post-implant. Duration of deafness was also found to have a significant weak negative correlation with CI alone speech perception in the SL group only. A significant correlation was found between pre-op 48A (dB) in the ear to be implanted and CI-HA speech perception at 3 months for the PL group only. Finally, significant weak negative correlations were found between age at implant and duration of deafness for both the SL and the PL groups.

Discussion

The overarching aim of this study was to compare the outcomes for postlingually deafened adults with sloping hearing loss who were implanted with standard length electrode arrays without an attempt at hearing preservation with outcomes from hybrid stimulation; the comparison was also made with a matched group of adults with profound hearing loss who had been clear candidates for cochlear implantation. The underlying concept of this analysis was to examine speech perception benefits available to recipients with pre-operative residual hearing, or SL, in a situation where all residual hearing was lost. The results of such an analysis can provide CI clinicians with information that can be used to counsel patients who risk their pre-operative low frequency hearing by proceeding with implantation in today’s clinical setting. The results demonstrated that cochlear implantation can provide significant benefits to adults with pre-operative SL, and the SL group can obtain equivalent levels of benefit to their implanted peers who had profound hearing loss.

The results of this study support the findings of Incerti et al. [22] who demonstrated that recipients achieved significantly better pre-operative speech perception scores compared to pre-operative using only the electric component of their EAS system. In the present study, hearing preservation techniques were not used and the recipients in the SL group did not use an EAS configuration; however, performance on speech perception tasks was equivalent to their peers in the PL group, and the SL group did indeed demonstrate significantly better scores pre-operatively compared to their pre-operative scores.

A major issue facing clinicians and patients today is the risk of losing natural residual hearing following cochlear implantation with a hearing preservation technique and whether the patient will be worse off in that instance. In a systematic review of 187 publications on EAS using both Nucleus and Med El devices and assessing a variety of outcomes including hearing preservation, Tallot and Hartley [23] found that 24% of recipients experienced greater than 20 dB hearing loss across all frequencies. The results of this study suggest that an SL patient with poor pre-operative speech perception is likely to have an equivalent level of improvement to a more typical CI patient, even if they lose all residual hearing. Should the patient retain their natural hearing after the CI procedure, we can expect their performance to be superior based on the reported benefits of EAS.

Previous studies have demonstrated that, for adults using cochlear implants, duration of deafness, age at implant, and pre-operative speech perception are factors that have a significant effect on outcomes [32-35]. In the present study, significant weak negative correlations were found between the speech perception outcomes of the SL group and age at implant (that is, older patients performed slightly poorer). The PL group demonstrated significantly better binaural speech perception with a higher pre-operative 48A in the implanted ear. In both groups, a significant weak negative correlation was found between age at implant and duration of deafness, indicating that the individuals in the group implanted younger had been deaf longer and waited longer for their implant.

Additionally, a weak negative correlation was found in the SL group between speech perception and duration of deafness, although this is contrary to what previous studies have found. There may be a number of reasons for this. Firstly, the number of participants in the SL group in this study was relatively small at 27 compared to the large group analyses noted previously [32,35]. A follow-up study with increased subject numbers may clarify this result. In addition, the question of duration of deafness is problematic in the SL group, given that they were technically using some natural low frequency hearing up to the point of cochlear implantation. Since duration of deafness is ill-defined in this group, this may have also contributed to an unusual correlation result. Finally, previous studies have noted that there is a relatively large amount of variability in outcomes that can not be accounted for by known predictive factors or pre-operative assessments [39], and this was evident in this population of recipients who had significant pre-operative residual hearing.

Patients with SL are presenting more regularly to cochlear implant centres, and they bring with them additional challenges in making treatment recommendations. Given their residual hearing, patients with SL may present with speech perception abilities that render them ‘touche’ candidates. Particular attention must be paid to the level of residual hearing this group of SI patients had prior to cochlear implantation. As discussed previously, despite this group having significant low tone hearing they were selected for standard Contour electrode arrays as their preoperative speech perception was relatively poor. Additionally, given their hearing configuration, the available electrode choice, and the clinical criterion for short-electrode insertion at the time, no attempt was made to provide the SI group with electro-acoustic stimulation. It should be noted that in today’s clinical setting use of newer electrode arrays specifically designed for preservation of residual acoustic hearing (e.g. Nucleus CI422, Med-El Flex20) may give patients with SL better chances of preserving and making use of their natural low frequency hearing and take advantage of EAS. Skrzynia et al. [36] have demonstrated high levels of hearing preservation in patients with pre-operative residual hearing when using full-length electrode arrays with deep insertion and surgical techniques designed to minimize electrode insertion trauma. The evolution of devices and surgical techniques provides an opportunity for more recipients to benefit from acoustic stimulation in combination with their CI. Turner et al. [14] highlighted the benefits of integrating electrical and acoustic hearing in patients implanted with the Iowa/Nucleus Hybrid device; the participants with the electroacoustic hearing had improved...
speech recognition in competing noise compared to participants using traditional cochlear implants. The authors attributed this difference to the preservation of low frequency hearing in the participants using the electrocochlear device. In these cases, the authors speculated that participants with preserved natural low frequency hearing would in turn have preserved outer hair cell tuning curves, leading to increased frequency resolution [14]. In contrast, a recent publication by Cosetti [37] demonstrated that while hearing could be preserved using conventional Contour implants, there was no correlation between hearing preservation and performance on speech perception tasks. The benefit of low frequency hearing preservation has been found in areas other than speech perception, such as improved speech reception in noise and improved music perception and appreciation in implanted recipients with electrocochlear hearing [38,39]. Cosetti [22] reviewed hearing and speech perception outcomes and fitting techniques across patients implanted with standard perimodiolar electrode arrays, standard to medium-length straight arrays, and electrocochlear arrays. This study highlighted the variety of devices available for use today in patients with pre-operative low frequency hearing, and the excellent hearing preservation that has been demonstrated in the literature with available electrode arrays.

Conclusions

The results of this study demonstrate that postlingually deafened adults with sloping hearing loss have the potential to gain significant benefit from electrical stimulation, and can achieve equivalent levels of improvement to typical candidates with profound hearing loss. The results presented in this paper provide evidence to support the prescriptive clinical counseling of patients with residual hearing. Patients with SL can be counseled that, should they lose their residual natural hearing because of the operation, they are still likely to gain a significant benefit from their cochlear implant. Should the patient retain their low frequency residual hearing, research suggests their outcome could only be further improved in terms of sound quality, naturalness and music perception. The results suggest that clinicians should consider recommending cochlear implantation for patients with sloping hearing loss in cases where conventional amplification fails to offer sufficient speech perception benefit and the patient is motivated to seek other options. When considering the proven benefits of EAS, the results of this study support the combination of a hearing preservation approach using a full-length electrode in patients with sloping hearing loss. Further research with larger numbers is required to assess the outcomes for adults with sloping hearing loss who receive CIs designed for hearing preservation.

Acknowledgements

The authors thank staff at the Melbourne Cochlear Implant Clinic, both past and present, whose contributions to research and data collection is invaluable in enabling projects like this to be completed.

References


Hearing Preservation Outcomes for 139 Cochlear Implant Recipients Using a Thin Straight Electrode Array

††Michelle Morin, ††Richard C. Dowell, †Claire Iseli, and †Robert J.S. Briggs

*University of Melbourne, Melbourne; ††Royal Victorian Eye and Ear Hospital, East Melbourne, and †The HEARing Co-operative Research Centre, Melbourne, Australia

Objectives: To assess the hearing preservation outcomes in a large group of adult cochlear implant recipients implanted with a thin straight electrode array using atraumatic surgical techniques. Factors affecting hearing preservation will be investigated.

Study Design: Prospective cohort study undertaken at the Royal Victorian Eye and Ear Hospital in Melbourne, Australia from December 2010 to May 2015.

