THE EFFECT OF ELECTRODE PLACEMENT ON COCHLEAR IMPLANT FUNCTION AND OUTCOMES

BY

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Submitted to the graduate degree program in Hearing and Speech and the Graduate Faculty of the University of Kansas in partial fulfillment of the requirements for the degree of Doctor of Philosophy.

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ABSTRACT

Cochlear implants have been an effective treatment for restoring profound sensorineural hearing loss to those who do not benefit from traditional hearing aids. Advances in surgical technique and electrode design allow for preservation of residual hearing. This allows cochlear implant candidacy criteria to expand to those with good low frequency hearing and severe high frequency hearing loss above 1000 Hz with poor speech discrimination. With a less traumatic surgical approach, low frequency hearing can be preserved resulting in combined low frequency auditory perception and mid- to high-frequency electric perception resulting in electro-acoustic stimulation (EAS). Despite the improvements in cochlear implantation, outcomes continue to vary significantly from one user to another. The variance in performance may potentially be due to the placement of the electrode within in the cochlea. This study focused on performance of patients compared to insertion depth, age, pitch perception and electrophysiologic measures. Patients with residual hearing were included and outcome measures were measured via speech perception tests. Radiographic imaging confirmed insertion depth, and the change in pure tone average was compared to this depth.

Hearing preservation was further accomplished with two patients who presented with residual mid and high frequency hearing. Custom atraumatic electrodes were inserted, and hearing was preserved across all frequencies. These cases allowed for electric and acoustic pitch matching experiments to be conducted in the same ear providing information on where in the cochlear the implant is actually stimulating. Several pairs along the cochlea were run between electric and acoustic pitches at varying rates of stimulation. Place to pitch mismatch varied depending on the area within the cochlea.

Lastly, objective measures were used in attempt to determine the variance in outcomes. Two main contributing factors govern implant performance, 1) the ability of the processor to effectively deliver the electrical signal to the ear, and 2) the patient's ability to process the information. Peripheral mechanisms were analyzed with the electric compound action potential and its amplitude growth function. The slope of the amplitude growth function was measured at the corresponding electrodes and compared to speech discrimination scores. Steeper slopes correlated with increased word understanding abilities. For further insight into the health of the cochlea, age effects were compared to hearing preservation. The pure tone averages were calculated before and after surgery. Pure tone averages following surgery elevated with increased age suggesting that the elderly may be at more risk for loss of residual hearing as compared to the general population.

ACKNOWLEDGEMENTS

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CHAPTER 1: INTRODUCTION

Approximately 35 million Americans endure hearing loss, most of which do not have profound sensorineural hearing loss (SNHL) (Kochkin, 2009). The most common form of hearing loss in adults is high frequency SNHL. This type of loss makes speech sounds, particularly consonants, difficult to distinguish, especially in the presence of background noise (Gordon-Salant, 2005). Patients are often frustrated with hearing aids or do not benefit from them due to poor word understanding abilities. Some studies suggest that this makes up more than 60% of the hearing aid population (Kaplan-Neeman, Muchnik, Hildesheimer, & Henkin, 2012; Kochkin, 2000). Cochlear implants were devised as a means to restore sensorineural hearing loss, but in the past were only available to those with severe to profound SNHL. These devices have since become the most effective treatment for individuals with SNHL loss that do not benefit from traditional amplification. Patients with good low frequency hearing and poor high frequency hearing with marginal discrimination were initially not considered cochlear implant candidates. The exclusion of individuals with this type of hearing loss was due to the belief that preservation of residual hearing was not possible and that the brain could not reconcile acoustic and electric input (Sohmer, 2007). Histopathologic assessments of temporal bones from cochlear implant recipients have shown damage to cochlear structures (Handzel, Burgess, & Nadol, 2006; Khan, Handzel, Damian, Eddington, & Nadol, 2005) including the basilar membrane, osseous spiral lamina, spiral ligament and Reissner's membrane (Berrettini, Forli, & Passetti, 2008; Chao, Burgess, Eddington, & Nadol, 2002; Nadol, Ketten, & Burgess, 1994; Rossi & Bisetti, 1998). Further studies of the temporal bone demonstrated degeneration of both supporting cells and spiral ganglion neurons apical to the tip of an implant when compared to the contralateral, unimplanted side (Khan, Handzel, Damian, et al., 2005). Should the implant electrode migrate through the scala media to the scala vestibuli as suggested by Finley and colleagues (Finley et al., 2008), the resulting damage may result in degeneration of residual functioning portions of the cochlea leading to poorer outcomes. Animal studies have suggested reduced spiral ganglion survival after sustaining trauma from electrode insertion (Leake, Stakhovskaya, Hradek, & Hetherington, 2008). The above findings led many researchers and clinicians to assume that preservation of hearing was unfeasible with the use of a cochlear implant.

To avoid the damage to the cochlea and surrounding structures caused by electrode insertion, Lenhardt modified the standard cochleostomy by placing it anteriorly to the round window region (Lehnhardt, 1993). The ability to successfully manipulate the instrument in the inner ear was then confirmed in animal models (Balkany, Hodges, Whitehead, Memari, & Martin, 1994). These modifications not only led to advancements in electrode design, but also permitted the expansion of cochlear implant candidacy criteria to patients with good, or aid-able, low frequency hearing and severe high frequency hearing loss above 1000 Hz with poor speech discrimination scores. Pure tone candidacy for hearing preservation cochlear implantation are shown in Figure 1.1.

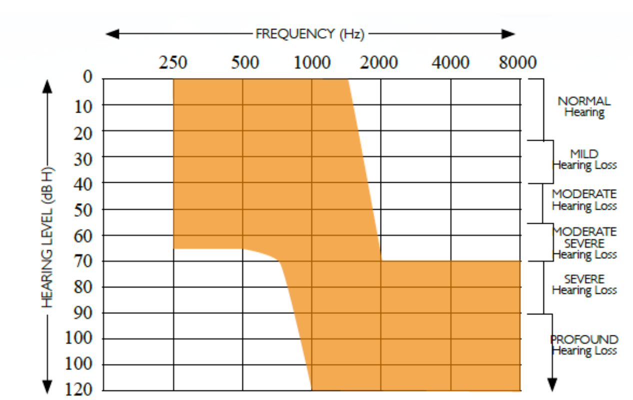


Figure 1.1: The shaded region of this audiogram represents the thresholds of the ideal candidate for hearing preservation cochlear implantation. If thresholds in the low frequencies are decreased, amplification in provided in this frequency region. Some patients will present normal hearing 250 to 1000 Hz and these patients can be treated with electrical stimulation of the basal half of the cochlea. (Image courtesy of Med-El, Gmbh. Innsbruck, Austria. Flex EAS implant and DUET sound processor are investigational and limited by US law to investigational use).

With a less traumatic surgical approach, low frequency hearing can be preserved resulting in combined low frequency auditory perception and mid- to high-frequency electric perception (O. Adunka, Gstoettner, et al., 2004; O. Adunka, Kiefer, Unkelbach, Radeloff, et al., 2004; Gantz et al., 2009; Gantz & Turner, 2003; W. Gstoettner et al., 2004; W. K. Gstoettner et al., 2008; Kiefer et al., 2004; Kiefer et al., 2005; Turner, Gantz, Vidal, Behrens, & Henry, 2004). An example of an EAS insertion is depicted in Figure 1.2.

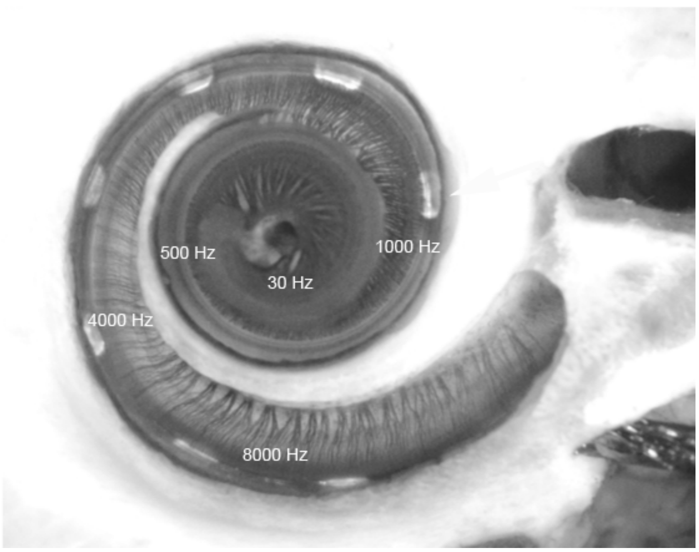


Figure 1.2: Electroacoustic stimulation (EAS) implies insertion of an electrode into the basal, damaged portion of the cochlea, with electric stimulation of the mid- to high-frequency spiral ganglion cells. Surviving hair cells in the apical region of the cochlea the patient with acoustic hearing in the low frequency domain. As seen in this temporal bone specimen, an implant electrode has been inserted approximately 20 mm to the 1000 Hz region. Hearing is intact apically from this point.

This combination of hearing can be achieved it two manners, 1) electro-acoustic stimulation (EAS) meaning acoustic and electric hearing in the same ear, and 2) bimodal hearing - electric stimulation with acoustic stimulation in the contralateral ear (Dorman et al., 2009; Dorman & Gifford, 2010; Dorman, Gifford, Spahr, & McKarns, 2008; Gifford, Dorman, & Brown, 2010; Gifford, Dorman, McKarns, & Spahr, 2007).

Importance of Acoustic Low Frequency Hearing

Low pitch acoustic hearing is required for localization and pitch recognition (Francart, Brokx, & Wouters, 2008, 2009; Gantz, Turner, Gfeller, & Lowder, 2005). Sound localization is governed by interaural time differences between when the sound reaches each ear. Those changes are detectable when they are about 10 microseconds apart, and this process begins to deteriorate with sinusoids above 1500 Hz. In addition, the acoustic low frequency hearing entails fine spectral information, which is not entirely replicated in the current cochlear implant speech coding strategies. The lack of fine spectral resolution results in poor detection in pitch frequency changes and pitch patterns (Gantz et al., 2005).

Hearing preservation with cochlear implantation adds a new dimension to the initial understanding of cochlear implantation. I.e., this possibility provides efficient access to the inner ear while utilizing the brain's capability to integrate acoustic and electric sound percepts. The addition of low frequency acoustic hearing helps patients to maintain localization abilities, understand speech better in the presence of background noise and in some, appreciate music (Gantz et al., 2005; Skarzynski et al., 2002; Skarzynski, Lorens, Piotrowska, & Anderson, 2007a, 2007b; Skarzynski, Lorens, Piotrowska, & Podskarbi-Fayette, 2009; Turner et al., 2004). In addition, atraumatic insertion of the implant should allow for the ability to replace the implant several times during the life span of the patient and preservation of cochlea neural structures.

Outcomes of Hearing Preservation and EAS

In addition to the surgical approach, the design of the electrode is imperative to achieve optimal hearing preservation results. The length, diameter and flexibility of the electrode must all be taken into consideration (von Ilberg, Baumann, Kiefer, Tillein, & Adunka, 2011). Many studies have been conducted showing the feasibility of hearing preservation cochlear implantation. Skarzynski and colleagues implanted 10 subjects, all of which had significant low frequency hearing. Partial insertion using the Med-El Combi 40+ (32 mm electrode) was completed using the soft surgical technique, which allowed for 8 electrodes to be inserted to a depth of approximately 20 mm. All but one subject had preserved hearing following surgery and maintained hearing 12 months post-operatively (Skarzynski et al., 2002; Skarzynski, Lorens, Piotrowska, & Anderson, 2006; Skarzynski et al., 2007b; Skarzynski et al., 2009; Skarzynski, Lorens, Piotrowska, & Skarzynski, 2010).

Garcia-Ibanez et. al. (Garcia-Ibanez et al., 2009) also implanted the Nucleus Contour Advance with the soft-surgical technique up to depths of 17 mm. Post-operatively, 36% of the subjects maintained hearing within 10 dB of their pre-operative thresholds, and approximately 67% within 20 dB of their pre-operative thresholds. As seen from the above studies, hearing preservation is attainable with a variety of electrode designs achieving insertion depths to the 1000 Hz region (20 mm) of the cochlea.

Performance with EAS

Several studies show that patients listening in the EAS condition perform better in background noise and have improved music appreciation as compared to those listening with electric stimuli only (Skarzynski et al., 2002; Skarzynski et al., 2007a, 2007b; Skarzynski et al., 2009; Skarzynski et al., 2010; Turner et al., 2004). Gantz and colleagues inserted a 10-mm electrode to demonstrate the feasibility of hearing preservation in cochlear implantation. In this initial study, 13 subjects were implanted to a depth of 6-10 mm from the cochleostomy (Gantz & Turner, 2003; Turner et al., 2004). Following implantation, the subjects could recognize familiar melodies more accurately than standard cochlear implant users without residual hearing. Furthermore, their performance in noise was significantly better than those with traditional implants.

James and colleagues implanted 12 patients with the Nucleus Contour Advance™ with insertions depths ranging between 17-19 mm. An in-the-ear (ITE) hearing aid was fit to the ipsilateral ear to amplify the preserved low frequencies. Speech understanding in quiet improved 20% and was accompanied by a 3 dB improvement in signal to noise ratio. Subjectively, patients reported an increase in performance with the added acoustic stimuli (James et al., 2005).

Disadvantages of Partial Insertions

The ideal parameters of hearing preservation surgery continue to be debated. It is clear that partial insertions are beneficial; however, is there added benefit with stimulation along the entire cochlear partition? A 6 mm insertion achieves high degrees of hearing preservation, but does not always optimize speech recognition. Significant improvements in hearing outcomes were noted when the subjects received a 10-mm implant (Gantz & Turner, 2003; Turner et al., 2004; von Ilberg et al., 2011) and even more so with a 16 mm insertion (Lenarz et al., 2009; von Ilberg et al., 2011). With limited access to the apical region, the effectiveness of the cochlear implant may be reduced in the event of progressive hearing loss or loss of residual hearing. Deeper implantation with sequential activation of apical electrodes presents a potential solution to this dilemma without the need for re-implantation (O. F. Adunka, Pillsbury, Adunka, & Buchman, 2010; Fitzgerald et al., 2008; von Ilberg et al., 2011). Insertions reaching 18-22 mm provide a broader spectrum of hearing, consequently resulting in more speech and pitch information (O. F. Adunka et al., 2010). Electrodes typically extend into 1.5 turns of the cochlea, which equates to 18-24 mm. Med-El designs an electrode intended for an insertion depth of 31 mm, covering the full length of the average cochlea. When fully inserted, the electrode reaches approximately 630^{o}. Spiral ganglion neurites continue to extend to 1000 degrees with an estimated frequency of 58 Hz (Boyd, 2011). Software for the cochlear implants allows frequencies to be reallocated to the apical end. Studies by Reiss et al, however, suggest that user's may require a significant amount of time to adjust to the frequency shift (Reiss, Gantz, & Turner, 2008; Reiss, Lowder, Karsten, Turner, & Gantz, 2011).

Maintaining low frequency acoustic hearing while implanting with complete cochlear coverage requires specialized electrodes. Insertions extending beyond 20 mm have shown increased cochlear trauma in temporal bone studies (O. Adunka & Kiefer, 2006). Gstoettner and colleagues (W. Gstoettner et al., 2004) demonstrated that reduced trauma is achievable with insertions beyond 20 mm in twenty-one subjects that were implanted with Med-El electrodes with depths ranging from 18-24 mm. Hearing was preserved in 85.7% of these patients and further showed increased listening performance in the EAS condition as compared to the electric only condition. Baumgartner and colleagues have documented further support of decreased cochlear trauma with deeper insertions. Twenty-three adult subjects with severe to profound sensorineural hearing loss were implanted with a specialized flexible 31 mm electrode manufactured by Med-El. This electrode features five single contacts in the apical end and seven pairs across the remaining portions of the array. Hearing preservation was achieved in four cases for up to 12 months. Mean scores for monosyllabic words improved from 3% pre-operatively to 54% correct at 12 months. Sentences in noise (+10 dB signal to noise ratio) also showed significant improvements in understanding with mean scores of >10% correct pre-operatively to 57% correct post-operatively (Baumgartner et al., 2007). Preservation of hearing with deeper insertions allows for electrode arrays to provide full cochlear coverage while maintaining the integrity of neural structures.