Setting: Tertiary academic hospital.

Patients: One hundred thirty-nine adults undergoing cochlear implantation (CI).

Main Outcome Measure: Primary outcome measure of interest was pre and postoperative pure-tone audiometry.

Results: Median low-frequency hearing change for the whole group of 139 recipients was −22.5 dB at the 3 months postimplant. Eighty-six participants had functional presacral low-frequency hearing (<70 dB average at 220 and 2801 Hz). Of these, 80% retained measurable hearing at 3 months postimplant.

Conclusion: Preservation of hearing is possible following atraumatic cochlear implant surgery with a thin straight electrode array, the amount of hearing preserved seems to be variable, and factors related to this variability are not yet known. The results of the present study suggest a presacral low-frequency hearing at or better than 45 dB may be related to preservation of functional hearing.

Key Words: Adults—Atraumatic techniques—Cochlear implants—Electroacoustic hearing—Hearing preservation.

methods. In 2013, the HEARING Group attempted to provide a standardised method of quantifying percentage of hearing preservation which provided some clarification regarding what defined "complex hearing preservation" where this method of calculation was used (10). The HEARING Group method does not, however, provide an insight into amount of useful hearing preserved as the percentage preservation is heavily related to the individual’s preoperative hearing. Additionally, this percentage preservation may not be easily calculated in a clinical setting using the audiogram itself, though it has clear merit in a research database setting for consistent recording.

It is important for research in this area of hearing preservation post-cochlear implantation to follow a patient cohort for a number of months. Research has shown that traumatic surgery plays an important, though not all-encompassing, role in hearing preservation. Post-implant factors also play a part in loss of hearing, as patients who have preserved some natural hearing often go on to have a rapid deterioration of hearing within the months after cochlear implant surgery (11, 12). There is therefore a need to understand the risks of loss of hearing, including the pattern of progression, to effectively counsel recipients preoperatively.

The aim of this research was to assess the hearing preservation outcomes in a large group of adult CI recipients using a thin straight electrode array (TSEA).

More specifically, this study aimed to assess which factors, whether controllable or noncontrollable, have an effect on the postoperative hearing. An understanding of these factors and how they affect hearing in preoperative patient counselling and expectation management.

The present study will present the hearing preservation data in a number of ways, with a view to providing insight that is relevant for clinical counselling of patients’ preimplant. Many techniques have been used for assessing hearing preservation in the literature. An approach that is highlighted in the literature is that certain techniques used will lead to a bias in the group hearing loss statistics (13-15). In addition to using the HEARING Group method to assess percentage of hearing preservation across the group, we will also present the raw data relating to change in hearing for the group. For this analysis, we have used the approach of representing nonmeasurable hearing thresholds as an arbitrary figure of 125 dB, used in a variety of previous studies (16-18). While it is acknowledged that this approach may underestimate the group means, the approach represents the individuals with nonmeasurable hearing thresholds and does not skew the distribution unduly.

Finally, we will analyse the group in relation to preservation of "functional" hearing. It is generally accepted in both clinical experience and the literature that conventional amplification may not always provide adequate benefit to patients with significant hearing loss. It has been found that for those with hearing loss in the severe regions, intelligibility of the speech signal may be reduced despite appropriate amplification. It is thought that this is due to damage in the cochlea not limited to the outer hair cells but also affecting the inner hair cells (19, 20).

METHODS

A prospective longitudinal study of hearing outcomes was undertaken at the Royal Victorian Eye and Ear Hospital (RVEEH), where institutional HREC approval was obtained under project number 15/1207H. Adult patients who were consented for and received a TSEA were observed preoperatively, and 3 and 12 months postimplantation. At each time point, audiological testing was performed in addition to speech perception test battery per RVEEH Clinical protocol.

Participants

The study was performed from December 2010 to May 2015, during which time 154 adults were implanted with a TSEA in accordance with RVEEH CI candidacy guidelines (21). Of those, 139 recipients had pre-implant audiology completed at 3 months postimplant to enable analysis (note of those, 74 recipients had pure-tone audiometry measures at 12 months postimplant and 65 did not). The 15 recipients from the original 154 who were not included in the analysis were either lost to follow-up (due to implant nonuse and/or being transferred to another CI service), had been previously determined to have auditory neuropathy spectrum disorder, or did not attend their evaluation session. Of the 159 recipients, 49 were involved in a double-blinded clinical trial assessing the effect of a large dose of steroid administered intraoperatively. As this trial is ongoing, the authors are currently blinded to which recipients were given the steroid and as such will account for this by including study involvement in the factor analysis (see Fig. 3).

Postoperatively, each recipient received the standard RVEEH clinical protocol and was programmed using behavioural techniques by experienced audiologists. Electrocochlear stimulation (EAS) devices were used where audiologically appropriate and where the recipient was interested to try this style of fitting.

Analysis of Pre- and Postoperative Hearing

For whole-group analyses, we have used the approach of representing nonmeasurable hearing thresholds as an arbitrary figure of 125 dB. We have used median values (and median change) to provide valid measures of hearing preservation (13).

In our application of the HEARING Group method, we used pure-tone thresholds from 250 to 4000 Hz where the maximum testing level was considered to be 125 dB HL. Finally, we used a technique whereby the low-frequency pure-tone median (LEPTM) was determined from each participant’s median hearing levels at 250 and 500 Hz. Given the patient population, this approach may be more representative of degree of hearing loss and change in hearing. The LEPTM was used in our assessment of preservation of functional hearing, with a LEPTM of 70 dB or better defined as "functional hearing." Those with functional hearing preoperatively were divided into two groups on the basis of the presence of functional hearing at 3 months postimplant. Group 1 were those who had functional hearing postoperatively and preserved it, where Group 2 were those who had functional hearing and lost it (refer to Fig. 1). Nonmeasurable postimplant hearing thresholds were accounted for...
in the statistics when looking at "loss of measurable hearing." As there was no valid way to quantify the degree of change accurately without bias, those who lost all measurable hearing were excluded from the analysis of change in hearing.

Surgery and Postoperative Radiological Analysis
All recipients received a Nucleus Slim Straight CI422 through the RVEEH service. Atrumatic surgical techniques were used in all cases using a round window approach. The true round window membrane was exposed by drilling the overlying bone out of the round window niche. The membrane itself was punctured with a hypodermic needle and the electrode slowly inserted without lubricant. Steroid administration was variable, as recipients either received either intravenous Dexamethasone (8 mg) or were enrolled in a clinical trial that involved an additional high-dose intravenous steroid. Surgery was performed by one of 10 RVEEH cochlear implant surgeons with variable levels of experience.

The final position of the electrode array was assessed by analysis of postoperative x-rays for 100 recipients who had available x-rays out of the population of 130 (72%). The analysis was completed by one of two experienced cochlear implant surgeons. The angle of electrode insertion was determined relative to the Round Window-Mid Modiolus line on cochlear view plain x-ray.

Data Collection
Information was collected on a series of patient-specific factors (see Table 1) to assess their effect on the preservation of hearing. Demographic data was collected as the recipients were implanted with the TSEA, with additional clinical data acquired at the 3 and 12 month postimplant points.