Publications from multicenter studies using atraumatic electrodes and a soft surgical technique provide evidence that residual hearing can be salvaged and remain stable over time after cochlear implantation. Most studies indicate improved hearing in background noise when listening in the EAS condition versus electric stimulation only. Review of the results from the U.S. Hybrid trial carried out with the Cochlear Nucleus device similarly report stable hearing for a large patient population (Gantz, Turner, & Gfeller, 2006). Amongst enhanced hearing in background noise, this study also established the potential for patients to centrally alter pitch perception over time. These findings open the possibility of improving hearing through implantation as well as rehabilitative strategies. Current research is focusing on optimizing the depth of implantation, developing customized processing strategies, and enhancing the ability to ensure acute and chronic stability of acoustic hearing after implantation.

As evident in the aforementioned studies, the addition of low frequency acoustic input to electric stimulation provides significant benefit in speech understanding, particularly in noise. However, outcomes continue to vary among patients with similar hearing losses. Perhaps more objective measures should be taken into consideration to assess the integrity of the auditory nerves and neural pathways. Electrically evoked potentials may exhibit characteristics unique to good performers, which in turn, can contribute to understanding the underlying pathways of sound and plasticity of the auditory system after extended use of the cochlear implant.

Experience at University of Kansas Medical Center

The Department of Otolarnygology Head and Neck Surgery at the University of Kansas Medical Center is currently participating in a clinical trial involving hearing preservation and cochlear implantation. In this trial, the external components consist of a hearing aid and a cochlear implant speech processor combined together in one unit. The first two participants implanted had similar history, were close in age and underwent the same surgery; however, they displayed very different outcomes. Figure 1.3 summarizes their performance over 12 months.

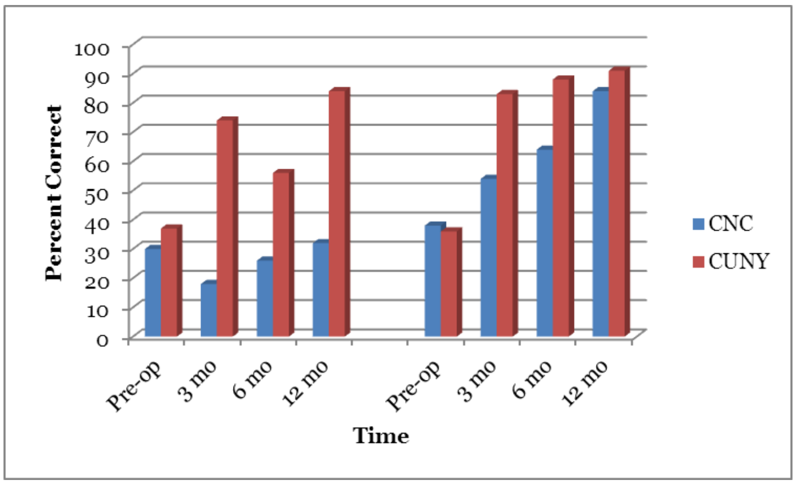


Figure 1.3: Results for CNC and CUNY scores from the first two clinical trial patients over the course of 12 months.

Results showed an improvement in sentence recognition. Sentence scores are depicted in red, while monosyllabic words are shown in blue. The first patient scored 37% correct with sentences in noise, preoperatively. Scores improved to 84% by 12 months. Sentence scores for the second patient improved from 36%, preoperatively to 91% correct at 12 months. CNC scores, however, remained essentially unchanged with patient one. Preoperative score was 30%, while the 12-month score was 32%. In contrast, patient two showed a significant improvement understanding 84% at 12 months compared to 38% preoperatively. The variation in scores for these two participants led to several questions regarding their difference in performance. When analyzing hearing preservation patients, how much is the acoustic hearing influencing outcomes? Given the previous discussion regarding electrode length, does the insertion depth correlate to loss of hearing? Where along the cochlear partition does stimulation occur and does it match with the appropriate frequency place? Are outcomes affected by nerve survival, and can we estimate nerve survival to predict outcomes? Beyond the periphery, what other factors might play a role in outcomes? Perhaps the elderly population is more susceptible to hearing loss following electrode insertions, or possibly, central processes are compromised due to dementia influencing speech recognition and understanding. It is likely that both peripheral and central processes combine to create variation in patient performance. The following series of experiments discuss the feasibility of hearing preservation and what we can learn about placement of the electrode by analyzing subjective and objective measures.

CHAPTER 2: PARTIAL DEAFNESS COCHLEAR IMPLANTATION AT THE UNIVERSITY OF KANSAS: TECHNIQUES AND OUTCOMES

ABSTRACT

Background: One of the most significant recent advances in cochlear implantation is the implantation of patients with residual hearing. These patients have a down sloping sensorineural hearing loss with poor speech discrimination and perform poorly with standard amplification. Studies using a variety of different electrode designs have demonstrated that it is possible to implant an inner ear and preserve residual hearing. Initial studies have demonstrated that a combination of residual acoustic hearing in the low frequencies with electrical stimulation in the mid to high frequencies resulted in superior hearing performance in background noise.

Purpose: The objective of this study was to determine the effect of electrode insertion depth on hearing preservation. Study Sample: 18 patients with mild to severe hearing loss in the low frequencies combined with poor word recognition were recruited for the study.

Intervention: Cochlear implantation

Data collection and analysis: Pre and post-operative hearing test, HINT and CNC testing. Data analysis was performed with Kruskal Wallis and Mann Whitney testing.

Results: In our study of 18 patients implanted with a Med-El Pulsar CI 100 we demonstrated the ability to preserve residual hearing with implant insertion depths ranging from 20-28 mm, giving us the possibility of near complete cochlear frequency coverage with an implant array, while preserving residual hearing. These patients performed well both in quiet and in 10 dB SNR conditions.

Conclusion: Hearing preservation achievable even with deep implant insertion. Patients performed well in combined acoustic and electric conditions.

Key Words: Cochlear implant, hearing preservation, partial deafness cochlear implantation, electro acoustic stimulation

Abbreviations: Electroacoustic stimulation (EAS), hearing in noise test (HINT), Consonant-Nucleus-Consonant test (CNC), signal to noise ratio (SNR).

Introduction

It is estimated that more than 31 million Americans are hearing impaired, most of whom do not have profound sensorineural hearing loss (SNHL) (Kochkin, 2005). The most common form of hearing loss in adults is high frequency SNHL, which makes it difficult to distinguish speech sounds, particularly consonants. Hearing function deteriorates further in background noise. These patients are often frustrated with hearing aids or do not benefit from them due to poor word understanding abilities. Cochlear implants have become a useful tool for the treatment and rehabilitation of severe to profound hearing losses. Individuals with good low frequency hearing and poor high frequency hearing were initially not considered cochlear implant candidates as preservation of residual hearing was not thought to be possible due to the trauma sustained from electrode insertion (Sohmer, 2007). However, with improved electrode designs and surgical technique, indications for cochlear implants have extended to those who have essentially good, or aid- able, low frequency hearing and severe high frequency loss above 1000 Hz. With a less traumatic surgical approach, low frequency hearing can be preserved resulting in low frequency auditory perception and mid to high frequency electric perception (O. Adunka, Gstoettner, et al., 2004; O. Adunka, Kiefer, Unkelbach, Radeloff, et al., 2004; Gantz et al., 2009; Gantz & Turner, 2003; W.

Gstoettner et al., 2004; W. K. Gstoettner et al., 2008; Kiefer et al., 2005; Turner et al., 2004). Several studies have shown that patients listening in the electro-acoustic condition (EAS) perform better in background noise and have improved music appreciation as compared to those in the implant only condition (Behr et al., 2007; Gantz et al., 2009; Lorens, Polak, Piotrowska, & Skarzynski, 2008; Skarzynski et al., 2006; Skarzynski et al., 2009; Turner et al., 2004). Gantz et. al., used a short electrode to demonstrate the feasibility of hearing preservation in cochlear implantation. Traditional long electrode users have shown poor pitch perception as compared to normal hearing persons, especially in complex tasks such as music perception. Acoustic low frequency hearing is important for pitch and spectral resolution. In this initial study 13 volunteers were implanted to a depth of 6 to 10 mm from the cochleostomy (Gantz & Turner, 2004; Gantz, Turner, & Gfeller, 2004; Gantz et al., 2006). Following implantation, their ability to recognize familiar melodies was significantly more accurate in comparison to standard cochlear implant users as was performance in speech in noise. Another study done by James et. al. showed improved speech recognition in noise with the EAS approach. The Nucleus® Contour Advance™ was implanted in 12 patients with insertion depths ranging between 17-19 mm. An in-the-ear hearing aid (ITE) was fit in the ipsilateral ear to amplify the preserved low frequencies. A 20% improvement with speech in quiet along with a 3 dB improvement in signal to noise ratio was observed in this study. Subjectively, patients were very satisfied with the bimodal hearing (James et al., 2005). Garcia-Ibanez et. al. (2008) implanted the Nucleus® Contour Advance™ up to 17 mm for the purpose of preserving residual hearing. They found that hearing thresholds were measurable post-operatively in 71-86% of their subjects. Thirty-six percent of these patients had preservation of thresholds within 10 dB of their preoperative thresholds and approximately 67% within 20 dB HL of the pre-operative thresholds (Garcia-Ibanez et al., 2009). Hearing preservation was thus attainable with a variety of different electrode designs with insertion depths to approximately the 1000 Hz region of the cochlea.

The purpose of our study was to evaluate the benefits of hearing preservation with fully inserted electrodes extending beyond 20 mm. Potential benefits of this approach include increasing the frequency coverage of the cochlea while preserving residual structure. This condition may be beneficial in terms of ensuring survival of neurotrophin producing cells in the cochlear apex and may also preserve balance function in the implanted ear.

Methods

Surgical Approach: The extended round window approach was used in all cases. After performance of a mastoidectomy and facial recess (posterior tympanotomy) approach to the middle ear, all bone dust was irrigated out of the wound. Hemostasis was obtained and 0.5 cc of decadron 10 mg/ml was applied to the round window niche. The bony overhang of the round window niche was then carefully removed with a 1 mm diamond burr and the round window clearly visualized by testing the round window reflex. For the extended round window approach the bone anterior inferior to the round window was removed, keeping the scala tympani endosteum intact. The wound was once again irrigated and Healon™ was used to cover the round window and endosteum. The endosteum was then opened with a small pick and the implant electrode is carefully inserted. For round window insertion, the implant was inserted through an incision in the anterior mid portion of the round window (Fig 2.1).

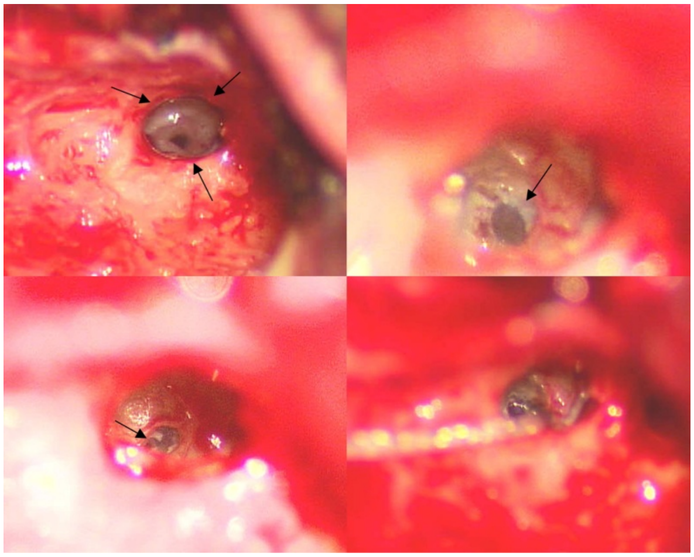


Figure 2.1: Surgical approach for hearing preservation. Insertion is made through the round window. Effective round window insertion requires a wide facial recess (A). The bone of the round window niche is then carefully removed with a small diamond burr (B). After identifying the round window through confirmation of the round window reflex, the round window is covered in Healon® and carefully incised (C). The electrode is then inserted (D).

All patients were implanted with Med-El Puslar C100 using either the standard (H) or medium (M) electrode arrays. These electrodes have 12 contacts distributed over 28 or 24 mm respectively. The opening into the scala tympani was sealed with a small piece of fascia and the wound closed. Depth of the electrode was confirmed radiographically.

Subjects and Outcomes Measures: A total of eighteen implant, 5 males and 13 females, candidates with varying degrees of hearing loss were recruited. Ages ranged from 26-84 with a mean age 63.17. Thresholds ranged anywhere from normal sloping to profound to severe to profound. Word discrimination scores tested via the hearing in noise sentence test (HINT) fell within Food and Drug Administration (FDA) or Medicare guidelines for implantation in the best-aided condition. FDA guidelines state that understanding ability must be less than 50% in the ear to be implanted and no better than 60% in the contralateral ear (http://www.audiologyonline.com/articles/article_detail.asp?article_id=2272). Medicare's criteria states that speech understanding must be less than 40% bilaterally (http://www.audiologyonline.com/articles/article_detail.asp?article_id=2272). The etiology of the hearing losses for the participants is unknown. Prior to implantation, all patients underwent blood testing to screen for autoimmune inner ear disease and had an MRI scan to rule out retrocochlear disorder. Lab work was negative for autoimmune inner ear disease for all patients. MRIs scans were also negative for cochlear malformation or retrocochlear pathology. The participants further denied any family history of hearing loss.

Informed consent was obtained prior to testing, and the University of Kansas Medical Center human subjects board approved the protocol. Pure tone thresholds were obtained before surgery and 2 weeks post-operatively using insert earphones. An example of a pre- and post-audiogram is shown in Figure 2.2.

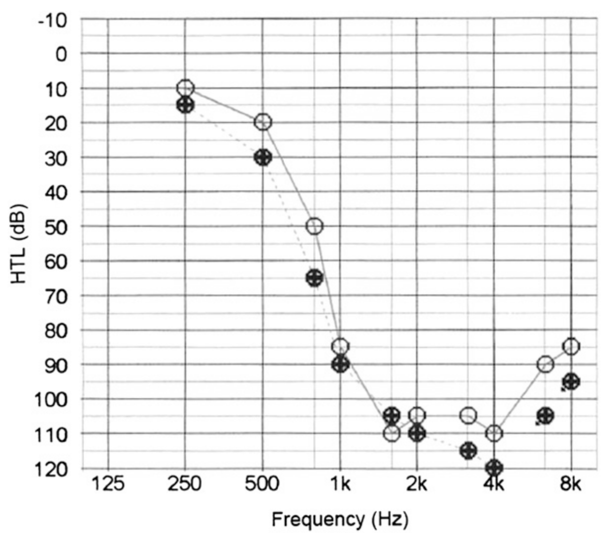


Figure 2.2: Pre- (open circle) and post-operative (crossed circles) audiogram from a patient with a right 24-mm insertion of a Med-El electrode, demonstrating preservation of hearing. Insertion was carried out via a round window approach.