TABLE 1. Assessment of change in low-frequency hearing versus patient-specific and surgical factors in 78 TSEA recipients

<table>
<thead>
<tr>
<th>Factor</th>
<th>Pearson r</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controllable factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insertion angle (degrees)</td>
<td>0.18</td>
<td>0.177</td>
</tr>
<tr>
<td>Time between Sx and T (d)</td>
<td>0.106</td>
<td>0.384</td>
</tr>
<tr>
<td>Surgical factors (high-dose steroid of chlor alc)</td>
<td>n/a</td>
<td>0.425</td>
</tr>
<tr>
<td>Latency*</td>
<td>n/a</td>
<td>0.083</td>
</tr>
<tr>
<td>Surgical factors (tumor)</td>
<td>n/a</td>
<td>0.073</td>
</tr>
<tr>
<td>Noncontrollable factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (yr)</td>
<td>n/a</td>
<td>0.312</td>
</tr>
<tr>
<td>Gender</td>
<td>n/a</td>
<td>0.672</td>
</tr>
<tr>
<td>Duration of loss (CL ear)</td>
<td>-0.413</td>
<td>0.215</td>
</tr>
<tr>
<td>Postoperative 500 Hz threshold</td>
<td>-0.091</td>
<td>0.427</td>
</tr>
<tr>
<td>Preoperative LPFTM</td>
<td>-0.039</td>
<td>0.466</td>
</tr>
<tr>
<td>Preoperative high-frequency pure-tone median TSEA, thin straight electrode array.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postoperative monosyllabic word score (N)</td>
<td>0.140</td>
<td>0.235</td>
</tr>
<tr>
<td>Age at CI (yr)</td>
<td>-0.164</td>
<td>0.152</td>
</tr>
</tbody>
</table>

Assessment conducted using other correlation analyses or Mood’s test of median as appropriate. Factors are divided into “controllable” and “noncontrollable” factors. Note the asterisk on “Latency” represents the factor is controllable as an extension—when both ears have the same similar hearing thresholds with normal anatomy on both sides, there may be control for side; however, this will not always be the case.

Statistical analysis was conducted using Minutah statistical software version 17. Appropriate parametric and nonparametric tests were used based on the distribution of the data being investigated, as noted in the Results section. An α level of 0.05 was used for all statistical tests.

RESULTS

Participants

Assessing the demographics of the group of 139, 68 (48.9%) were females and 71 (51.1%) were males. Mean duration of deafness in the implanted ear of 14.9 years (SD = 11.3). The average number of days between surgery and activation was 17.2 days (SD = 1.3) with a mean angular depth of insertion of 420.5 degrees (SD = 46.7). Finally, 31 recipients (20.1%) of the TSEA were second side CI recipients.

In our assessment of preservation of functional hearing and factors affecting change in hearing, a number of participants were excluded to enable accurate analysis. Fourteen participants with a prelingual hearing loss were excluded, and an additional 39 recipients were excluded as they were not considered to have functional low-frequency hearing preimplant. In this way, the profoundly deaf recipients and those without functional hearing were excluded to attempt to create a more uniform group to study. This left a study group of 86 participants.

Change in Hearing—Whole-Group Analysis

Assessment of hearing preservation was conducted across the whole group of 139 TSEA recipients for 3 months postimplant time point. Using the HEARING Group criteria, mean hearing preservation was 58.4%. According to the criteria, 36.7% of recipients had complete hearing preservation (HP), 46.8% had partial HP, 6.5% had minimal HP, and 10.1% had loss of hearing to HP. Mean change in low-frequency hearing (LPFTM) from preimplant to 3 months postimplant was found to be -22.5 dB, and ranged between -12.5 dB and -57.5 dB. Note that one recipient demonstrated threshold improvement postoperatively, with the reason for this being unclear. Median pre- and postoperative audiometric thresholds in addition to median change at each individual frequency are displayed in Figure 2.

The data were further analyzed for the 74 recipients with hearing measured to the 12 month postop point. The average hearing preservation was 44.4% by 12 months postop, according to the HEARING Group criteria. Breaking this down into the individual categories, it was found that by 12 months 20.3% of recipients had complete HP, 47.3% had partial HP, 19.0% had minimal HP, and 14.7% had no HP. Median change in low-frequency hearing (LPFTM) from preimplant to 12 months postimplant in this smaller group of 74 recipients was found to be -34.1 dB, and ranged between 0 dB and -105 dB change.

Preservation of Functional Hearing

Assessment of the group with functional preoperative low-frequency hearing was conducted at 3 months postimplant, where the LPFTM at or better than 70 dB was considered “functional hearing.” Of the 56 TSEA recipients in this group, a total of 8 recipients (9.3%) lost all measurable hearing. Of the remaining group, 78 retained measurable hearing (90.7%) and 31 retained functional hearing (59.5%).

FIG. 2. Median pre- and postoperative audiometric thresholds for 139 TSEA recipients at 3 months postimplant. The squares show median change at 3 months postop. Error bars on the graph represent the interquartile range of the data at each frequency.

Otology & Neurotology, Vol. 30, No. 6, 2007
HEARING PRESERVATION IN COCHLEAR IMPLANT RECIPIENTS

Excluding the 8 participants who lost all measurable hearing postimplant, the group of 78 were further analyzed to assess difference between those who lost functional hearing versus those who did not. Group 1 were those who had functional hearing and retained it (n = 31), Group 2 were those who had functional hearing and lost it postimplant (n = 47). There was no significant difference between the groups for number of days between surgery and activation (Group 1 mean = 17.8 days, Group 2 mean = 16.7 days, p = 0.245), age at implant (Group 1 mean = 64.7 yr, Group 2 mean = 66.2 yr, p = 0.384), angular depth of insertion (Group 1 mean = 420.8 degrees, Group 2 mean = 412.2 degrees, p = 0.481) or duration of severe to profound loss in the implanted ear (Group 1 mean = 11.5 yr, Group 2 mean = 13.2 yr, p = 0.444). There was an even spread between the groups for those included in the additional blinded steroid study (Group 1 38.7%, Group 2 38.3%). Proportion of males and females differed slightly between the groups (Group 1 38.7% males, 61.3% females; Group 2 55.3% males, 44.7% females). Group 1 had significantly better preoperative low-frequency hearing compared with Group 2 (Group 1 mean LF = 36.3 dB, Group 2 mean = 54.5 dB, p < 0.001). This is demonstrated in Figure 3.

As would be expected from the division into respective groups, Group 1 had significantly better low-frequency hearing at 3 months postimplant compared with Group 2 (Group 1 mean low-frequency hearing = 51.7 dB, Group 2 mean = 89.9 dB, p < 0.001). There was a significant difference in the low-frequency hearing between the groups at 12 months postimplant, where Group 1 continued to retain significantly better hearing compared with Group 2 (Group 1 mean low-frequency hearing = 58.6 dB, Group 2 mean = 98.9 dB, p < 0.001). For both Group 1 and Group 2, significant deterioration in hearing was noted from preimplant to the 3 month postimplant time point (p < 0.001). Between 3 and 12 months postimplant however, Group 1 participants did not demonstrate a significant deterioration in low-frequency hearing (p = 0.065). In contrast, there was a significant deterioration observed in the low-frequency hearing thresholds for Group 2 between 3 and 12 months postimplant (p = 0.004) (see Fig. 4).

Factors Contributing to Hearing Loss

From the 13 analyses conducted against change in LFPTM at 3 months, no patient or surgical factors were shown to have significant relationships. This data is presented in Table 1. Angular depth of insertion had no relationship with change in LFPTM at 3 months postimplantation (p = 0.177). This lack of relationship is demonstrated in Figure 5. Of the group of 78, 57 of those had available x-rays for analysis (73%), with 29 of Group 1 and 28 of Group 2 having available imaging.

FIG. 3. The pre- and postimplant low-frequency pure-tone median (LFPTM), using the median threshold at 250 and 500 Hz, for 78 TSCA recipients with functional preimplant low-frequency hearing. The diagonal line represents the ideal scenario where postimplant hearing is the same as preimplant. The data are separated into groups—Group 1 (n = 31) represented in circles being those who had functional preimplant hearing and retained it postimplant, Group 2 (n = 47) represented in squares are those who had functional hearing group and subsequently lost it. Horizontal data points here are for 3 months postimplantation.

FIG. 4. Change in low-frequency pure-tone median (LFPTM) over time, comparing Group 1 (n = 31) (those who had functional group hearing and retained it postimplant), and Group 2 (n = 47) (those who had functional group hearing and lost it). A significant deterioration in low-frequency hearing is shown for both groups from preop to 3 months postop (p < 0.001). A further significant deterioration is evident for Group 2 between 3 and 12 months postimplant (p < 0.001).