The HINT and consonant-nucleus-consonant (CNC) word tests were administered to evaluate word discrimination and word recognition abilities. Sentences and words were presented with the patient seated in a sound-treated booth at 0 degrees azimuth at 70 dB SPL via recorded voice. The tests were administered in three conditions: acoustic only (A), implant only (E), electric plus acoustic (EAS) in the ipsilateral (implanted) ear. To ensure the patient was only hearing with electric stimulation, both ears were plugged with an earplug to eliminate any acoustical hearing. The ipsilateral earplug was then removed for the EAS condition. A contralateral hearing aid was not used in any of the patients to isolate the implanted ear. HINT testing was also performed in a +10 dB SNR in the electric and EAS conditions. After the sentences or words were presented, the patients were asked to repeat back any words that they may have understood and were encouraged to guess if unsure. Scores were based on words repeated back correctly in each sentence and divided by the total number of words possible.

Statistics: Outcomes were analyzed by Kruskal Wallis and Mann-Whitney. Testing administered using SPSS v. 17.0. Significance was set at $p<0.05$.

Results

Residual hearing was preserved in all 18 patients. The change in pure tone averages was calculated using 250, 500 and 750 Hz. This change was graphed as a function of insertion depth and is shown in Figure 2.3.

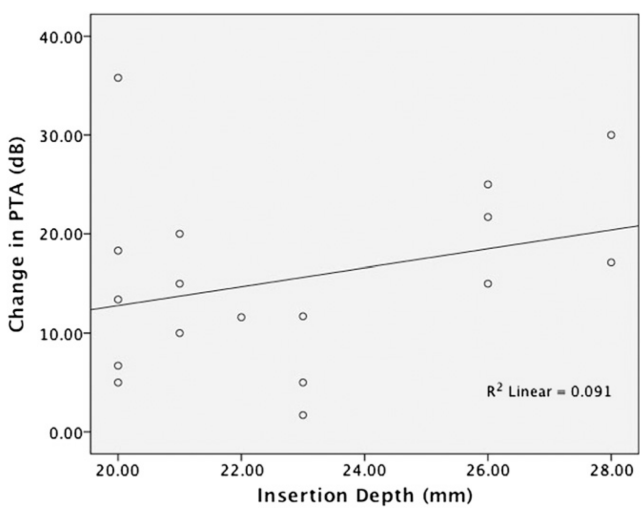


Figure 2.3: Effect of electrode insertion depth on post-operative change in hearing. Using a round window approach, there was no clear relationship between implant insertion depth and change in post-operative pure-tone average (PTA). The PTA was chosen as an outcome measure since all of the patients we implanted had residual low-frequency hearing. This demonstrates that access to the low-to mid-frequency region of the cochlea is possible with hearing preservation.

There is no clear relationship between insertion depth and amount of hearing preserved indicating that the apical region of the cochlear can be reached without compromising hearing thresholds ($r2=0.091$). The advantage of residual hearing used in conjunction with electric stimulation was measured using the HINT test presented in quiet and +10 dB SNR as well as CNC word lists. Outcomes for the quiet condition are graphed in figure 2.4.

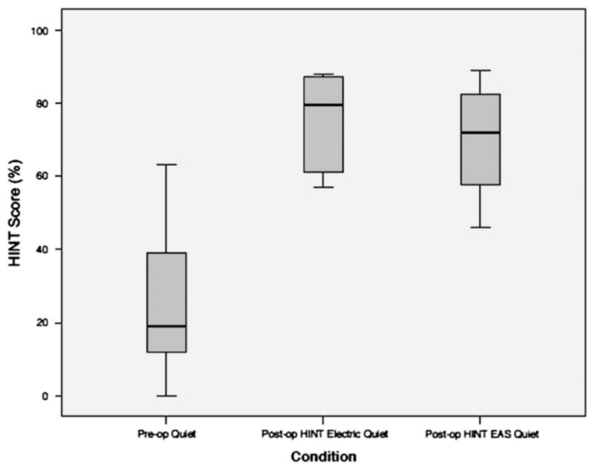


Figure 2.4: Post-operative performance in quiet. This box plot summarizes the pre-operative and post-operative Hearing in Noise Test (HINT) scores recorded in 2 conditions: (1) electric only and (2) electroacoustic stimulation (EAS). The black line represents the median HINT score. The boxes represent the 25th through the 75th percentile, whereas the lower and upper lines represent the standard deviation. Pre-operative HINT scores had a median of 19%. Post-operative activation of the implant resulted in significant improvement in HINT scores for both the electric only and EAS conditions. Electric only scores had a median of 79.5%, and EAS HINT scores averaged 72%. There is no statistical significance between the electric only and EAS conditions.

The pre-operative HINT score in quiet had a mean of 24.3% correct. When tested in the electric only condition, the mean score improved to 75.3% correct. When presented in the acoustic plus electric condition, the mean score was 69.9% correct. This represents a significant difference in the aforementioned three conditions ($p \leq .001$). The Mann-Whitney test was then performed to find that there were statistical differences in the pre-operative and electric only condition ($p \leq .001$) as well as the pre-operative and EAS conditions ($p \leq .001$). There was, however, no statistical difference between the electric and EAS conditions ($p = .573$).

Patients tested in the +10 dB SNR condition showed pre-operative scores of 25.7% correct. Mean scores improved to 64.33% correct in the electric only condition, and to 65.89% correct in the EAS condition. The Kruskal-Wallis test confirmed a significant difference between groups ($p = .001$). Similar to the electric only condition, Mann-Whitney test showed a significant difference between pre-operative scores and post-operative HINT in the electric only condition ($p = .001$) in addition to significant differences in pre-operative and post-operative HINT scores in the EAS condition ($p \leq .001$). There was no statistical significance evident when the two post-operative conditions were compared ($p = .955$) (Fig 2.5).

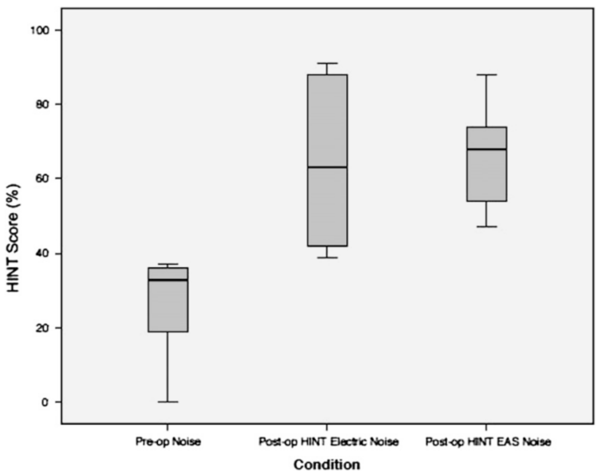


Figure 2.5: Post-operative performance in quiet. This box plot summarizes the pre-operative and post-operative Hearing in Noise Test (HINT) scores when presented in +10 dB signal-to-noise ratio. Pre-operative scores demonstrated a median of 33%. Post-operative scores were 64% and 68% in the electric and electroacoustic stimulation (EAS) conditions. The black line represents the median HINT in noise score. The boxes represent the 25th through the 75th percentile, whereas the lower and upper lines represent the standard deviation. There was statistical significance in pre-operative scores and post-operative scores in the electric condition as well as in the EAS condition; however, there was no statistical difference in the electric and EAS conditions.

Speech understanding outcomes were also measured using CNC word lists (Fig 2.6).

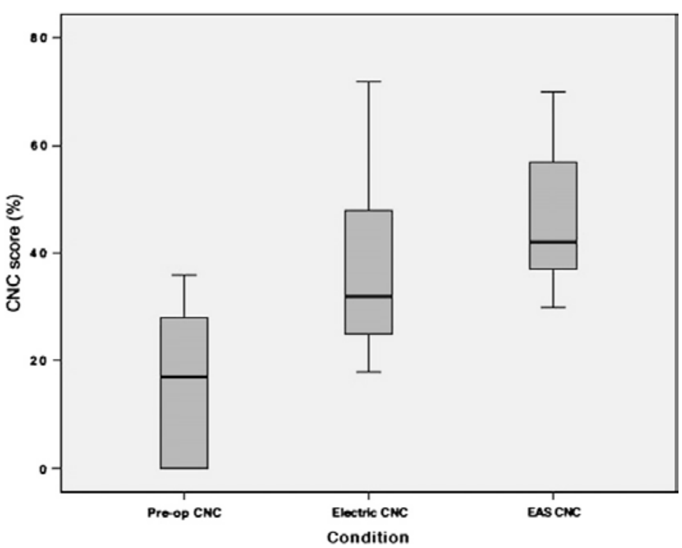


Figure 2.6: Change in consonant-nucleus-consonant (CNC) recognition after implantation. Pre-operative scores had a median of 17% correct. Post-operative scores improved to a median of 32% correct in the electric only condition and 42% in the electroacoustic stimulation (EAS) condition. The black line represents the median CNC score. The boxes represent the 25th through the 75th percentile, whereas the lower and upper lines represent the standard deviation. There was statistical significance in pre-operative scores and post-operative scores in the electric condition as well as in the EAS condition; however, there was no statistical difference in the two post-operative conditions.

Pre-operative mean scores were 16.67% correct out of 50 words. Scores improved to an average of 38% correct in the electric only condition and to 47.1% in the EAS condition. Using the statistical tests mentioned above, results were consistent in that a statistical difference was found when comparing pre-operative scores to post-operative scores in the two different conditions; 1) electric only ($p = .004$), 2) EAS ($p = .000$); however, no statistical difference was found when comparing the two post-operative CNC scores ($p=.193$).

Discussion

In our group of patients, insertion of a thin electrode array via a round window approach was able to achieve hearing preservation. In contrast to other studies, we were able to achieve insertions of up to 28 mm with preservation of residual hearing (Fig 2.3). In temporal bone studies, insertions that extend beyond 360 degrees (about 20 mm) showed increased cochlear trauma (O. Adunka & Kiefer, 2006). This finding was not observed in our series of patients since preservation of hearing serves as a proxy for evaluation of damage apical to the implant. The primary advantage of deeper implantation is the potential to stimulate apical regions of the cochlea should hearing deteriorate over time.

Although short electrodes have been shown to be beneficial for speech understanding, deep insertions also have advantages, even for hearing preservation candidates. With limited access to the apical regions, the implant may be less effective in the event that the residual hearing is lost. Frequency allocations may be reassigned to the apical end; however, Reiss et. al. suggests that it may require a significant amount of time for the users to adjust to the frequency shift (Reiss et al., 2008; Reiss, Turner, Erenberg, & Gantz, 2007).

Gstoettner et. al. (2004) found that deeper insertions could be achieved with the Med-El electrode arrays. This finding is significant since implantation to 20mm is predicted to give patients electrical hearing through the 1000 Hz range, leaving the apical, hearing portion of the cochlea intact. Twenty-one patients were implanted with insertions depths ranging from 18-24 mm. Hearing was successfully preserved in 85.7% of the patients. When compared to the electric-only condition, all patients performed better in the EAS condition. A key component to preserving hearing in these cases was found to be an atraumatic (“soft”) surgical approach (W. Gstoettner et al., 2004).

Newer electrode designs have tried to combine thin, atraumatic insertion with implantation to at least 20mm (O. Adunka, Kiefer, Unkelbach, Lehnert, & Gstoettner, 2004). Potentially even deeper insertion into the cochlea with limited damage is possible. Baumgartner et. al. implanted 23 adults with a specialized flexible 31 mm electrode manufactured by Med-El. The electrode features five single contacts in the apical end and seven pairs across the rest of the array. With this design, the apical end is much thinner. Hearing preservation was achieved in four cases up to 12 months. Improvements were seen with monosyllabic words, as well as hearing in noise (+10 db signal to noise ratio) with mean scores of 54% and 57%, respectively (Baumgartner et al., 2007).

Findings from our study indicated a significant improvement in speech understanding with the use of a cochlear implant in patients with residual hearing compared to their performance with standard hearing aids. Interestingly, the residual acoustic hearing did not improve speech discrimination scores significantly over electric hearing alone. These results are contrary to the literature that suggests electric acoustic hearing is superior to electric hearing alone. It is important to note that there was a large range in scores where some individuals did perform as well in the EAS condition as compared to other studies that have been published. Several variables may have played a role in speech discrimination. One of which is if the patient was properly fit with standard hearing aids and if the ear was properly stimulated prior to surgery. Age may have also played a role in that the geriatric population may have more difficulty in distinguishing and adjusting to the mixed signals. Our age range was quite large, which may have influenced the mean scores.

Additional theoretical benefits are the potential for preservation of structures apical to the implant. Recent temporal bone histopathology studies have demonstrated degeneration of both supporting cells and spiral ganglion neurons apical to the tip of an implant when compared to the contralateral un-implanted side (Khan, Handzel, Damian, et al., 2005). If an implant electrode migrates through the scala media to the scala vestibule as suggested by Finley et. al., the resulting inflammation may result in degeneration of residual functioning portions of the cochlea and poorer outcomes (Finley et al., 2008). Some animal studies also suggested that traumatic insertions affected spiral ganglion survival (Leake et al., 2008). Lack of hearing loss with deeper insertions suggests that it is possible to maintain the apical structures of the cochlea while being able to electrically stimulate very low frequencies.

Conclusion

As seen with our data, atraumatic cochlear implantation has shown benefit in preserving hearing. Contrary to other studies we have not seen a difference in performance of our patients in electric only versus the EAS condition in background noise. This is mainly due to our patients' excellent performance in the electric only condition. Future studies will focus on understanding the physiologic differences that affect performance in these different groups.

CHAPTER 3: EXPANDING COCHLEAR IMPLANTATION TO PATIENTS WITH RESIDUAL MID AND HIGH FREQUENCY HEARING

Abstract

Cochlear implantation has long been indicated to restore profound hearing loss and is the most effective intervention for patients that do not benefit from standard amplification. Recent innovations in implant design and surgical technique have expanded allowed implantation with preservation of residual hearing. In these cases the goal is shallow to mid depth implantation in order to restore as much hearing as possible while preserving apical low frequency acoustic hearing in patients with ski slope losses with poor speech discrimination. We report a series of ears with up sloping hearing loss deeply implanted with custom thin electrodes in which residual hearing is preserved. These patients were poor hearing aid users and required restoration of hearing in the low frequencies. This represents a change in the previous practice of avoiding implantation of areas of residual hearing. These cases demonstrate the feasibility of preservation of acoustic hearing in all frequency regions and represent and opportunity to further expand cochlear implantation to novel patient populations.

Background

Cochlear implantation was devised and traditionally used as a means to restore hearing to individuals with profound hearing loss who could not benefit from hearing aids. More recently, there has been a push towards implanting patients with ski slope hearing losses while preserving low frequency acoustic hearing. To preserve their residual hearing, surgical techniques and cochlear implant electrodes have been devised to inflict minimal trauma to the more apical regions of the cochlea where deeper tones are processed (Gantz et al., 2009; Podskarbi-Fayette, Pilka, & Skarzynski, 2010; Wilson, 2010). These patients are then rehabilitated using acoustic input for the residual low frequency hearing and electrical input for the middle to high frequencies. This approach represents a significant change in how we treat patients with residual hearing since prior to the establishment of these techniques, cochlear implantation resulted in loss of all residual hearing in the ear being implanted.

While cochlear implant patients may perform reasonably well in quiet environments, patients using both electric and acoustic signals (EAS) stimulation have the advantage in environments with competitive speech. EAS patients are able to recognize and suppress the competitive speech by their ability to process lower frequency speech. This condition is referred to as glimpsing (Li & Loizou, 2008). Studies have also shown improvements in music appreciation when compared to standard CI users. Recently, novel speech processing strategies have shown improvements in music perception and increased perception of speech quality (Arnoldner et al., 2007; Galindo et al., 2013; Lorens, Zgoda, Obrycka, & Skarzynski, 2010; Muller et al., 2012). Use of these strategies requires an implant that can stimulate the apical third of the cochlea.

Key components of successful hearing preservation are surgical technique and surgeon experience. Hearing preservation can be achieved through a carefully placed cochleostomy (Bruce, Bates, Melling, Mawman, & Green, 2011), however the use of a round window insertion instead of a cochleostomy appears to be gaining widespread acceptance (Roland & Wright, 2006; Roland, Wright, & Isaacson, 2007). Theoretical benefits to this approach have been described. Decreased necessity for drilling likely lowers acoustic trauma, infection rate, leakage of perilymph, and entrance of bone dust into the cochlea. In addition, the round window niche provides ease of sealing the cochleostomy around the electrode. Other techniques described in soft CI surgery include deferring the cochleostomy until immediately before electrode insertion, no suctioning of perilymph, gentle electrode insertion, and potential use of a lubricant to facilitate insertion(O. Adunka, Gstoettner, et al., 2004; O. Adunka, Unkelbach, et al., 2004). Although these are elegant techniques and provide obvious theoretical limits to cochlear damage, they lack evidence for superior outcomes. Rather it seems that duration of deafness and patient age may be predictors of success (Turner, Gantz, Karsten, Fowler, & Reiss, 2010). Introduction of blood into the cochlear environment is another concern during cochlear implant. Intrascalar administration of blood into guinea pig ears has been shown to result in both transient and permanent hearing loss (Radeloff et al., 2007).

Application of these techniques has made hearing preservation a feasible outcome after cochlear implantation in multiple centers. Initial studies with 20 mm insertion depth had an 85% success rate of preserved low frequency hearing in 21 cochlear implant patients with shallow electrode devices and since then these results have been replicated in multiple centers (Baumgartner et al., 2007; W. Gstoettner et al., 2004; Skarzynski et al., 2002; Skarzynski et al., 2010). Insertion depth appears not to increase the incidence of hearing loss (Prentiss, Sykes, & Staecker, 2010; Punte, Vermeire, & Van de Heyning, 2010; Usami et al., 2011), opening the possibility of preserving hearing in most types of hearing loss. In this paper we report the use of the aforementioned techniques to implant a series of ears with rare up-sloping hearing loss. These patients had significant residual hearing above 4000 Hz. The goal in these cases was to achieve and implantation that could take advantage of fine structure processing (FSP) strategies, while preserving sound awareness in the high frequencies.

Methods

Patient selection: Two patients were identified with up sloping hearing losses that met standard implant selection criteria (PTA < 70 dB; SD <60% in better hearing ear, <50% in the ear to be implanted). Pre-operative testing included and MRI with gadolinium of the brain and internal auditory canals; full pure tone audiometry, and testing in best aided condition using HINT, CNC, AZ Bio tests performed in quiet and in noise. Post-operative testing using the same test battery was performed at 2 weeks, 3, 6, 9 and 12 months after implantation.

Surgical Approach: The extended round window approach was used in all cases. After performance of a mastoidectomy and facial recess (posterior tympanotomy) approach to the middle ear, all bone dust was irrigated out of the wound. Hemostasis was obtained and 0.5 cc of decadron 10 mg/ml was applied to the round window niche. The bony overhang of the round window niche was then carefully removed with a 1 mm diamond burr and the round window clearly visualized by testing the round window reflex. For the extended round window approach the bone anterior inferior to the round window was removed, keeping the scala tympani endosteum intact. The wound was once again irrigated and Healon™ was used to cover the round window and endosteum. The endosteum was then opened with a small pick and the implant electrode is carefully inserted so that the 12th contact is inside the round window membrane (Fig 3.1).

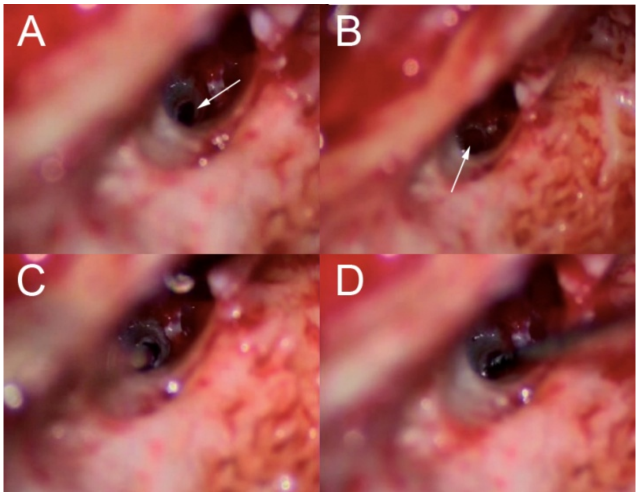


Figure 3.1: Surgical approach for hearing preservation implantation. A wide facial recess is drilled exposing the round window niche (A, arrow). It is important to lower the facial ridge to the greatest degree possible so that the optimal insertion angle for the long electrode can be obtained. Care must also be taken to avoid contact with the incus while drilling. Using a 1 mm diamond bur the round window niche overhang is removed (B). Exposure of the round window is checked by palpating the stapes and looking for a round window reflex. This is not seen if there is still pseudomembrane over the round window. The round window is covered with hyaluronic acid (C) and opened. This allows the insertion of the electrode (D) with minimal contamination of the perilymph with blood.

All patients were implanted with Med-El Sonata using custom made electrode arrays designed for these patients. These electrodes have 12 contacts distributed over 26.5 mm in a 31.5 mm long array. The apical 5 electrodes are single contacts with an electrode diameter of 0.5 x 0.8 mm. The opening into the scala tympani was sealed with a small piece of fascia and the wound closed. All patients underwent intraoperative imaging to ensure that there were no hairpin turns or kinks in the array. Depth of the electrode was determined by imaging as previously described (Boex et al., 2006). All patients were discharged home the same day with oral antibiotics and a 10 day course of methylprednisolone. Patients were activated 1 months post op and programmed with the FSP speech strategy.

Results

Case 1: is a 48-year-old female with a longstanding history of bilateral non-syndromic hearing loss. There was no family history of hearing loss. Her initial audiograms revealed profound up-sloping hearing loss with preservation in her high frequencies (Fig 3.2A). Preoperative CNC score in then left ear was 5%, HINT in quiet 40% and HINT +10dB 0%. She underwent implantation with a custom Mel-El device with a thin electrode and soft surgery technique. Pre- and post-operative audiograms are shown in Fig. 3.2.

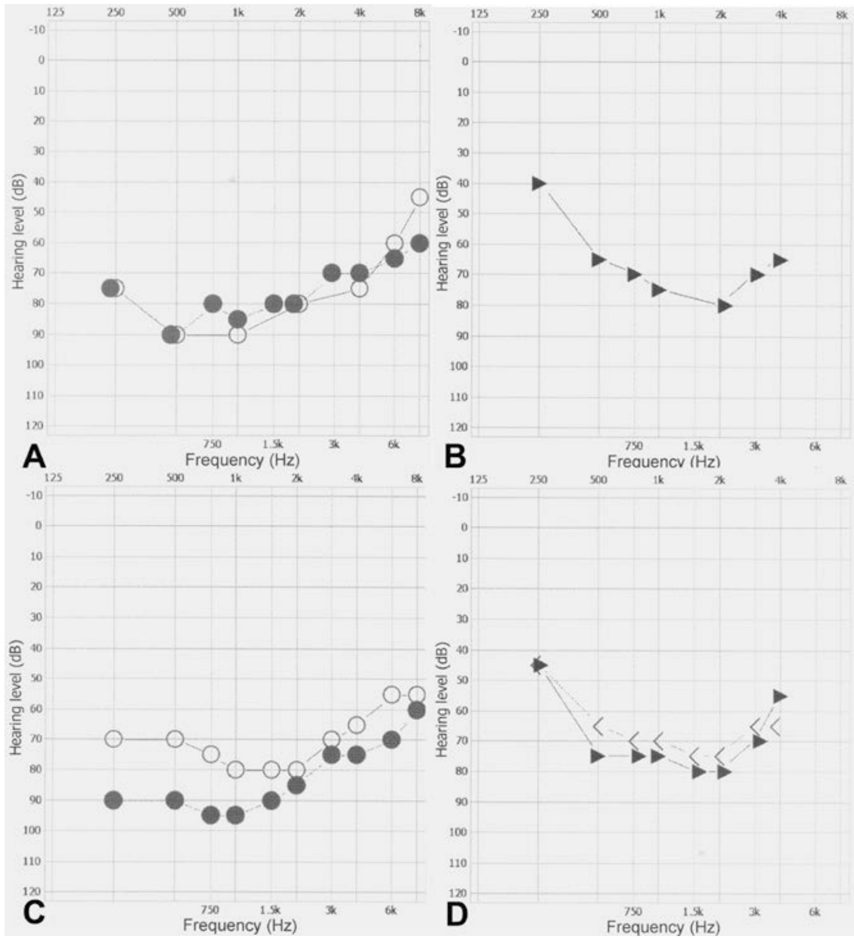


Figure 3.2: Pre- and post-operative audiograms for cases 1 and 2. Pre-op pure tone thresholds are shown as open circles. Post-operative pure tone thresholds are shown as closed circles. As seen in Fig 2A, case 1 demonstrates excellent preservation of pure tone thresholds. Post-operative masked bone conduction scores (B) demonstrate several suprathreshold responses in the low frequency region. Case 2 pre and post- operative pure tone thresholds are seen in C. There is a 20 dB change in hearing in the low to mid frequencies. This is most likely a conductive hearing loss as demonstrated by the masked bone thresholds (D).

Thresholds remained stable throughout testing. At six months post implant activation HINT scores were 95% in quiet, 85% at +10 dB. CNC scores at six months were 90%. Interestingly, addition of a hearing aid in the contralateral ear (bimodal condition) did not result in improvements in scores (HINT 90%, HINT + 10dB 85%, CNC 85%). Scores and hearing thresholds have remained stable for 24 months post implantation. Analysis of CT scans (Fig 3) and reconstructed Stenvers view x rays at 1 year post implantation demonstrate that the electrode position has remained stable at a 680^{o} insertion angle.

Case 2: After long term stable performance with her unilateral implant, the patient requested implantation in her contralateral ear. She underwent implantation using a similar device in the right ear again using soft surgery technique. Pre- and post-operative audiograms are shown in Figs 3.2 C and D. Similar to the left ear, the patient experienced substantial preservation of hearing across all frequencies. Only 20-15 dB loss occurred at frequencies less than 1500 Hz. Based on bone conduction thresholds, this appeared to be a conductive loss (2D). For her right implant alone CNC scores at 6 months were 84%, HINT = 100%; HINT +10 dB=100%. Again using CT temporal bone to construct a three-dimensional image implant position was determined. Measurements for the right ear show rotational angle of 700 degrees. Figure 3.3 shows CT scans of both temporal bones after implant insertion.

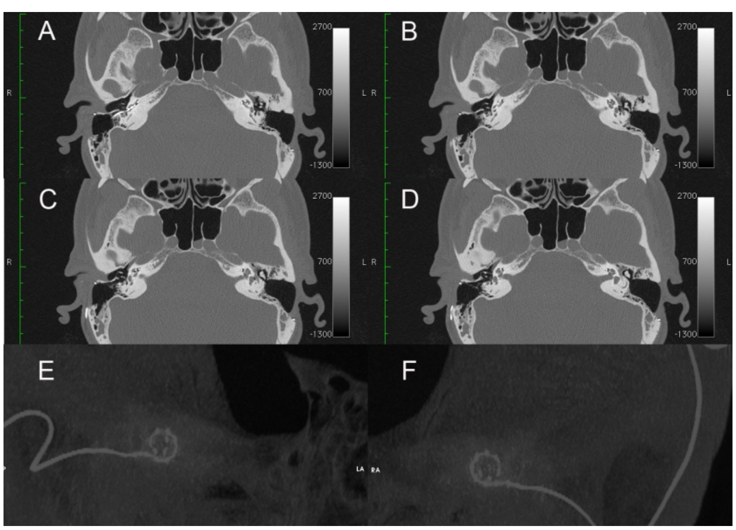


Figure 3.3: Imaging of cases 1 and 2 using post-operative CT (A-D) and Stenvers projections based on CT data for case 1 (F) and case 2 (E). As can be seen on the serial CT sections, the electrode contacts are distributed throughout the length of the cochlea. The individual DICOM data was then projected as Stenvers views using OsiriX software. These projections demonstrate a 680o insertion in case 1 (F) and a 700o insertion in case 2 (F)

Case 3: Patient presented with a >15 year history of non-syndromic up sloping hearing loss. Preoperative CNC test showed a score of 26%; AZ Bio test = 39%. Hearing tests at 3 months post implantation demonstrated preservation of hearing with the presence of a conductive hearing loss in the low frequencies (Figs 3.4 B,C). Overall insertion depth based on estimation from imaging was 700° (Fig 3.4A).

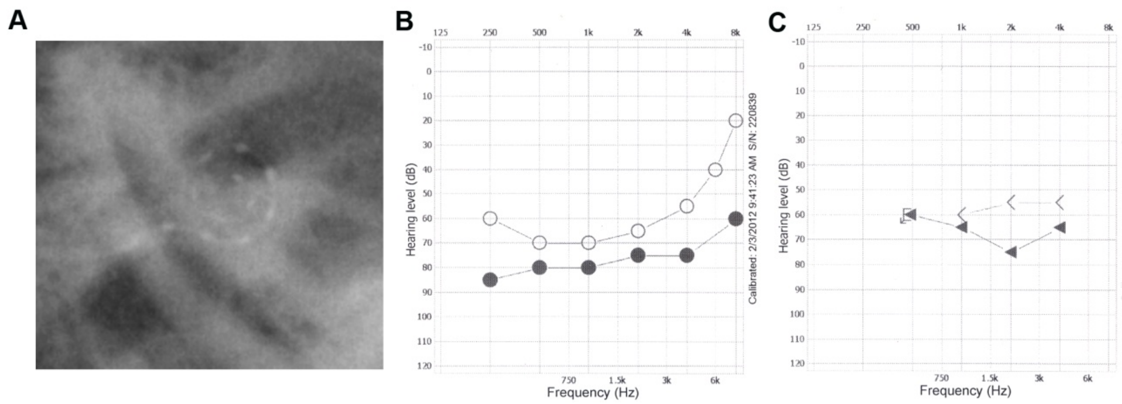


Figure 4: The post-operative Stenvers view for case 3 can be seen in A. Full insertion of the custom 31.5 mm electrode results in a 700 degree distribution of the electrode contacts that are distributed over 28.5 mm of the electrode length. Pre- and post-operative pure tone thresholds show a 10 -20 dB hearing loss resulting from this insertion (B). Measurement of bone conduction thresholds (C), suggests that at least for 500- 4000 Hz measurements the postoperative loss is predominantly a conductive loss.

Discussion

Hearing preservation cochlear implantation developed from the use of short (10mm) electrodes that were implanted in the basal turn of the cochlea so that residual low frequency hearing could be preserved (Gantz & Turner, 2003). Several pioneering studies in the field demonstrated that 20mm insertions to the 1000 Hz region could be performed without sacrificing residual cochlear function (W. K. Gstoettner et al., 2008). In all of these cases the electrode array was inserted into the region of the cochlea that was devoid of residual hearing. Recent studies have demonstrated that there was no relationship between the depth of insertion and hearing preservation if flexible electrodes and soft surgery techniques were used (Prentiss et al., 2010; Tamir, Ferrary, Borel, Sterkers, & Bozorg Grayeli, 2012). Following this logic, deep implantation in patients with atypical up sloping hearing loss should be feasible, which is demonstrated in the cases described above. An interesting observation in these cases is that that there is a 10-20 dB conductive hearing loss across the low frequencies is observed in two of the three cases (Figs 2,4). Potential causes could include contact between the implant and the ossicular chain versus a mechanical effect of the electrode within the scala tympani. We have not observed a similar degree of conductive hearing loss in patients implanted for ski slope hearing loss so the later explanation is more likely.