FIG. 5. Scatterplot of angular depth of insertion versus change in low-frequency pure-tone median from preimplant to 3 months postimplant for n = 78 adult recipients of a thin straight electrode array (TSEA). No significant relationships were found (p > 0.177).

Otolaryngology & Neurotology, Vol. 38, No. xx, 2017

Copyright © 2017 Otolaryngology & Neurotology, Inc. Unauthorized reproduction of this article is prohibited.
There was no significant difference in the angle of insertion between those who preserved functional hearing and those who lost hearing (Group 1 mean = 406 degrees, SD = 51.5; Group 2 mean = 419.9 degrees, SD = 58.8, p = 0.254). To evaluate consistency in reporting, 10 postoperative x-rays were analyzed by both surgeons. As the data was not normally distributed, a Mann-Whitney analysis of medians was used. There was no significant difference between reported angular insertion depth between the two surgeons.

DISCUSSION

The results of the present study demonstrate that hearing preservation is possible when using a TSEA. Median low-frequency change by 2 months postimplant was 22.5 and 34.1 dB by 12 months, with some recipients showing no change in low-frequency hearing. These outcomes are consistent with results in the literature demonstrating the preservation of functional hearing postimplant (12,22,23).

The present data set showed a variety of outcomes from complete hearing preservation through to total loss of hearing. However, in those with "functionally useful hearing" postimplant (i.e., 1PPTM of 70 dB or better, as determined by the criterion set in the present study), it was identified that degree of hearing loss was a predictor for the preservation of hearing postoperatively. Those with better hearing postimplant had better low-frequency hearing postimplant.

While it is not surprising that better postimplant hearing is predictive of better postop hearing, it is important to observe the distribution of the data presented for those with functionally useful preoperative hearing. When assessing the distribution of preoperative hearing of both groups in Figure 1, a third quartile and Group 2’s first quartile figures, it would seem that low-frequency hearing at 45 degrees or better is an important marker for hearing preservation. Approximately 75% of Group 1 had preoperative hearing ≤45 dB, and 75% of Group 2 had preoperative hearing >45 dB. Using these postimplant results, cochlear implant surgeons and clinicians can be guided in their discussion of hearing preservation for potential recipients with useful preoperative low-frequency hearing.

Where the recipient has a preoperative low-frequency median of 45 dB or better, counselling would reflect a 75% chance of preserving functionally useful hearing. More importantly for recipients with low-frequency hearing of 50 dB or poorer, careful counselling should be employed to inform candidates that there may be a 75% chance of losing functional hearing.

The figure of 70 dB was used in this study as the differentiator between functional and nonfunctional low-frequency hearing. It is worth noting that this is a more stringent measure of "functional" hearing compared to the use of a "line in the wood," and results presented may have been different should another figure have been chosen. Clinically, we know that there remains a point that, while measurable, an individual’s hearing is no longer useful for the purposes of acoustic amplification. The authors acknowledge that there may be disagreement in the field about how much low-frequency hearing is considered "functional," however for the purposes of this study we propose the figure of 70 dB.

In contrast to the literature suggesting a deeper insertion depth is likely to lead to increased loss of residual hearing (9), this study demonstrated no correlation between the depth of insertion and loss of hearing. Angular depth of insertion ranged from 320° to 530° degrees with no relationship to degree of hearing loss evident (see Fig. 5). Further research at RVEEH using intraoperative electrophysiology to assess electrode position and depth postoperatively. Recent electrophysiological research has provided evidence to show that all patients who had detectable changes in their intraoperative electrocochleography (ECochG) response lost all residual acoustic hearing (16). Campbell et al. (25) have demonstrated the ability of intraoperative ECochG using the CI itself. These techniques may prove useful in intraoperative monitoring and allow better hearing preservation outcomes in the future.

The majority of patients encountered in implant centres have a progressive hearing loss; therefore, preoperative counselling must also touch on the possibility of further hearing loss over time. It is important to consider use of a full-length electrode array given the likelihood of further hearing deterioration over time.

Continued audiological monitoring of both the CI ear and the contralateral ear is important, with contralateral ear hearing one factor we were unable to assess in the present study. Long-term follow-up is necessary, particularly for patients using electroacoustic stimulation, as change to hearing may necessitate changes to amplification settings, cross-over frequencies, and their general EAS setup in the future.
CONCLUSION

In a study of 130 recipients of a thin-straight electrode array, good hearing preservation was demonstrated up to 12 months postoperatively. There is a large amount of variability in the preservation of hearing for adults with a TSEA and the causes for this variability are not known. It is likely there are patient-specific factors at play that we are either unaware of, or unable to measure at present. This study has identified that degree of hearing loss preimplant is a predictor for the preservation of hearing. Patients with low-frequency hearing of 45 dB or better seem to have a 75% chance of preserving significant hearing postop. Further study is warranted in this area, with both adult and pediatric CI recipients, which may allow researchers to identify specific factors related to the preservation of hearing. Additionally, while outside the scope of the present study, future study of the functional outcomes of CI recipients with preserved hearing is warranted with a view to further understanding the benefits of EAS in this group.

Acknowledgments: The authors gratefully acknowledge the efforts of the RYVIM Cochlear Implant Clinic staff in their ongoing support of research and data collection. Projects such as this could not be completed without your much appreciated assistance.

REFERENCES

14. Appendix D – Publication Proofs Reprint (Chapter 6)

Speech Perception Outcomes for Adult Cochlear Implant Recipients Using a Lateral Wall or Perimodiolar Array

*††|Michelle Moran, ‡‡‡|Andrew Vandali, ‡§§|Robert J.S. Briggs, †||Shani Detman,
†|Robert S.C. Cowan, and †|Richard C. Dowell

*††|The HEARing CRC, Melbourne: The Royal Victorian Eye & Ear Hospital; |The University of Melbourne, Melbourne; ‡‡‡|Cochlear Ltd and ‡§§|The Rincon Institute, Melbourne, Australia

Aims: To assess the speech perception outcomes of adult CI recipients with significant preimplant low frequency hearing, examining differences between perimodiolar and lateral wall electrode placement in order to provide clinical guidance for clinicians and surgeons.

Methods: A prospective cohort study was undertaken identifying all adults who received a trans-axial electrode array (TSEA) at the Royal Victorian Eye & Ear Hospital (RVEEH) from 2010 to 2015 and who had a preimplant low frequency pure tone median of 70 dB HL (n = 63). A retrospective review was completed of the RVEEH database to identify a comparison group who had been implanted with a perimodiolar electrode array, comparing adult implanted between 2004 and 2011 (PM Group) with preimplant hearing equivalent to the TSEA group (n = 70). The TSEA Group were further divided into subgroups in which n = 19 used EAS (TSEA-EAS) and n = 44 used electric-only hearing (TSEA-Standard).

Results: There was no significant difference in median speech perception outcomes between the TSEA and PM Groups (TSEA 61.9%, PM 63.7%, p = 0.954). A significant difference was found between the TSEA-EAS and TSEA-Standard subgroups for median speech perception outcome (TSEA-EAS median 73.5%, TSEA-Standard median 58.3%, p = 0.041).

Conclusions: Significant speech perception benefit following cochlear implantation was achieved with both the perimodiolar and lateral wall electrode arrays and no significant difference was found between outcomes with these array types. Those that received a TSEA, had preserved hearing, and utilized an EAS sound processor performed better than those with a TSEA and electric-only hearing.

Key Words: Adults---Cochlear implants---Electrode array---Outcomes---Speech perception.