Use of soft surgery techniques previous described coupled with custom thin electrode devises may provide the opportunity to safely preserve hearing in these atypical up sloping hearing loss patients. Several key factors have been identified as important in consistently achieving hearing preservation. Although hearing preservation has been described using the advanced off stylet technique in modiolar hugging implants, mechanical studies demonstrate that more flexible electrodes lead to lower degrees of insertion trauma (O. Adunka, Kiefer, Unkelbach, Lehnert, et al., 2004; Jolly et al., 2010). This is particularly important since there is some evidence that over insertion with less flexible electrodes can lead to poorer implant outcomes, even when considering electric only conditions (Finley et al., 2008). Therefore when targeting the low frequency regions of the inner ear for stimulation, a long and atraumatic electrode is required. We used a custom electrode that is based on the Med-El flex design. The apical 5 electrodes are single contacts that create a flexible atraumatic tip. The basal end to the electrode featured extra reinforcement to make it easier to advance into the apical third of the cochlea. Other important factors to consider are the surgical approach. We have implanted all of these electrodes via a round window approach. Variability in the orientation of the round window and the initial sharp turn the electrode needs to navigate the hook region, have been cited as potential disadvantages of using the round window as an entry point to the inner ear (Roland & Wright, 2006; Roland et al., 2007). A cochleostomy or removal of the bony ridge anterior to the round window has been advocated to overcome these obstacles. As with other hearing preservation cases, care was taken to avoid blood and bone dust from entering the inner ear. All patients also received intraoperative and post-operative steroids since animal studies strongly suggest that the use of steroids can mitigate implant related damage (Braun et al., 2011; Rajan, Kuthubutheen, Hedne, & Krishnaswamy, 2012).

Patients with significant residual hearing have previously faced a dilemma; implants offered electrical stimulation across all frequencies but at the price of loss of residual hearing. These cases may represent a step toward a solution for patients who are fearful of losing residual hearing or who want the benefit of acoustic hearing when they are not wearing their implant. This situation opens the possibility of implantation to a wide range of patients who have significant residual hearing but perform poorly with hearing aids. A key to identifying these patients is expanding the use of the minimum test battery and raising awareness of audiologists and physicians of current implant criteria. Additionally, deep implantation in up sloping hearing loss allows for the opportunity of examining pitch rate/place perception with electric/acoustic hearing across multiple frequencies in the same ear. Because the patients experience electrical stimulation in areas with acoustic hearing, the electrical stimulation can be precisely mapped. Variation in rate of stimulation can then be correlated with perceived pitch and the acoustic residual hearing can be used as a same ear control. Results from these studies may provide finer tuning of cochlear implant devices in the future.

Acknowledgements: We would like to thank Claude Jolly for his expertise on electrode design, which was integral to completion of this project.

CHAPTER 4: ADVANTAGES OF DEEP INSERTION COCHLEAR IMPLANTATION: A CASE STUDY OF UP-SLOPING HEARING LOSS WITH PRESERVED HEARING ACROSS MULTIPLE FREQUENCIES.

Abstract

Frequency allocation can potentially be improved by cochlear implants that access the apical third of the spiral ganglion. The ultimate goal of stimulating the apical end is to provide the maximum amount of spectral information to the user. Reconstruction of human temporal bones demonstrates a mismatch between hair cell position and spiral ganglion position in the apical third of the cochlea. Frequency allocation based on the Greenwood map may be inaccurate. We had the unique opportunity to work with a patient who presented with a severe sensorineural hearing loss rising to within normal limits and poor speech discrimination scores. The patient was implanted with the Med-El Corporation $\text{Sonata}_{\text{TI}}$100 31 mm electrode. Insertion angle reached approximately 700° with preserved hearing across multiple frequencies allowing for electric to acoustic pitch comparisons in the same ear.

Key words: cochlear implant, electroacoustic stimulation, hearing preservation, pitch matching, stimulation rate

Introduction

Improvements in electrode design and surgical technique allow surgeons to accomplish insertions into the cochlea less traumatically to the surrounding structures. This is documented with preserved hearing in the lower pitches following implantation. Preserving hearing often requires a shorter insertion depth to spare the structures in the apical end of the cochlea; however, providing electrical stimulation to the apical end may benefit the user as well (Boyd, 2011). Stimulating the apical portion of the cochlea could provide more spectral information to the user, thereby acting more similarly to the normal cochlea. Additionally, the stimulation may result in an overall lower-pitched sound resulting in a more natural sound quality (Boyd, 2011). Anatomically, the apical region of the cochlea differs in that the spiral ganglion cell bodies do not extend beyond the second turn (Adamson, Reid, & Davis, 2002; Otte, Schunknecht, & Kerr, 1978). When the electrode is placed in the apical region, it stimulates different neurons from the rest of the cochlea, which suggests the apical end behaves differently from the basal end. To gain further insight into the function and contribution of the apical end numerous studies have documented changes in pitch perception with manipulations of stimulation parameters using electrical stimulation (Carlyon, Lynch, & Deeks, 2010; Vermeire et al., 2008). In addition to the effects on pitch perception due to place of stimulation, increases in pulse rate have been shown to result in higher pitch percepts up to a few hundred pulses per second across the electrode array. Studies have also made comparisons of pitch elicited by electric stimulation to one ear compared to acoustic stimulation to the contra-lateral hearing ear (Dorman et al., 2007). In the cases of CI recipients without residual hearing, the studies have been restricted to procedures providing pitch estimates or scaling procedures that do not provide a measure of the overall range of percepts (Boyd, 2011) and in the cases of comparing CI electrical stimulation to hearing in the contralateral ear results have been confounded by the ability of the subjects to compare the pitch of acoustic signals to the electrical signals of the CI.

This study explored the rare opportunity of examining Pitch Rate/Place perception with electric/acoustic hearing across multiple frequencies in the same ear.

Subject

The subject for this investigation met criteria for cochlear implantation under the Food Drug & Administration guidelines. Cochlear implantation was performed using a MED-EL custom long electrode and a soft-surgery hearing preservation, round window technique. An insertion depth of 29mm was achieved as seen with post-operative imaging and indicating an insertion angle of 720^0. The subject had approximately 18 months of experience using the implant at the time of testing. Audiometric thresholds, pre- and post-implantation are seen in Fig. 4.1.

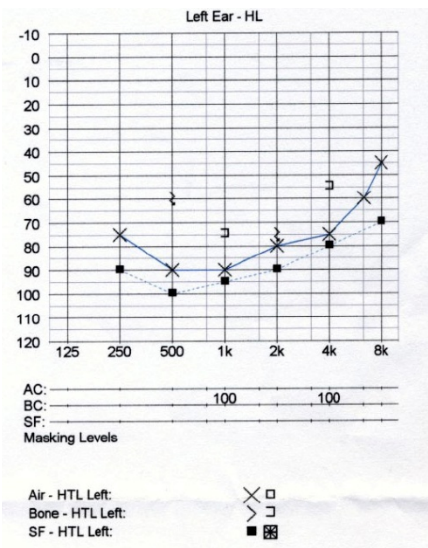


Figure 4.1: Patient's thresholds are plotted before and after surgery. The X represents hearing pre-surgery while the black boxes show thresholds post-operatively

Methods

Pure tone, acoustical signals were generated in 100 Hz increments for the frequency range of 100-8200 Hz. Each tone had an onset and offset ramp of ~5 ms with a stimulus duration of 500 ms. Electrical pulse trains of 500 ms at a 60% loudness of the dynamic range and using stimulation rates of 100, 200, 300 and 1100 pps were loudness balanced to the pure tone(s) that best approximated the pitch elicited by the electrical signal. A sequential analysis pitch ranking procedure (Fig 4.2.) was then completed.

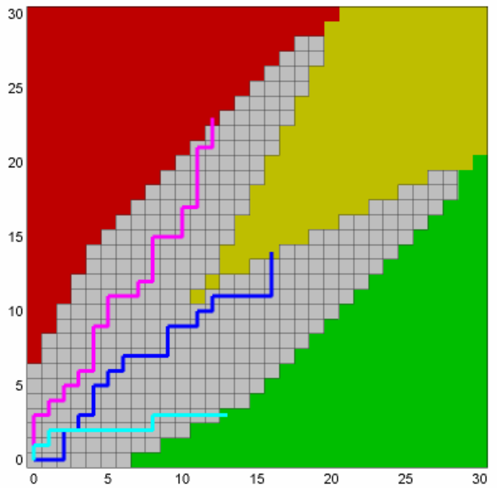


Figure 4.2: The patient is presented with two signals in a randomized order and asked to indicate which has the higher pitch. This continues until a statistically significant outcome is achieved. Figure 2 illustrated the three possible outcomes. Each trial starts in the lower left-hand corner with a response noted as either to the right (green signal was higher) or upward (red signal was higher). For signals that are indistinguishable the responses would reach a trajectory falling into the yellow area (Bross, 1952).

Multiple pairs of electric and acoustic signals were tested simultaneously. Once statistical significance was reached on a particular pair, the acoustic signal was then adjusted in frequency in order to bracket the pitch percept of the electrical signal. This procedure was completed for each data point until a statistical match was found or the pitch was bracketed within a 100 Hz range.

Results

Decreases in the electrical stimulation rate resulted in decreases in pitch perception for each of the electrodes. For this subject, electrode pitch/rate saturation appears to occur at around 200 pps for electrodes 5 & 6. For the remaining electrodes, pitch/rate saturation appears at or above 300 pps as can be seen in Fig 4.3.

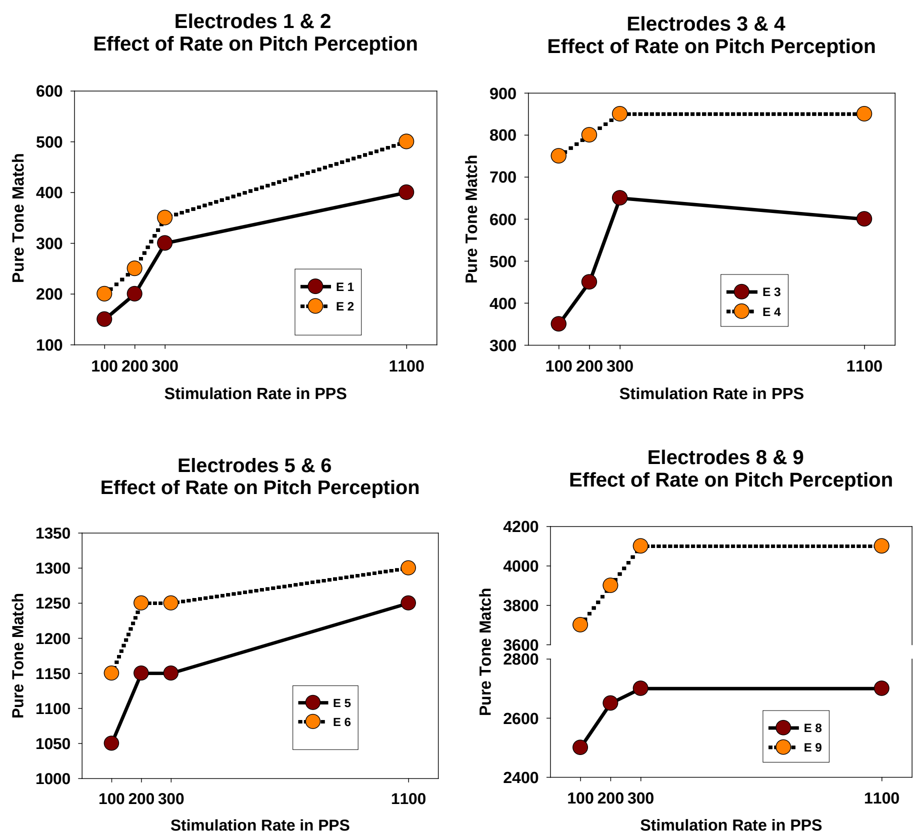


Figure 4.3: The effects of stimulation rate on pitch perception graphed for 4 electrode pairs. Decreases in rate result in decreased pitch perception.

The decreases in pitch with decreasing rate are similar to those found by previous studies (Baumann & Nobbe, 2004; Zeng, 2002), however when provided with an acoustic match in the same ear, the amount of change in terms of cochlear position was much smaller than anticipated. Figure 4.4 shows the changes in pitch perception with changes in rate plotted against a log scale mimicking the cochlea. The results show that there is fairly close agreement between electrode position in the cochlea and place relating to Greenwood's map at stimulation rates above pitch/rate saturation. In addition, changes in pitch percepts due to decreases in stimulation rate are much more robust in the apical region of the cochlea.

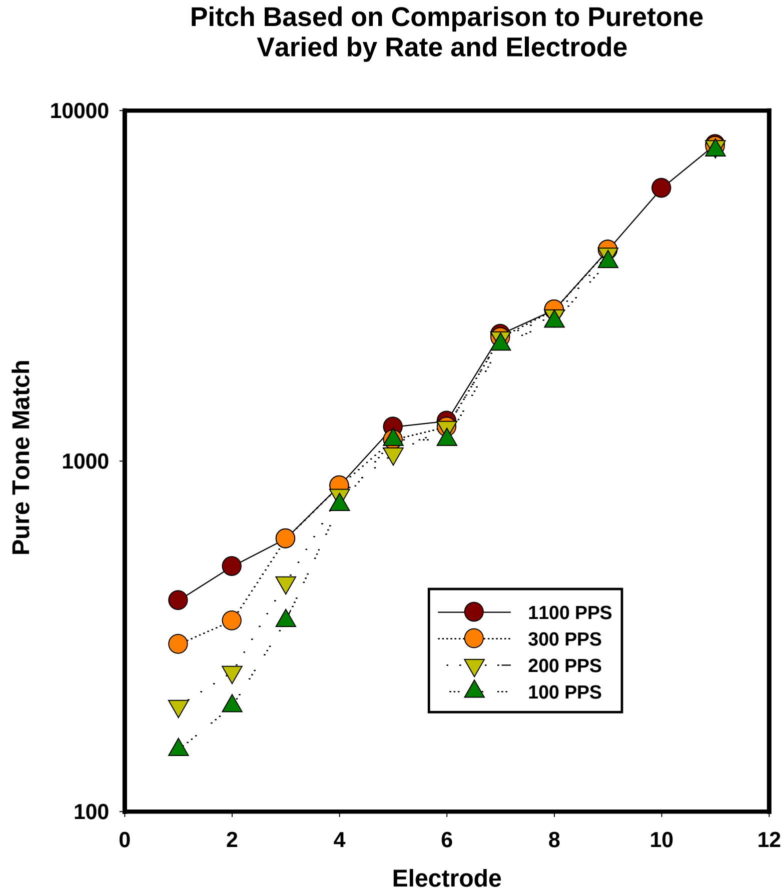


Figure 4.4: The changes in pitch perception with changes in rate are plotted against a log scale mimicking the cochlea. The results show that there is fairly close agreement between electrode position in the cochlea and place relating to Greenwoods map at stimulation rates above pitch/rate saturation. Changes in pitch percepts due to decreases in stimulation rate are much more robust in the apical region of the cochlea.

Interestingly, this patient subjectively reported that as stimulation rate was decreased on electrodes basal to E4, the sound acquired an increasing “buzzing” sound quality as opposed to the apical electrodes that remained tone like with decreases in rate. Preliminary testing on some of the apical electrodes revealed that the subject could not differentiate electric from acoustic stimulation independent of stimulation rate.