Developments in internal and external components of the cochlear implant (CI) have led to improvements in speech perception outcomes and the gradual expansion of candidacy criteria to include those with more residual hearing (1,2). Many patients seeking advice regarding their own CI candidacy may have higher expectations of speech perception benefit than in the past. As with any medical intervention, a thorough evaluation of the relative risks and benefits is essential. It is the clinician’s role to assess the needs of their patient and recommend a device that provides the greatest speech perception benefit whilst balancing the potential risk of loss of hearing. This benefit-risk trade-off must also incorporate the patient’s own preferences in the decision-making process, as the perception of risk may be greater for some than others (3).

Research suggests that the greatest hearing preservation occurs when there has been the least trauma to the cochlea at the time of implantation. Several studies have demonstrated that with increased angular depth of electrode insertion there is a decreased likelihood of preserving usable hearing (4,5). Sahling and colleagues demonstrated increased hearing loss as depth of insertion into the cochlea increased (6). The rate of hearing preservation was poorer where the electrode array had been advanced beyond the point of first resistance (7). Moran and colleagues (8) found that angular depth of insertion was not related to degree of hearing loss for adult CI recipients; however, a key limitation in that study was the imaging techniques were restricted to plain x-ray. Improved hearing preservation outcomes have been reported in the literature for shorter electrode arrays and for arrays specifically designed to reduce insertion trauma (8–13). Regardless of the device chosen or surgical procedure, there remains the possibility that CI recipients lose all hearing during or after the
procedure; thus it is important to provide accurate information about this risk in addition to expectations regarding speech perception benefit during counseling.

Certain demographic and surgical device-related variables have been identified as having a significant effect on speech perception benefit for adults with acquired hearing loss who receive CIs. Increasing age at implantation is generally accepted to have a negative effect on speech perception performance (14–18). There appears to be a stronger negative effect in the elderly population who receive a CI, though there is likely some confounding factor to this effect due to known changes in auditory and cognitive processing in this age group (15,16,20). Duration of deafness has traditionally been seen to have a negative effect on speech perception outcomes, though to be a result of deteriorating central auditory processing skills with increasing years of auditory deprivation (2,14,16,21). In Blamey and colleagues’ update to their 1996 study, while duration of deafness was a significant factor it had a smaller effect size than in their original study (21). Further reducing the potential changes in CI candidates, Holden and colleagues (15) did not find a significant correlation between duration of deafness and speech perception outcomes, which the authors proposed was related to the group’s use of hearing aids pre-CI, mitigating the effects of auditory deprivation. Additionally, higher levels of preimplant speech perception appear to have a positive effect on postimplant speech performance (14,18).

Position of the electrode array within the cochlea appears to be important, in that scala tympani location has been shown to provide superior outcomes compared to scala vestibuli location (22,23). Finley and colleagues (24) discussed the possibility of “cross-turn stimulation”, for an electrode array in scala vestibuli, whereby activation of a single electrode site has the possibility of stimulating two populations of spiral ganglion cells in different cochlear turns, leading to pitch confusions and therefore diminished speech perception. If the electrode array trajectory is cutaneous from scala tympani to scala vestibuli, this will lead to trauma, including fixation of the basilar membrane at the point of penetration; loss of the surviving hair cells; or potentially loss of spiral ganglion cells, and reduced benefits (25,26).

The proximity of the electrode array to the modiolus has also been investigated in regard to speech perception outcomes. CI electrode arrays that are curved and designed to be positioned adjacent to the modiolus (i.e., perimodiolar) are closer to the target neural receptors than straight arrays that sit against the lateral wall. Perimodiolar arrays have been reported to have lower current requirements than lateral wall arrays, and potentially reduced channel interaction leading to better speech perception (27,28). However, there have been limited studies directly comparing perception outcomes with perimodiolar arrays versus lateral wall arrays. In a retrospective study of 466 adult CI recipients, Dowell (29) reported that those using a curved perimodiolar electrode array had significantly better speech perception outcomes as compared to adults implanted with straight lateral wall arrays. Similarly, in a study of 114 adults using a variety of CIs, Holden and colleagues (14) found that positioning of the electrode array closer to the modiolus was significantly correlated with better speech perception outcomes.

The aim of the present study was to assess the speech perception outcomes of adult CI recipients with significant preimplant low frequency hearing, with a view to providing clinical guidance for realistic expectation of benefit for the present adult CI candidate population. An additional aim was to examine differences in speech perception outcomes between perimodiolar and lateral wall electrode placement, by comparing populations using nuclear contour advance electrode arrays (hereafter described as perimodiolar) and nucleus slim straight electrode arrays (hereafter described as thin straight electrode arrays, TSEA). To examine the benefit hearing preservation may offer, speech perception outcomes were also analysed for a subgroup of recipients using lateral wall electrode arrays with and without electroacoustic stimulation.

MATERIALS AND METHODS

This prospective cohort study identified 154 adults who received a TSEA between December 2010 and May 2015 at the RVEEH CI Clinic in Melbourne, Australia. The standard assessment protocol involved audiological testing and aided speech perception test battery preoperatively, and at 3 and 12 months postimplant. These data were collected prospectively and entered with demographic detail into a database. In order to compare speech perception outcomes by device type, a retrospective analysis of the RVEEH database also identified 166 adults who received a perimodiolar electrode array at RVEEH CI Clinic between 2004 and 2011 and who also completed the standard audiological and speech perception protocol.

Participants

Participants were included in the study if their audiometric testing indicated normal and audible low frequency hearing (LFP<40 dB HL). For participants with bilateral cochlear implants, test data from the first side was included in the analysis. Those with prelingual onset of hearing loss, re-implanted patients, non-English speakers, and those with any comorbid neural or cognitive issues were excluded.

Data from 61 participants with a TSEA (TSEA Group) and 70 participants with a perimodiolar electrode array (PM Group) were included in this study.

Postoperatively, each recipient was programmed using behavioral techniques by experienced audiologists. Electroacoustic stimulation (EAS) was used only with the TSEA Group, where clinically appropriate. For all postoperative assessments, participants used the sound processor provided at the initial activation which had been programmed as per standard clinical protocols. The PM Group used Freedom and Nucleus 5 (CP9010) sound processors (4% (n=38) and 46% (n=32) respectively). The TSEA Group used Nucleus 5 (CP9010) and Nucleus 6 (CP9010 or CP920) sound processors if using a standard device (69% (n=31) Nucleus 5, 21% (n=13) Nucleus 6). Around 30% (n=19) of the TSEA Group used an

Otolaryngology & Neurotology, Vol. 38 No. xx, 2009

215
EAS set-up, using either Freedom Hybrid (n=4), Nucleus 6 Hybrid (n=14), or CP810 with an optimized ITE hearing aid (n=1). All recipients were programmed using the Advanced Combination Encoder (ACE) sound coding strategy and used Adaptive Dynamic Range Optimization (ADRO) regardless of the sound processor used(30,31). Recipients were programmed at initial activation using the default software settings.

Materials

Recorded open-set word and sentence materials were used for all tests using a native Australian English speaker, via audition alone at 65 dB SPL at an azimuth of 0°. For tests in noise, the noise was presented from the same loudspeaker.

Open-set monosyllabic word testing was conducted using computer-generated consonant-vowel-consonant (CVC) words spoken by a male speaker, with lists of 50 words scored for the number of correctly identified words and phonemes (32). Open-set sentence-in-noise testing was conducted using the City University of New York (CUNY) sentences, in which lists of 12 sentences were scored for the number of correctly words from a total of approximately 102 keywords per list (33). For each test, two lists were presented and the average of the two scores was taken. CUNY sentence testing was conducted in eight talker babble background noise with a signal-to-noise ratio (SNR) of +10 dB, using a female speaker. Appropriate masking was introduced to the contralateral ear where required.

Preoperative speech perception data were obtained during implant candidacy assessment with optimized hearing aids. For the purpose of this assessment, only monaural scores from the ear to be implanted were included in the analysis. Postoperatively, where the recipient used bilateral ICOMs in their CI, this condition was used in the CI speech perception analysis (i.e., their ‘everyday’ configuration).

Surgery and Postoperative Radiological Analysis

Surgery was performed by 1 of 10 RVEH/L cochlear implant surgeons with variable levels of experience. All recipients in the PM Group received Contour Advance electrode arrays, manufactured by Cochlear Limited (Sydney, Australia). These devices were either Nucleus Freedom or Nucleus CS12 implants (74% (n=52) and 26% (n=18) respectively). For all the Contour Advance electrodes, insertion was through an extended round window or separate cochleostomy approach. For the TSEA Group, all participants received the Nucleus Slim Straight CI422 implant, manufactured by Cochlear Limited. In the majority of cases the electrode was inserted through an incision in the round window membrane. In the proximal basal turn, the TSEA electrode was placed to the modiolus by the inferior edge of the round window and then assumed a lateral wall position. The electrode arrays for both groups were wire 22 half-handed platinum stimulating electrodes.

For the TSEA Group only, the position of the electrode array was assessed by analysis of postoperative cochlear view x-rays in 45 of the 63 recipients (71%) who had x-rays available. The analysis was completed by one of two experienced cochlear implant surgeons. The angle of electrode insertion was determined relative to the round window—mid-modular line on cochlear view plain x-ray.

Data Management

Data pertaining to known variables likely to affect postimplant speech perception were collared (see Table 1). For the TSEA Group, demographic data were collected at the point of implant reconfiguration, with additional clinical data acquired at the 6 and 12 month postimplant points. For the PM Group, all data were collected retrospectively from the clinic database.

Speech perception data were assessed using a principal components analysis. This showed 90.5% of the variance in the data was well explained by one component—a weighted average of the three scores. Given this, a Total Speech Perception Score (TSPS) was formulated by calculating an average of a recipient’s open-set word, phoneme, and sentence in noise score in order to obtain a single metric that could be used in our analysis to provide the most reliable statistical measure of

TABLE 1. Demographic comparisons for the TSEA Group and the Perimodiolar Group. Duration of deafness refers to duration of severe to profound hearing loss in the implanted ear prior to CI, measured in years.

<table>
<thead>
<tr>
<th></th>
<th>TSEA Group (n=93)</th>
<th>Perimodiolar Group (n=70)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at implant, years</td>
<td>66.7</td>
<td>71.1</td>
<td>p = 0.139</td>
</tr>
<tr>
<td>Duration of deafness, years</td>
<td>10.0</td>
<td>10.0</td>
<td>p = 0.366</td>
</tr>
<tr>
<td>Pre-implant LPPM, dB</td>
<td>50.0</td>
<td>77.5</td>
<td>p = 0.004</td>
</tr>
<tr>
<td>Post-implant LPPM, dB</td>
<td>80.0</td>
<td>106.3</td>
<td>p = 0.001</td>
</tr>
<tr>
<td>Pre-implant speech perception (%)</td>
<td>10.0</td>
<td>4.0</td>
<td>p = 0.0001</td>
</tr>
<tr>
<td>Phonemes</td>
<td>36.0</td>
<td>17.0</td>
<td>p = 0.0001</td>
</tr>
<tr>
<td>Sentences in noise</td>
<td>13.0</td>
<td>0.0</td>
<td>p = 0.020</td>
</tr>
<tr>
<td>Total Speech Perception Score</td>
<td>27.7</td>
<td>10.8</td>
<td>p = 0.004</td>
</tr>
<tr>
<td>Postimplant speech perception (%)</td>
<td>50.0</td>
<td>55.0</td>
<td>p = 0.432</td>
</tr>
<tr>
<td>Phonemes</td>
<td>75.0</td>
<td>76.0</td>
<td>p = 0.661</td>
</tr>
<tr>
<td>Sentences in noise</td>
<td>68.0</td>
<td>70.0</td>
<td>p = 0.783</td>
</tr>
<tr>
<td>Total Speech Perception Score</td>
<td>68.7</td>
<td>67.3</td>
<td>p = 0.954</td>
</tr>
</tbody>
</table>

LPPM represents the low frequency pure tone median measured in decibels, in this study referring to thresholds at 250 and 500Hz. The postimplant LPPM is an average score postoperatively. The Total Speech Perception Score represents an average of the open-set word, phoneme, and sentence in noise scores. The postimplant speech perception scores represent the average score for each test at either 6 or 12 months postimplanting the most recent test score for each individual. Data presented as median values. Note: Some participants did not complete sentence in noise testing, as a result for Sentences in Noise and therefore Total Speech Perception Score have lower participant numbers in the analysis (preimplant TSEA n = 73; Perimodiolar n = 62; postimplant TSEA n = 79; Perimodiolar n = 67).

Otolaryngology, Vol. 19, No. xx, 2009
performance. Scores are also presented for pre- to postoperative improvement by calculating the percentage point difference between the preoperative score and the best postoperative score. Statistical analysis was conducted using Minitab statistical software version 17. Data analysis was completed using non-parametric tests, as the data were not normally distributed. To assess the equality of group medians, Mood's median test was used in place of an analysis of variance. Regression analyses were used to examine the impact of various factors on the postoperative speech perception outcomes for both groups. An α level of 0.05 was used for all statistical tests.

RESULTS

TSEA and PM Group Comparison

Mood's median test indicated no significant differences between the groups in terms of the age at implantation (TSEA Group 66.7 yrs, PM Group 71.1 yrs; \( p = 0.139 \)) and duration of severe to profound deafness (TSEA Group 10.0 yrs, PM Group 10.0 yrs; \( p = 0.366 \)), or postoperative speech perception scores (TSEA Group 61.7%, PM Group 67.3%; \( p = 0.954 \)). There was a significant difference found between the groups in terms of their median preoperative hearing levels (TSEA Group LPTMT 50.0 dB HL, PM Group LPTMT 75.5 dB HL, \( p < 0.004 \), see Fig. 1). The TSEA Group also showed significantly better median acoustic hearing thresholds postoperatively (TSEA Group LPTMT 80.0 dB HL, PM Group LPTMT 106.3 dB HL, \( p < 0.001 \)). The TSEA Group had significantly better preoperative speech perception than the PM Group (TSEA Group TSPS 21.7%, PM Group 10.8%, \( p = 0.004 \); see Table 1). As the TSEA and PM Groups differed with respect to factors associated with preimplant hearing ability (i.e., LPTMT and TSPS), post-hoc examination of the degree of improvement were also completed in an effort to assist preimplant counselling discussions. While there was no difference in overall functional hearing outcomes as noted above, a significant difference was observed between the TSEA and PM Groups for the degree of improvement for TSPS, with the PM Group showing greater improvement (TSEA Group 38.2 percentage point improvement, PM Group 46.8 percentage point improvement; \( p = 0.029 \)).

Factors Affecting Speech Perception Outcomes

Multifactor regression analysis was used to assess which factors may have had an influence over the postoperative speech perception outcomes. Factors included in the statistical model were age at implantation, duration of deafness, preimplant LPTMT, preimplant TSPS and electrode position type (TSEA or perimodular). The outcome variable used in the model was postimplant TSPS.

Factors shown to significantly influence the variance of the postimplant TSPS were age at implant (\( F = 34.64, p < 0.001 \)) and duration of deafness (\( F = 4.00, p = 0.048 \)). This model accounted for 26.75% of the variance (\( R^2 \) adj) in postimplant TSPS Total Speech Perception Score. None of preoperative LPTMT, preoperative TSPS, nor electrode array used were significantly associated with speech perception results (\( F = 0.28, p = 0.600 \); \( F = 3.43, p = 0.067 \); \( F = 1.28, p = 0.260 \), respectively).

TSEA Group Analysis

In order to investigate the potential impact of use of EAS and/or angular depth of insertion on postoperative speech perception, separate analysis of data for the TSEA Group was conducted.