Discussion

This subject presented a unique opportunity to compare both acoustic and electric pitch perception in the same ear and across a broad frequency spectrum. The results suggest that there is good agreement between Greenwood's map and electrode position within the cochlea as seen previously (Carlyon et al., 2010; Vermeire et al., 2008). These findings differ from those reported by Dorman et al (2007) and Boex et al (2006) when they found that pitch-frequency place veered from the Greenwood map by as much as two octaves lower (Boex et al., 2006; Dorman et al., 2007). Furthermore, electrodes 1-4 matched at very similar pitches, whereas in our study, the apical electrodes match at different frequencies. It should be noted that Dorman et al used a fast stimulation rate of 1652 pps, and our study stimulated at 1100 pps (Dorman et al., 2007). Interestingly, the varying stimulation rates in our study had little effect on pitch match in the basal electrodes; however, significant differences were noted in the apical electrodes. Reiss and colleagues found similar results with a shorter electrode array in which little pitch perception changes were noted with stimulation rates above 800 pps (Reiss et al., 2008).

The acoustic hearing in the same ear as the implant provided a quantifiable metric for establishing the size and spread of the perceptual intervals related to place and rate of stimulation. These results show that, for this subject, place pitch is the primary influence for pitch perception in the cochlear region basal to 1000Hz and that both place and temporal cues result in changes of pitch perception in the apical region. The subject's report that electrical stimulation maintained a tone-like percept in the basal/mid cochlear regions only when signals were above pitch/rate saturation while changes in rate for the apical region did not adversely affect the tone quality provides some insight regarding the viability of temporal cues for different regions of the cochlea.

This study provides information on the behavior of different areas of the cochlea, which can be applied clinically when programming the cochlear implant. Knowing where the electrode is stimulating along the cochlea may aid us in aligning the center frequencies. Additionally, it may be useful to vary the stimulation rate along the different regions of the cochlea considering the pitch perception decreases with decreased stimulation rate. Providing a closer relationship between electric stimulation and frequency placement could result in better speech understanding and music appreciation. However, mapping this patient was performed with the FSP coding strategy without manipulating frequency range or stimulation rate. Subjectively, the patient reports outstanding speech discrimination and enjoys listening to music. Hearing in noise test (HINT) and consonant-nucleus-consonant (CNC) scores also reflect excellent performance with scores of 100% and 90%, respectively.

Although the sound generated by the electrode may be stimulating mismatched frequency and placement, the brain may learn to adapt to the misrepresentation of the sound (Reiss et al., 2008)(Reiss et al., 2008)(Reiss, et al., 2008)(Reiss, Gantz et al. 2008). Reiss and colleagues studied the pitch perception of those implanted with a shorter electrode (10 mm) and had preserved hearing. In a five-year period, pitch sensations through the cochlear implant changed. Patients originally perceiving high pitch sensations dropped to lower pitch sensations over time, which the opposite occurred for those with lower pitch sensations. Differences occurred mostly between 500 and 1500 Hz, which is primarily the speech frequency region. Despite insertion depth, residual hearing provides added benefit in adapting to spectrally shifted speech

(Reiss et al., 2008; Reiss et al., 2007). Additional research may be needed to determine if mapping parameters should be manipulated after the patient has reached a plateau in performance as defined by speech discrimination scores, or perhaps, manipulations should occur in the beginning months to minimize the severity of the shifted speech spectrum to provide better speech understanding earlier.

Conclusion

Electric place and temporal cues generate different pitch percepts depending on the region of the cochlea receiving the stimulation. Electrical stimulation exploiting the normal hearing process through the use of a long electrode array that extends deep into the cochlea coupled with stimulation strategies that can provide temporal and place cues can extend the range of pitch perceptions by cochlear implant recipients. The relationship of the electrode position to the Greenwood map further confounds the debate regarding dendritic vs. spiral ganglion cell stimulation as this patient has fairly robust survival of both cell populations as suggested by preserved residual hearing. Through temporal bone studies, Stakhovskaya, Sridhar, Bonham and Leake (2007) found that the spiral ganglion cell bodies do not extend beyond approximately 720^0 and suggests the Greenwood map place map is 1-2 octaves below the pitch stimulation in the upper third of the cochlea. This study indicates that the radial nerve fibers are stimulated, as the subject was able to pitch match in agreement to Greenwood's map in the apical region where spiral ganglion cell bodies do not extend.

CHAPTER 5: ANALYSIS OF THE ELECTRICALLY EVOKED COMPOUND ACTION POTENTIAL AND SPEECH PERCEPTION

Abstract

Aim: Although cochlear implants have been an effective treatment to those with severe to profound hearing loss, speech perception abilities continue to vary greatly from one user to another. This paper analyzes the peripheral mechanisms that may contribute to speech understanding by using the electrically evoked compound action potential.

Methods: Auditory response telemetry was measured on twenty-five implant users. The slope of the amplitude growth function was measured for different areas of the electrode and compared to 6-month consonant-nucleus-consonant scores.

Results: Correlations were found between the slopes of mid-frequency region and CNC. The most basal and apical electrodes did not correlate with CNC scores.

Conclusion: ARTs correlate with word recognition depending on placement in the cochlea.

Key Words: Acoustic Response Telemetry; electric compound action potential; cochlear implantation; speech perception

Introduction

One of the more prominent issues in cochlear implantation is determining the wide variability in performance amongst users. Candidates with similar histories and implanted with the same device can demonstrate outcomes on both ends of the spectrum. One may have very poor speech while the other can understand open-set speech (Carlson, Driscoll, Gifford, & McMenomey, 2012). Advances in electrode design and surgical technique have allowed for atraumatic insertions, thereby extending the cochlear implant candidacy to those with lesser degrees of hearing loss. Despite these changes, outcomes continue to vary greatly from one user to another. There are two main contributing factors to implant performance 1) the ability of the processor to effectively deliver the electrical signal to the ear, and 2) the patient's ability to process the information (Pfingst et al., 2011). More specifically, factors can be broken down into age, duration of deafness, surgical technique and device characteristics (Carlson et al., 2012; Firszt, Chambers, Rd, & Kraus, 2002; Firszt, Chambers, Kraus, & Reeder, 2002). Other potential factors include neuronal survival, electrode positioning and central auditory processing abilities (Carlson et al., 2012). Objective measures have become more commonly utilized to further understand the neural pathways of the auditory nerve and central nervous system (Miller, Brown, Abbas, & Chi, 2008). This paper will focus on the peripheral mechanisms that may impact speech perception. The growth factor of the electrically evoked compound action potential (eCAP) is analyzed and compared to monosyllabic words. The eCAP represents a collective response from numerous neurons. It is likely that a steeper slope implies more efficient responses to a stimulus. Therefore, we hypothesize that a steeper amplitude growth function will correlate with higher consonant-nucleus-consonant (CNC) scores.

Numerous studies have been able to link the eCAP and/or the electric auditory brainstem response (eABR) with the number of surviving neurons in animals. Smith and Simmons, 1983, deafened cats and later placed an electrode on the round window to record brainstem electrical activity via ABRs. The intensity of the signal (input) was graphed against the resulting voltage response (output) to create an input/output function. Thresholds for the ABRs were found to be poor predictors of neuronal survival; however, at supra-threshold levels, increased input/output functions correlated with more spiral ganglion cell survival. ABRs were not measureable in cats with no surviving spiral ganglion cells. Prad0-Guitierrez and colleagues manipulated the interphase gap and phase duration in deafened guinea pigs. Both of these manipulations correlated with nerve survival (Prado-Guitierrez, Fewster, Heasman, McKay, & Shepherd, 2006). In monkeys with cochlear implants, lower thresholds and larger dynamic ranges were associated with more neuronal survival (Pfingst, Sutton, Miller, & Bohne, 1981) More recently, Earl and Chertoff measured CAPS on gerbils before and after nerve-induced damage. Histologically, the eCAP did not correlate with CAP thresholds; however, when a mathematical model was applied, strong correlations existed between eCAP and nerve fiber density at high stimulus levels (Earl & Chertoff, 2010). Objective measures have yet to be correlated with neuronal survival in humans nor have they been a reliable predictor of speech perception abilities.

The eCAP provides information regarding the functionality of the electrode, the contact between the electrode and the nerve and perhaps placement of the electrode. Further clinical uses include programming the speech processor for those users who cannot report behaviorally or for children (Miller et al., 2008). There are some discrepancies in the literature as to how well eCAPs correlate with threshold levels and/or comfort levels. Each of the cochlear implant companies in the United States has neural response recording systems to accomplish these tasks.

Additional information can be collected from eCAP recordings, one of which is the amplitude growth function. The eCAP amplitude per electrode is plotted against the stimulation current and a slope can be extracted from the graph (Spitzer, Strahl, Leander, & Franz, 2011). There appears to be a somewhat linear relationship between eCAP amplitude and the number of nerves until a certain point, where saturation occurs. Furthermore, the recovery function of the eCAP can be analyzed, which offers more information regarding the periphery.

Recordings from electrodes differ depending on placement within the cochlea. Brill et. at. studied the eCAP in the Med-El implant and found that the properties can differ depending on the region of the cochlear that is stimulated. Sixty-seven patients were tested. The amplitude, threshold, slope of the amplitude growth function and refractory time were tested and compared at the basal, mid and apical regions of the cochlea. They found that the apical end behaves differently than the rest of the cochlea. Mean amplitude was significantly larger and thresholds were significantly lower in the apical region versus the basal and mid regions. Furthermore, slopes for eCAP growth functions were significantly steeper in the apical end versus the basal and mid regions, although eCAP amplitudes from the recovery function and the recovery inter-pulse intervals showed no significant differences among cochlear regions (Brill et al., 2009).

Methods

Twenty-five patients implanted at the University of Kansas Medical Center with either the Med-El Sonata$_{TI}$100 or the Concert multi-channel electrode were included. Each recipient underwent the "soft-surgical" technique with insertion through the round window, and had at least 6 months experience with the device. Auditory response telemetry (ART) was recorded via the Maestro software from Med-El, Inc. Pulse trains were elicited with a minimum amplitude of 300 current units (cu) and a maximum amplitude of 1200 cu. Twenty-five iterations were recorded with a pulse phase duration of 30 microseconds. Artifact rejection methods created within the software are automatically applied to reduce stimulus artifact. The amplitude for each stimulus is shown individually and the corresponding amplitude growth function was plotted (Fig. 5.1).

Figure 5.1: Example of an ART recording with the corresponding amplitude growth function.

The electrodes were grouped into four groups outlining different areas of the cochlea. Group 1 consisted of basal electrodes (10-12); group 2 included mid to basal electrodes (7-9); group 3 lower mid region (5-7) and group 4 was the apical electrodes (1-4). The amplitude of the response was then plotted against the stimulation current resulting in an amplitude growth function, from which the slope can be interpolated. Recorded CNC lists were administered at 60 dB SPL with the patient seated at 1 meter from a loudspeaker at 0 degrees azimuth. Scores were recorded in percent correct. Pearson's correlations were used to assess the eCAP slope and CNC scores ($p<0.05$).

Results

ARTs were successfully recorded on all 25 patients with measureable amplitude growth function slopes. Slopes tended to be steeper in the apical and mid region as opposed to the basal end. The slope was plotted as a function of CNC scores. Results varied depending on placement within the cochlea. In the most basal and apical group, no correlations existed between the slope of the eCAP and CNC score (r = .068, $p > 0.05$; r = .18; $p > 0.05$). However, there was a significant correlation between the two mid-region groups (group 2: r = .62, $p < 0.05$; group 3: r = .52; $p < 0.05$). Results are shown in figure 5.2. Slopes were also compared to hearing in noise test scores. No correlations existed with any group of electrodes (data not shown).

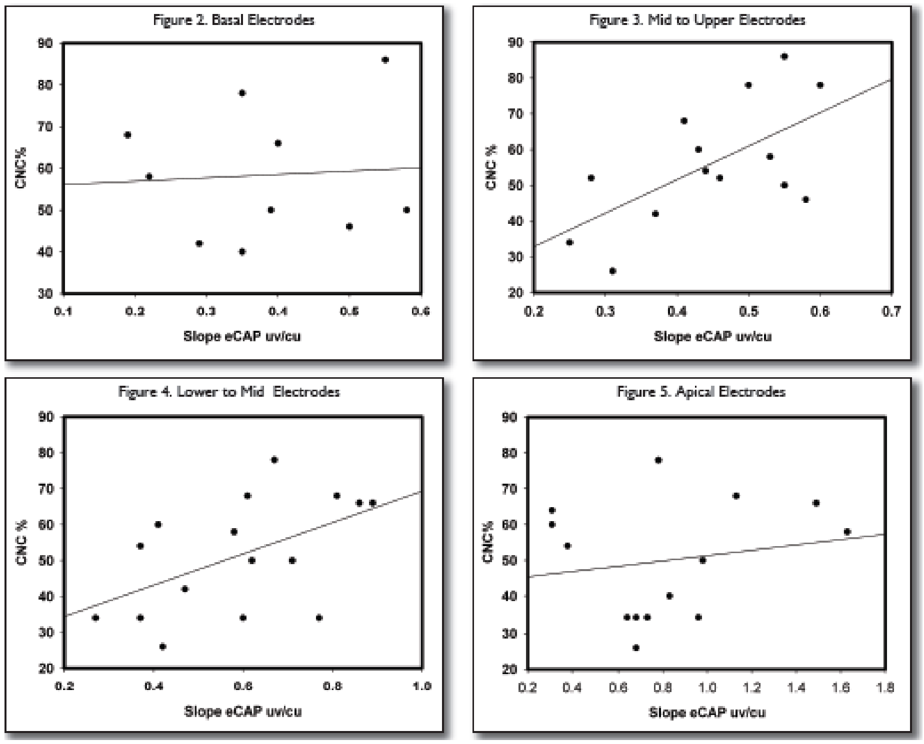


Figure 5.2: In the most basal and apical group (top left and lower right), no correlations existed between the slope of the eCAP and CNC score ($r = .068$, $p > 0.05$; $r = .18$; $p > 0.05$). Significant correlation exists between the two mid-region groups (group 2: $r = .62$, $p < 0.05$; group 3: $r = .52$; $p < 0.05$) depicted in the top right and bottom left graphs.

Discussion

The debate continues to determine if nerve count is directly correlated to speech perception; however, if a correlation exists, the relationship is most likely non-linear (Brown & Patuzzi, 2010). In fact, postmortem examination of cochlear implant users found that the individuals whose cochleae had the least amount of spiral ganglion cells performed the best on monosyllabic word tests (Miller et al., 2008). Human studies involving peripheral objective measures and speech perception have yielded mixed results. Speech perception includes additional cognitive variables that bypass the auditory periphery. However, results from this study suggest that eCAP slope can correlate to speech perception outcomes based on the electrode's position in the cochlea. This is in agreement with a study by Kim and colleagues in which a significant correlation between eCAP slope and CNCs were found with the Cochlear Nucleus Hybrid implant. This finding was compared to the standard Nucleus CI24M and CI24RE. No correlation was noted between the CI24M, and a weak correlation was noted with the CI24RE. The stronger correlation with the hybrid implant along with the results found from the current study indicate that more intact auditory nerve and surrounding structures of the cochlea are correlated with better speech perception scores (Kim et al., 2010). Although, the slope of the eCAP may not directly correlate to surviving neurons, perhaps it encompasses further information about the health of the nerve that may assist with predicting speech outcomes. Choudhury and colleagues demonstrated that the use of electrocochleography (ECoG) intraoperatively may help determine functionality of the neurons in individuals undergoing cochlear implantation. A monopolar probe was placed on the round window of twenty-five subjects. The cochlear microphonic, summating potential, compound action potential and auditory nerve neurophonic were recorded, each potential representing responses from various neural elements within the cochlea. Responses were recordable in twenty-three of the twenty-five subjects despite limited hearing (Choudhury et al., 2012). The ability to assess cochlear and nerve integrity prior to cochlear implantation could aid in the selection and placement of the electrode. Residual neural functionality may also determine candidacy for neurotrophin therapy. Delivery of neurotrophins has shown improvement in implant function as seen in animal models. Studies demonstrate that delivering electrical current in conjunction with neurotrophin therapy further enhances neural survival and improves the functionality of the cochlear implant as shown by Shepherd and colleagues (2005). In this experiment, animals sustained induced aminoglycoside ototoxicity inducing loss of hair cells and peripheral production of neurotrophins. BDNF was delivered to the cochlea in addition to electrical current. Implant function was assessed with eABRs. The neurotrophin treated animals showed reduced eABR thresholds, which is not the case for the animals treated with delivery of perilymph with electrical stimulation alone. Furthermore, spiral ganglion count is increased in the neurotrophin treated animals. The idea that the more surviving neural elements in the cochlea and cochlear nerve leads to better performance has been widely debated; however, studies have been unable to support this idea in humans (Fayad & Linthicum, 2006; Khan, Handzel, Burgess, et al., 2005; Nadol & Eddington, 2006). Intraoperative monitoring may give way to a hair cell deficit, which could potentially benefit from neurotrophin therapy to provoke survival and production of neurons. Comparing objective measures from the cochlea, nerve and central auditory system across hearing preservation patients and traditional cochlear implant patients may also be beneficial in providing further insight into the effects of electrical stimulation on the central auditory pathways and changes overtime. Additional studies of the eCAP could possibly aid in calculating surviving spiral ganglion cells which is also possible in animal studies (Earl & Chertoff, 2010). Variations in score may also occur as speech outcomes are measured across the entire electrode array, not from just a portion of the cochlea, which can lead to further variations in scores. Objective measures recorded beyond the auditory nerve may give further insight into the effects of electrical stimulation on the central auditory pathways and changes overtime. Those subjects with more hearing preservation most likely produce more neurotrophins, which in turn, would promote spiral ganglion survival. Increasing our understanding of the factors that improve speech perception can lead to better rehabilitation strategies or possibly intervention to improve spiral ganglion health.