The TSEA Group was divided into two subgroups based on the sound processor used. The TSEA-EAS Group (\( n = 19 \)) included those using a sound processor with EAS, and TSEA-Standard Group (\( n = 44 \)) included those using a sound processor in the standard electric-only configuration. There was no significant difference in preoperative median TSPS (TSEA-EAS median score 24.0%, TSEA-Standard median score 15.8%, \( p = 0.107 \)). Mood's Median Test indicated that the postoperative TSPS was significantly better for the TSEA-EAS Group (TSEA-EAS median score 73.5%, TSEA-Standard median score 58.3%; \( p = 0.042 \)). Pre-implant LPTMT was significantly better in the TSEA-EAS group compared to the TSEA-Standard group (TSEA-EAS Group median LPTMT 35.0 dB HL, TSEA-Standard group 55.0 dB HL, \( p = 0.006 \)). The difference in LPTMT was also present at the 3 and 12 month postoperative points, with the TSEA-EAS group showing better hearing thresholds than the TSEA-Standard group (3m: TSEA-EAS Group LPTMT 50.0 dB HL, TSEA-Standard Group mean 90.0 dB HL, \( p < 0.001 \); 12m: TSEA-EAS Group LPTMT 55.0 dB HL, TSEA-Standard Group mean 100.0 dB HL, \( p = 0.027 \)). Refer to Table 2 for details of these comparisons.

The TSEA-EAS Group was also compared to the PM Group to assess any difference in speech perception outcomes. Whilst there were no differences for postimplant LPTMT and TSPS (TSEA-EAS Group 26.7%, PM Group 11.7%, \( p = 0.004 \)), no significant difference was found for postimplant TSPS implant (TSEA-EAS Group 73.5%, PM Group 67.3%, \( p = 0.175 \)) or TSPS improvement scores (TSEA-EAS Group 38.0 percentage point improvement, PM Group 46.8 percentage point improvement, \( p = 0.072 \)).

To assess how much variance in the TSEA Group's postoperative speech perception score was influenced by the angular depth of insertion of the electrode array, a regression analysis was completed. The angular depth of insertion varied between 350.0 and 530.0° in the TSEA group, with the average being 417.2°. Angular depth of insertion was not significantly associated with postoperative TSPS (\( p = 0.482, R^2 \) adjusted 0%).

DISCUSSION

Changes to cochlear implant candidates in terms of preoperative residual hearing thresholds are evident worldwide. This changing CI candidate pool is reflected in the present study. Despite following an audiometric inclusion criterion, the prospectively-recruited TSEA Group had significantly better preimplant LPTMT than 217
FIG. 1. A and B. Comparison of pre- and postoperative hearing for the TSEA Group. A and Perimodiolar Group. B. Group average hearing levels shown in dB HL preoperatively and as measured at 3 months postimplant, error bars indicating 95% confidence interval of the mean. Pre-op and post-low frequency pure tone median (LFPTM) shown for both time points as indicated by the dashed horizontal line on each graph. Refer to Table 1 for values. Both groups demonstrate a deterioration in pure tone thresholds postoperatively. LFPTM indicates low frequency pure tone median.

Otolaryngology, Vol. 38, No. xx, 2019
<table>
<thead>
<tr>
<th></th>
<th>TSEA-RAS (n = 13)</th>
<th>TSEA-Standard (n = 41)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at implant, years</td>
<td>69.5</td>
<td>66.3</td>
<td>p = 0.329</td>
</tr>
<tr>
<td>Duration of deafness (spurred), years</td>
<td>10.0</td>
<td>10.0</td>
<td>p = 0.736</td>
</tr>
<tr>
<td>Pre-implant LPTPM, dB</td>
<td>55.0</td>
<td>61.6</td>
<td>p = 0.860</td>
</tr>
<tr>
<td>Post-implant LPTPM, dB—1 months</td>
<td>50.0</td>
<td>90.0</td>
<td>p = 0.001</td>
</tr>
<tr>
<td>Post-implant LPTPM, 12 months</td>
<td>55.0</td>
<td>100.0</td>
<td>p = 0.827</td>
</tr>
<tr>
<td>Preimplant speech perception (%)</td>
<td>12.0</td>
<td>9.0</td>
<td>p = 0.390</td>
</tr>
<tr>
<td>Phonemes</td>
<td>45.0</td>
<td>34.5</td>
<td>p = 0.105</td>
</tr>
<tr>
<td>Sentences in noise</td>
<td>22.0</td>
<td>6.0</td>
<td>p = 0.107</td>
</tr>
<tr>
<td><strong>Total Speech Perception Score</strong></td>
<td><strong>24.0</strong></td>
<td><strong>15.8</strong></td>
<td>p = 0.107</td>
</tr>
<tr>
<td>Postimplant speech perception (%)</td>
<td>58.0</td>
<td>45.0</td>
<td>p = 0.365</td>
</tr>
<tr>
<td>Phonemes</td>
<td>78.0</td>
<td>73.5</td>
<td>p = 0.283</td>
</tr>
<tr>
<td>Sentences in noise</td>
<td>76.5</td>
<td>65.0</td>
<td>p = 0.199</td>
</tr>
<tr>
<td><strong>Total Speech Perception Score</strong></td>
<td><strong>73.5</strong></td>
<td><strong>58.3</strong></td>
<td>p = 0.043</td>
</tr>
</tbody>
</table>

*These values are based on the postimplant TSEA-RAS (n = 14) and postimplant TSEA-Standard (n = 41). The significance levels were calculated using the paired t-test. The study was conducted at thresholds of 250 and 500 Hz. The postimplant LPTPM was measured 3 months postoperatively. The Total Speech Perception Score represents the average score for each test at color 3 or 12 months postimplant using the most recent test scores for each individual. Data presented as median values. Note: Some participants did not complete sentence-in-noise testing, as a result for Sentences in Noise and therefore Total Speech Perception Score has lower participant numbers in the analysis between TSEA-RAS (n = 13), TSEA-Standard (n = 38), postimplant TSEA-RAS (n = 14), TSEA-Standard (n = 41).*

In the PM Group who received their CI between 2004 and 2011. As identified by Blamey and colleagues (21), this suggests that people are not waiting as long to access hearing technology. No significant difference was seen between the TSEA and PM Groups for speech perception outcomes. Both groups received significant benefit from the CI, further evidence supporting the use of CI as a treatment option for individuals with significant preimplant low frequency hearing loss (34–36). The factors affecting speech perception outcomes in this cohort were consistent with previous studies including age at implant and duration of deafness. Recent literature suggests decreasing importance of "loss of deafness" as a factor in CI studies given that candidates have much more hearing pre-CI than in the past. Individuals seeking CIs in the present day are typically making some use of hearing aids and residual low frequency hearing (35). The present study indicated a significant negative effect of duration of deafness, which post-hoc analysis showed was related to the sentence perception in noise task only. This may be due to the effect of auditory deprivation on higher level central auditory processing and the effect is therefore more pronounced for a sentence in noise task. Neither preimplant speech perception nor LPTPM were found to be associated with postimplant TFS in this study.

The TSEA Group maintained significantly better postoperative hearing thresholds than the PM Group. In a systematic review of 27 studies, Incerti and colleagues (35) examined detailed hearing preservation data. They found that while hearing preservation hearing preservation was possible for a variety of electrodes including those with a perimodiolar design, it was improved with shorter or thinner electrodes specifically designed for hearing preservation, compared with conventional perimodiolar electrodes or straight electrodes used with varying insertion depths. Wann and colleagues (23) studied a series of 116 cases and found that lateral wall arrays were more likely to stay in scala tympani than perimodiolar arrays (89% vs. 58%). This result is supported by a recent systematic review by Horsley and colleagues (27) who found a 17% rate of insertion trauma from 653 implantations, 7.8% of which related to electrode array translocation. This was shown to be more common for curved rather than straight electrodes (37). Given the increased complexity in achieving ideal perimodiolar electrode insertion, it is possible that surgeon skill and/or device experience may contribute to variability. Recent review of experience with perimodiolar electrode positioning at the RVHHL demonstrated an 18% rate of scala tympani insertion and 9% scala vestibuli insertion for Contour Advance electrodes that were intended for scala tympani insertion. These findings were associated with a significant reduction in speech perception scores, approximately 15% poorer than those where the array lies wholly in scala tympani (38). Given these results, we must consider the group of implanting surgeons in the present study as a potential source of variability which may in turn have affected the average outcomes for the PM group. While the surgical group had the varying levels of experience, all 10 surgeons were fellowship-trained CI surgeons and full electrode insertion was achieved in all cases as confirmed by x-ray. In a previous study by our group assessing hearing
SPEECH PERCEPTION OUTCOMES BY CI ELECTRODE ARRAY TYPE

preservation for 139 TSEA recipients and the same 10 CI
surgeons, there was no significant correlation found
between surgeon and change in low frequency hearing
preservation (16).

The results of the current study differ from previous
studies that have reported better speech perception out-
comes using perimodiolar arrays (14,29). It is important
to note that the present study differs from those in the
literature in that it assesses outcomes for a particular
group of implant recipients (i.e., preimplant functional
debriefing and probe positioning, perimodiolar array,
and as a result these outcomes may not be representative of all
CI recipients. Given the recent results reported by Shail
and colleagues (38) discussed above, it is worth consid-
ering whether the rate of electrode arrays being posi-
tioned in scala vestibuli or transcortical may be similar
for the perimodiolar group in the present study. While
cine beam CT imaging was not available for the popula-
tion in the present study, it would be of interest to
compare the speech perception outcomes with the TSEA
to perimodiolar devices with complete scala tympani
placement. In light of the evidence suggesting perimo-
diolar devices may yield improved speech perception
outcomes, but with higher rates of trauma, there appears
to be a need for a perimodiolar electrode array with a
more consistent scala tympani placement. McLinkin
and colleagues (39) recently published experience with a
new slim modular device (Nucleus Slim Modular CI532)
with 74% complete scala tympani insertions in a study of
117. Another study of the same device yielded 100% com-
plete scala tympani insertions for a series of 45
implantations (40). Recent findings from RVEEH also
demonstrate 100% scala tympani insertion in a study of
CI532 implantations (38). These figures are higher than
previously published data on perimodiolar devices,
which is promising for future CI recipients.

Considering the risk-benefit trade-off of hearing preser-
vation and probe positioning, perimodiolar array with a
predictable and consistent scala tympani placement cou-
pied with atraumatic surgical technique may provide
the ideal balance. Further studies on the hearing preservation
rate of such devices are needed.

As is the nature of studies using retrospective clinical
data, a key limitation is that certain data points may be
unavailable or not recorded. The subanalysis looking at
electro-acoustic fittings and imaging results conducted
with the TSEA Group would have been useful with the
entire cohort; however, the necessary data were not
available. An additional limitation of the present study
was that only the TSEA Group was recruited and
assessed prospectively, and as a result there was some
variation in sound processing technology used. As would
be expected from newer generations of sound processors,
improvements were introduced in the CP600 generation
of sound processors used by some of the TSEA Group
which were not available to the PM Group at the time of
their assessment. Improved microphone directionalitv
and the introduction of a single channel noise reduction
algorithm have been shown to provide improved speech
perception outcomes in adults and children, which may
have impacted the results seen in the present study when
comparing groups (41–43).

The benefits of EAS fittings are well reported in
the literature. There is agreement within the field that if
low frequency hearing can be preserved and successfully
integrated with an EAS sound processor fitting, it is
possible to have improved outcomes in domains relying
on low frequency/time cues. In the present study, it was
observed that those with preserved hearing utilizing an
EAS device (TSEA-EAS) performed significantly better
than their counterparts with electric-only hearing (TSEA-
Standard), with a median Total Speech Perception Score
that was 15.2% greater. This difference was not observed
when the TSEA-EAS Group was compared to the PM
Group, however the TSEA-EAS Group did demonstrate
superior outcomes (TSEA-EAS median 73.5%, PM
Group 67.5%, p = 0.175). More sensitive test methodol-
y and a larger EAS population may provide more
insights in future.

Finally, it is important to address the question of power
when assessing clinical data such as this. As no signifi-
cant difference was found between the TSEA and PM
Groups for TSPS, it is important to address whether the
study was adequately powered to do so. Post hoc analyses
were completed to assess the margin of error based on the
standard deviation observed in the TSPS data. Conserva-
tively taking the larger standard deviation of the two
groups for TSPS (21.19), it was found that we would
require a sample size of 111 to detect a difference within
±4%. Given the total population included in this assess-
ment was 125, it would appear this study was sufficiently
powered to detect a clinically significant difference if it
was present for this population. Additionally, to verify the
result seen in the TSEA perimodiolar analysis and the
ability to truly detect a 15.2% difference, a margin of
error analysis was conducted based on the TSEA TSPS
standard deviation (17.95). Based on this information, it
was calculated that with a sample size of 52 it would be
possible to detect a difference within ±5%. Previous
studies have accepted a difference of 10% as being a
clinically significant (29,44–45). It can therefore be
concluded that the analysis of the TSEA group is appropri-
ately powered and we can accept this as a clinically
significant difference.

CONCLUSION

In this group of 133 adult CI recipients with preimplant
low frequency hearing, significant benefit to overall
speech perception was achieved with either perimodiolar
or lateral wall electrode array positioning. Electrode
array type was not shown to have a significant relation-
ship with speech perception outcomes. In those that
received a TSEA, the angular depth of electrode insertion
was not related to speech perception outcomes. Those
who received a TSEA and utilised an EAS sound pro-
cessor performed better than their peers with a TSEA and
electric-only hearing.

Otology & Neurology, Vol. 39, No. 10, 2019
Irrespective of the CI device used, in order to provide realistic expectations to this group, audiologists and surgeons must counsel appropriately on the factors at hand (i.e., duration of loss, age at implant) in relation to the individual’s chance of improvement. In light of the reality that equivalent gains in speech perception outcomes found, for patients with no significant residual hearing to risk it would be reasonable to recommend either a TSEA or a perimodiolar device where the surgeon has a high degree of skill and confidence with the procedures. Where it is desirable that functional low-frequency hearing be preserved, the device chosen and surgical techniques used should be in the interest of preserving and using this residual hearing given the significant benefits demonstrated in the present study.

Acknowledgments: The authors acknowledge the financial support of the HEARing CRC, established under the Australian Government’s Cooperative Research Centres (CRC) Program. The CRC Program supports industry-led collaborations between industry, researchers and the community.

In addition, the authors gratefully acknowledge the devoted efforts of the RVECH Cochlear Implant Clinic staff in their ongoing support of research and data collection. Projects such as this could not be completed without your much appreciated assistance. We also recognize and salute the many cochlear implant recipients generously who give their time for research and the advancement of the field.

REFERENCES


Otolaryngology, Vol. 39, No. 2, 2019
SPEECH PERCEPTION OUTCOMES BY CI ELECTRODE ARRAY TYPE


Author/s: Moran, Michelle

Title: Outcomes for adult cochlear implant recipients with functional pre-operative hearing

Date: 2019

Persistent Link: http://hdl.handle.net/11343/224195

File Description: Complete thesis

Terms and Conditions: Copyright in works deposited in Minerva Access is retained by the copyright owner. The work may not be altered without permission from the copyright owner. Readers may only download, print and save electronic copies of whole works for their own personal non-commercial use. Any use that exceeds these limits requires permission from the copyright owner. Attribution is essential when quoting or paraphrasing from these works.