Conclusion

The eCAP amplitude growth function correlates with speech perception outcomes dependent upon the position of the electrode in the cochlea. Further research is this area is needed to understand electric stimuli on the auditory nerve and central nervous system with hope to shape more individualized rehabilitation strategies.

CHAPTER 6: IS HEARING PRESERVATION COCHLEAR IMPLANTATION IN THE ELDERLY DIFFERENT?

Abstract

Hearing preservation cochlear implantation has become commonplace and give patients who are poor hearing aid candidates but have significant residual hearing an opportunity to take part in the hearing world. Hearing preservation cochlear implantation has been extended into pediatric populations yet little attention has been paid to geriatric implantation. In this paper we review some of the factors that may affect hearing preservation in the elderly. In particular we focus on the potential role of mitochondria in hearing loss and discuss whether the elderly have similar hearing preservation outcomes as the general population.

Introduction

The fact that preservation of residual low frequency hearing improved cochlear implant (CI) function has been widely described. The elderly represent a population where down-sloping hearing losses with poor speech discrimination are common, and hence provide the potential to recruit hearing preservation CI candidates. A key question is if the elderly have the same outcomes in terms of hearing preservation as younger patients. To address this question, we looked at change in hearing after implantation as a function of age and then examined the correlation between age and change in pure tone average. We also studied cochlear implant outcomes as a function of age for hearing preservation patients. We discuss some of the potential causes of observed differences between patient populations.

Methods

Subjects and Outcomes Measures: Informed consent was obtained prior to testing, and the protocol was approved by the University of Kansas Medical Center human subjects board. A total of eighteen patients with residual hearing between 125 and 500 (5 males and 13 females) were implanted between 2009 and 2011. Ages ranged from 26-84 with a mean age 63.17. All candidates fell within Food and Drug Administration (FDA) or Medicare guidelines for implantation. Prior to implantation, all patients underwent blood testing to screen for autoimmune inner ear disease and had an MRI scan to rule out the presence of retrocochlear disease.

Surgical Approach: The extended round window approach was used in all cases. After performance of a mastoidectomy and facial recess (posterior tympanotomy) approach to the middle ear, all bone dust was irrigated out of the wound. Hemostasis was obtained and 0.5 cc of decadron 10 mg/ml was applied to the round window niche. The bony overhang of the round window niche was then carefully removed with a 1 mm diamond burr and the round window clearly visualized by testing the round window reflex. The wound was once again irrigated and Healon™ was used to cover the round window (RW). The RW was then opened with a small pick and the implant electrode is carefully inserted. All patients were implanted with Med-El medium (M) electrode arrays. Pure tone thresholds were obtained before surgery and 2 weeks post-operatively using insert earphones.

Results

As seen in Fig 6.1 there was a linear relationship between age at implantation and change in hearing in the low frequencies ($r^2=0.52$; $p<0.05$).

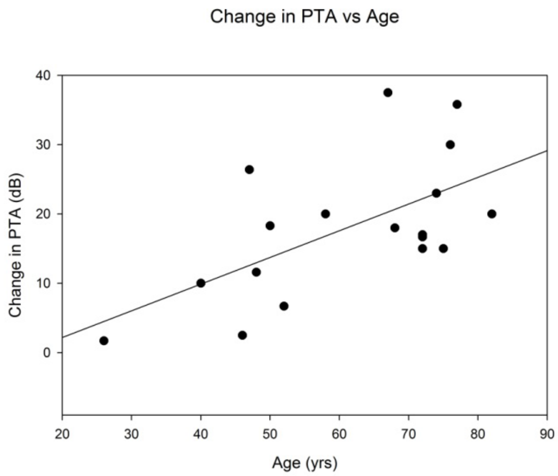


Figure 6.1: Scatter plot of change in pure tone average versus age. There is a linear relationship between the patients' age at time of implantation and degree of hearing preservation.

When arbitrarily divided at age 65, the average change in hearing for the younger patient group (Average age= 46.5) is 13.42 dB and the older patient (average age=74.5) group is 19 dB (p=0.12). As seen in the box plot of this data (Fig 6.1), the range of data distribution is broader for the older age group, resulting in a large standard deviation.

Discussion

The development of reliable approaches for hearing preservation has led to a rapid expansion of cochlear implantation to novel patient populations (Skarzynski et al., 2010). The audiologic configuration that makes the patient a candidate for hearing preservation implantation is common in the elderly (Hoffman, Dobie, Ko, Themann, & Murphy, 2012). A recent review of cochlear implantation in the older individuals suggests that earlier implantation, when patients have less hearing loss may result in better hearing outcomes (Lin et al., 2012). Successful expansion of hearing preservation implantation into the elderly population thus represents an important goal.

Overall our data suggest that hearing preservation is feasible in the elderly and that on average hearing preservation outcomes are similar to younger patients (Fig 6.2).

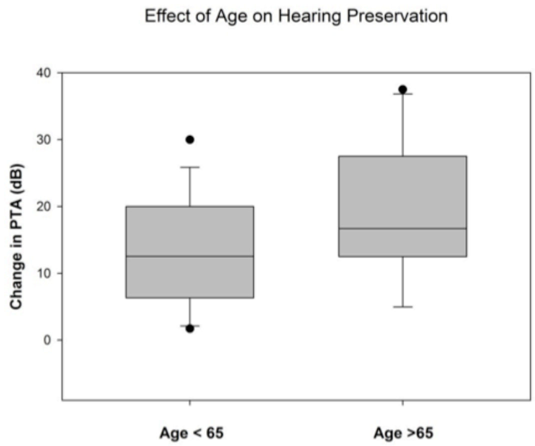


Figure 6.2: Box plot of average change in hearing for patients age less than and greater than 65. Younger patients tend to have slightly less change in hearing and older patients demonstrated a wider range in change in residual hearing after implantation. This was not statistically significant.

However, when examining the data more closely, the range of hearing loss after implantation is higher in older patients and regression analysis does suggest that with increasing age, the amount of hearing loss after implantation is increased (Fig 6.1). As we have previously reported we did not see any significant differences in implant function between our patients based on age (Prentiss et al., 2010), therefore, despite slightly increased loss of low frequency hearing, hearing preservation implantation is still a valuable intervention. Accumulation of increased patient numbers may allow us to divide patients into 10-year cohorts, allowing us better risk stratification based on age.

The relationship between age and central auditory dysfunction has been well documented but little is known about the effects of age on the cochlea's sensitivity to damage. A potential source of age related sensitivity to damage is the function of mitochondria within the inner ear. Damage to mitochondrial DNA has been documented to occur in all regions of the inner ear with increasing age (Crawley & Keithley, 2011; Seidman, Ahmad, & Bai, 2002; Someya & Prolla, 2010; Yamasoba et al., 2007). The accumulation of mitochondrial DNA damage can lead to sensitivity to further stress and subsequent induction of apoptosis (Fariss, Chan, Patel, Van Houten, & Orrenius, 2005). This opens the possibility that completely different protective molecules that stabilize mitochondria could be applied to improve our hearing outcomes in the elderly.

Conclusion

Hearing preservation cochlear implantation is feasible in the elderly although slightly higher rates of hearing loss may be observed compared to younger patients.

CHAPTER VII: THE EFFECT OF INSERTION DEPTH

Hearing Preservation is Feasible

Treatment for severe high-frequency hearing loss has expanded beyond hearing aids. Cochlear implants have been an effective treatment for restoration of profound sensorineural hearing loss, and are now becoming a successful treatment for those with milder degrees of hearing loss. The utilization of less traumatic electrodes and innovations in surgical technique allow for preservation of low frequency hearing after cochlear implantation. Our studies confirm that hearing preservation can be accomplished in a variety of configurations, and further that the change in hearing before and after implantation is independent of insertion depth. Updated data is shown in figure 7.1.

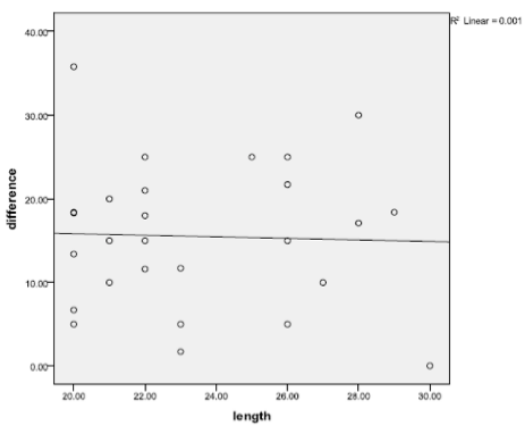
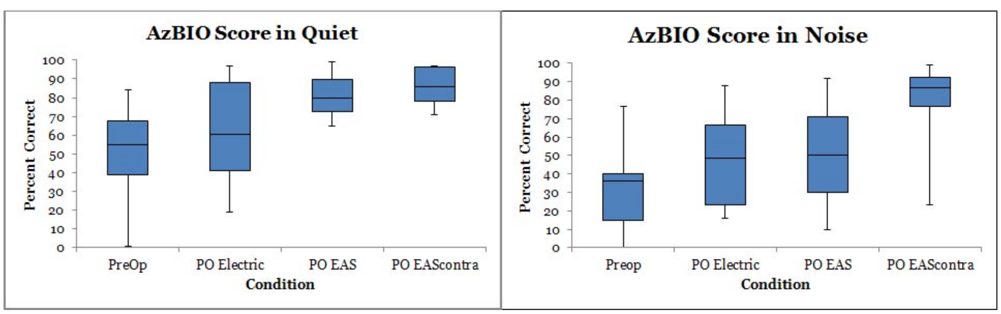


Figure 7.1: Evaluation of hearing loss versus insertion depth for 26 patients implanted with Med-El electrodes. Hearing change is listed as change in pure-tone average (PTA) as patients in this group had only low frequency hearing. There was no correlation between insertion depth and change in hearing with insertions up to 30 mm.

Advantages of Hearing Preservation Cochlear Implantation

Patients presenting with residual low frequency hearing treated with acoustic and electric hearing via a cochlear implant tend to perform better in background noise than patients using a hearing aid alone or a cochlear implant alone (Gantz et al., 2009; Lorens et al., 2008; Skarzynski et al., 2006; Skarzynski et al., 2009; Turner et al., 2004); however, there is no account for the variance in performance among users. While our study does not demonstrate significant benefit from acoustic hearing as demonstrated in chapter 2, several factors may account for the discrepancies. As mentioned previously, sentence tests have since changed to the AzBIO, which is a more difficult listening task. Unlike previous sentence in noise tests, the AzBIO provides little contextual cues making it more difficult to fill in the word. Our patients scored very high with the implant alone, and it was difficult to see a significant improvement when the acoustic hearing was added. Furthermore, the tests used in chapter 2 were presented with a +10 dB SNR, which may not be adequate in replicating a realistic listening setting. Figure 7.2 shows the updated data with AzBio scores in quiet and in noise for our hearing preservation patients.



A B

Figure 7.2: Six-month outcome measures with 21 hearing preservation patients. Graph A shows the AzBIO pre- and post-operative scores with electric only, electric plus acoustic in the same ear and EAS plus the contralateral ear. Graph B shows the same information only in a +10 noise condition. The graphs suggest that acoustic hearing does supplement electric hearing especially when adding the contralateral ear.

The above data suggest that acoustic hearing is beneficial when added to electric hearing especially when the contralateral ear is added. This finding could potentially be due to the advantages of bilateral stimulation. Twelve month data are not available at this time, but may show more pronounced differences when the user has more experience. Measuring outcomes continue to evolve. Clinics are moving towards more complex listening situations and using +5 or + 8 dB SNR.

Are we stimulating spiral ganglion cell bodies or neurites?

Implant patients presenting with residual hearing allow us to perform a variety of pitch matching experiments. To analyze these we need a clear understanding of cochlear anatomy. Placement of the electrode within the cochlea will vary depending on the size and length of the cochlea itself. Discrepancies in anatomy may result in increased trauma and/or stimulating different areas from one person to the next. Patients may have altered pitch percepts, which, ultimately, can influence speech understanding.

Erixon and colleagues studied seventy-three casts of the human cochlea (Erixon, Hogstorp, Wadin, & Rask-Andersen, 2009). Measurements included width, length and height of different turns. The cochleae were also divided into quadrants. Quadrants 1 through 4 comprise the first turn, 5-8, the second turn and 9 -12 constitute the third turn, which is depicted in the following figure 7.3.

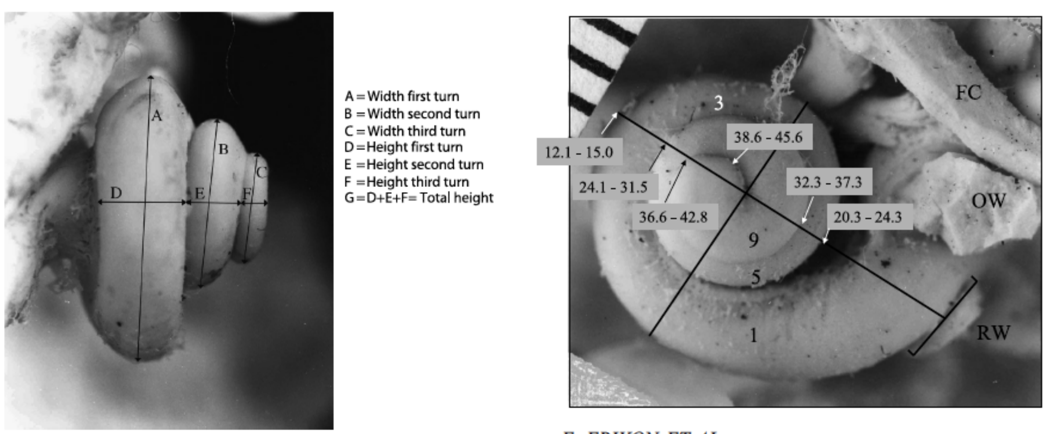


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Figure 7.3: A: Demonstration of a human cochlear showing the different height and lengths of the cochlear turns. B: Demonstration of a human cochlea divided into 12 quadrants with quadrants 1 to 4 comprise the first turn; 5 to 8, the second; and 9 to 12, the third turn. FC represent the facial canal; OW is the oval window and RW is the round window.

Each cochlea was found to be unique with large differences in measurements. The number of quadrants ranged from 8-12 with further discrepancies in the length of each turn. From the outer wall, the total length of the cochlea ranged from 38.6 mm to 45.6 mm with a mean of 42.0 mm (Erixon et al., 2009).

Jolly et. al performed a meta-analysis of the cochlear duct length. Data was collaborated from two studies to include 95 cochlear measurements. The distance from the round window to the helicotrema averaged to approximately 31 mm with minimum of 25.3 mm and a maximum of 35.5 mm (Jolly et al., 2010). The distribution is shown in figure 7.4.

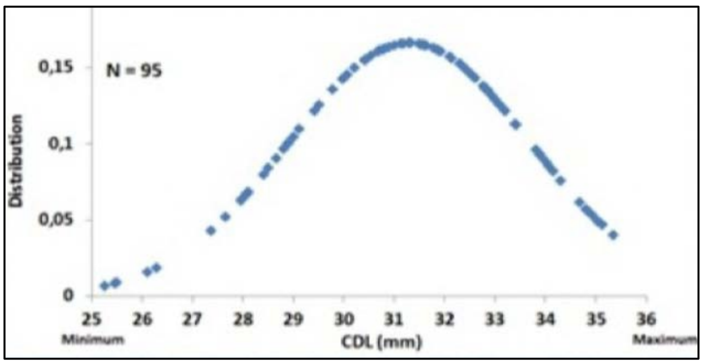

Figure 7.4: Distribution of cochlear duct length based on 95 temporal bone studies. The distance is measured from the round window to the heliocotrema. Distances ranges from 25.3 to 35.5 mm.

The human ear hears the same frequency range 20 Hz to 20,000 Hz, regardless of the length of the cochlea. Electrodes are not customized for each cochlea, rather they are designed for the average cochlear length. This situation can lead to a compressed or expanded frequency map (Stakhovskaya, Sridhar, Bonham, & Leake, 2007) and ultimately decrease speech perception abilities. A patient with a cochlear duct length of 24 mm and an electrode insertion depth of 20 mm will have more complete cochlear coverage, whereas the same insertion depth for a longer cochlear duct of 36 mm may not provide the electrical stimulation in the apical end resulting in different speech and sound percepts. Mapping the cochlear implant to match the actual stimulation site of the electrodes may lead to increased performance. Figure 7.5 demonstrates the cochlear implant array depth compared to cochlear duct length.

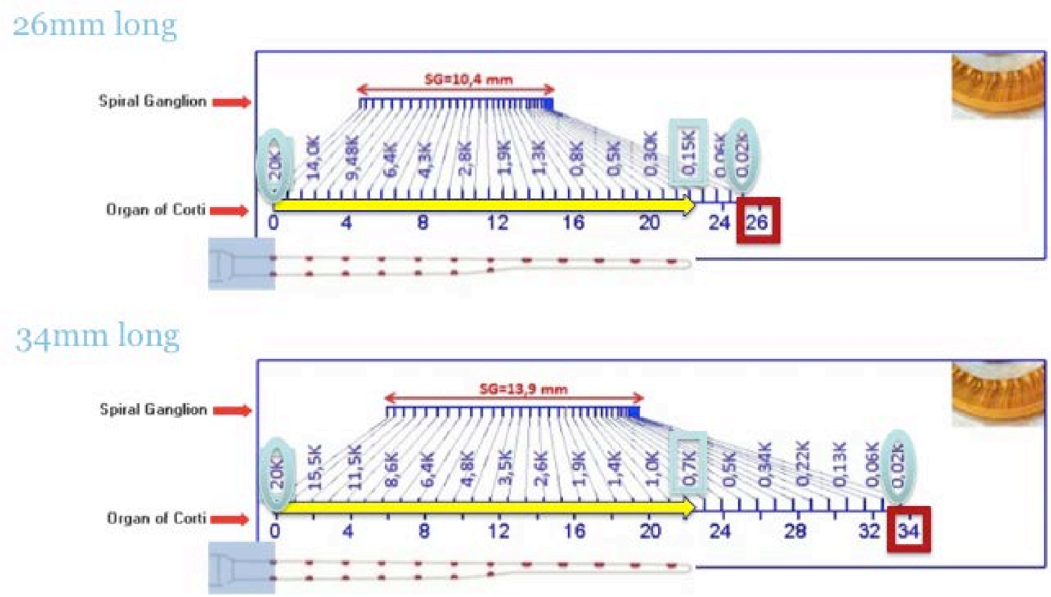

Figure 7.5: Schematic of two unrolled cochleae. The first shows a cochlear duct length of 26 mm, the second, 36 mm. Both patients have the same speech frequency range from 20 Hz to 20000 Hz. The first picture represents a patient with a shorter cochlear duct length, and second with and elongated cochlear duct length. If we insert the same cochlear implant array in both patients, it stimulates frequencies from 20,000 Hz to 150Hz in the first patient and from 20,000Hz to 700Hz in the second patient.

The stimulation site is argued with two different frequency position maps. Pitch position of acoustic hearing is defined by Greenwood (Greenwood, 1990) along the organ of Corti. The Greenwood function has commonly been used to estimate place of electrode stimulation; however Stakhovskaya et. al. offered another theory that the electrodes are actually stimulating at the level of the spiral ganglion and derived a map of the spiral ganglion cell bodies. This map illustrates that spiral ganglion cell bodies stop around 720° and the dendrites extend to the most apical end as seen in figure 7.4 below.

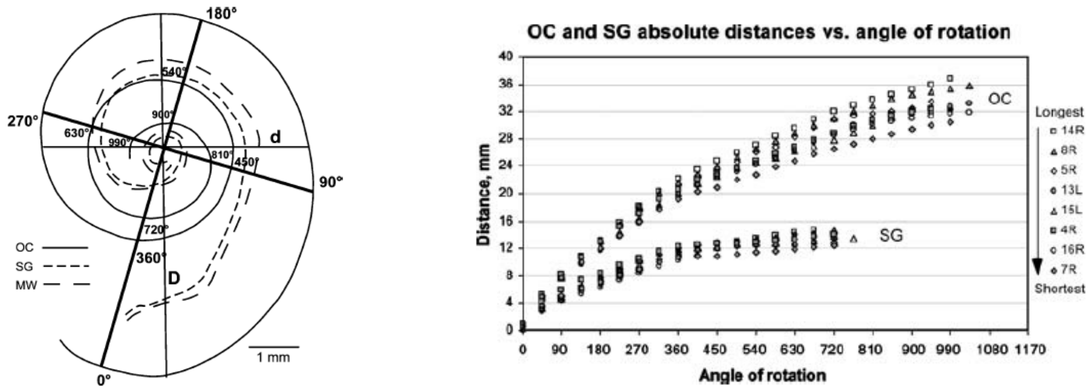

Figure 7.6: A) Schematic drawing of the mismatch between the spiral ganglion cell bodies and the organ of Corti. The organ of Corti is depicted by the black solid line and extends to approximately 990°. The spiral ganglion cells stop around 720°. B) Graph of the absolute distances in mm to reach a certain angle of rotation.

It is important to note that the places of excitation may have different distances to the organ of Corti, altering pitch percepts. The greater the angle of rotation from the round window, the more mismatch exists between the frequency range of the organ of Corti and the spiral ganglion. This feature is demonstrated in Table 7.1.

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TABLE 3

Frequencies along the OC and SG at different angles of rotation

Angle of rotation from round window	*OC mean freq*	*OC freq range*	*SG mean freq*	*SG freq range*
0°	17,857	17,623–18,120	17,225	14,734–20,677
90°	6,501	5,867–7,253	6,193	5,111–7,132
180°	3,239	2,812–3,567	3,174	2,700–3,496
270°	1,659	1,460–1,906	1,539	1,381–1,832
360°	920	809–1,063	785	676–916
450°	601	531–699	550	444–699
540°	407	331–462	366	283–400
630°	263	208–302	215	170–262
720°	152	93–184	58	20–172
810°	86	63–108		
900°	44	20–61		
990°	27	20–39		

Table 7.1: Mean frequency and frequency ranges of the organ of Corti and spiral ganglion cells at certain angle of rotation from the round window.

Theoretically, the closer the stimulation to the organ of Corti, the closer it should match to the correct pitch range. To achieve the best possible outcomes, intracochlear electrode position remains arguable among cochlear implant companies. Cochlear and Advanced Bionics design a perimodiolar electrode with the intent to stimulate the spiral ganglion cell bodies, whereas Med-El's electrode involves a longer electrode that is designed for positioning along the organ of Corti to stimulate radial nerve fibers (Stakhovskaya et al., 2007).

To test the accuracy of frequency-position functions, pitch-matching experiments have been conducted comparing the pitch perception from the cochlear implant to the unimplanted contralateral ear with significant residual hearing. With these pitch-matching experiments, the electrode match in the mid to basal end was significantly lower than that of Greenwood's predictions (Baumann & Nobbe, 2006; Boex et al., 2006; Dorman et al., 2007). Interestingly, the apical channels were perceived as the same pitch. These findings contrast with the findings from our study. As seen in chapter 4, our data show a fairly close relationship to Greenwood's map depending on the rate of stimulation.

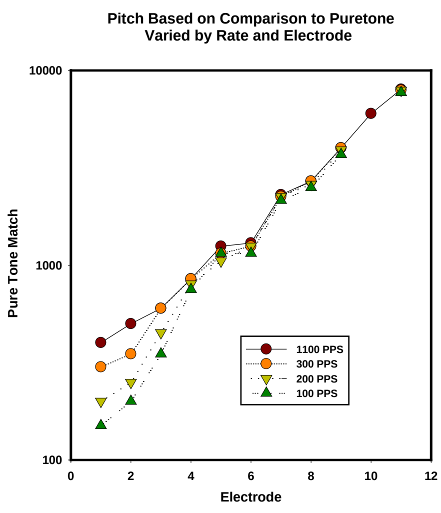

Figure 4.4: The changes in pitch perception with changes in rate are plotted against a log scale mimicking the cochlea. The results show that there is fairly close agreement between electrode position in the cochlea and place relating to Greenwoods map at stimulation rates above pitch/rate saturation. Changes in pitch percepts due to decreases in stimulation rate are much more robust in the apical region of the cochlea.

Our study is unique in that we were able to pitch-match in the ipsilateral ear, however, similarities were noted in that the apical end tends to behave differently than the basal end. Reiss et. al. suggests that the placement of the electrode does not determine pitch sensations, rather the implant map that is used (Reiss et al., 2008). Quite possibly this is linked to the neurophysiology (Baumann & Nobbe, 2006). Studies mentioned previously consistently show that pitch percepts occur approximately one octave lower than that of Greenwood's predictions. Perhaps, excitation is occurring at the level of the spiral ganglion rather than the organ of Corti (Boex et al., 2006); which may explain the place/frequency mismatch.

In our case study, the implant was positioned along the outer wall and closely followed that of Greenwood's function in the basal end. It is possible that we are stimulating two different areas, which can potentially lead to pitch confusion. However, when looking at the human histopathology, loss of peripheral nerves is more common than loss of spiral ganglion bodies. Nerve fibers from the damaged organ of Corti degenerate at a faster rate than the spiral ganglion cell bodies (Fayad & Linthicum, 2006; Stakhovskaya et al., 2007), suggesting that the spiral ganglion cells and the central axons are the stimulated structures by cochlear implants. However, if the rate of stimulation is manipulated, our pitch matching data suggest that with variation in rate, it is very possible that we are stimulating neurites in the apical end as the neurites extend further along the organ of Corti than the spiral ganglion cell bodies.

eCAP Growth Function and Outcomes

A potential cause of differing outcomes is the viability and functioning of the spiral ganglion cells. Interestingly, the relationship between neural survival and patient performance has yet to be established. The eCAP amplitude growth function seen in chapter 6 would suggest that neural function indeed correlates with speech understanding, again, dependent upon place within the cochlea. The amplitude growth function demonstrates a significantly steeper slope in those with better CNC scores; however, only in the mid region of the cochlea. The basal region and the apical region showed much weaker responses and shallower slopes.

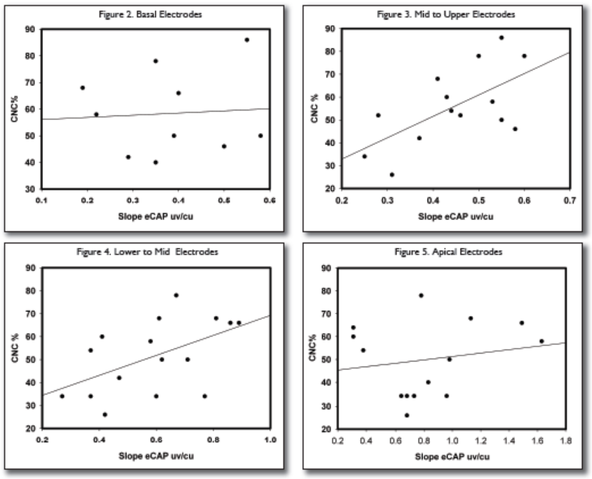

Figure 5.2: In the most basal and apical group (top left and lower right), no correlations existed between the slope of the eCAP and CNC score (r = .068, $p > 0.05$; r = .18; $p > 0.05$). Significant correlation exists between the two mid-region groups (group 2: r = .62, $p < 0.05$; group 3: r = .52; $p < 0.05$) depicted in the top right and bottom left graphs.

Past histopathology studies have shown that the basal region degenerates much faster than the apical end (Nadol et al., 2001), which may explain why eCAPs are absent. Perhaps, in the apical end, the electrode is not reaching the appropriate neurons to elicit a robust response. These results suggest that the health of the neurons influences outcomes; however, temporal bone studies would suggest otherwise. Fayad and Linthicum (2006) counted the spiral ganglion cell bodies in the temporal bones of 14 cochlear implant users. The nerve count was compared to the performance based on words and sentence scores, and found to have no correlation (as seen in table 7.2 below).

	Basal Turn			Middle Turn			Apex	
Case No.	HC	PP	SG	HC	PP	SG	HC	PP
1	0	25	70	0	65	65	0	85
2	0	30	40	0	75	85	25	100
3	0	5	10	20	5	25	0	0
4	0	0	40	0	0	20	0	5
5	30	30	50	35	80	75	40	100
6	0	0	30	0	0	20	0	0
7	0	0	20	0	0	0	—	0
8	0	0	50	0	85	75	0	90
9	0	0	40	0	0	40	0	35
10	0	0	57	0	0	40	0	0
11	0	0	20	5	0	10	0	0
12	0	0	10	30	0	5	5	0
13	—	0	5	0	0	5	0	0
14	0	0	10	0	0	10	0	0

Fayad and Linthicum: Histopathology of Cochlear Implants

Case No.	Performance Rank	High Word Score (%)	High Sentence Score (%)
1	Fair	6	11
2	Good	—	—
3	Poor	—	—
4	Fair	4	41
5	Poor	—	—
6	Excellent	64	96
7	Fair	10	50
8	—	—	—
9	Good	18	65
10	Fair	4	19
11	Good	34	78
12	Excellent	60	90
13	Fair	16	40
14	Fair	30	66

Table 7.2: A) Estimated percentages of neural survival with HC (hair cells), PP (peripheral processes/dendrites) and SG (spiral ganglion cells). B) Table of the corresponding implant recipients and their performance in word and sentence scores.

Peripheral processes appear to affect outcomes to some degree. As mentioned previously, patients with residual hearing using both electric and acoustic stimulation typically perform better than those patients using only electric stimulation. This finding could potentially be a result of an increase in neuronal survival.

Which brings about the question, does patient age affect outcomes? Based on our results in chapter 6, the elderly population may be more prone to hearing loss after implantation. Updated data in figure 7.7 continues to show a trend for increased hearing loss with increasing age.

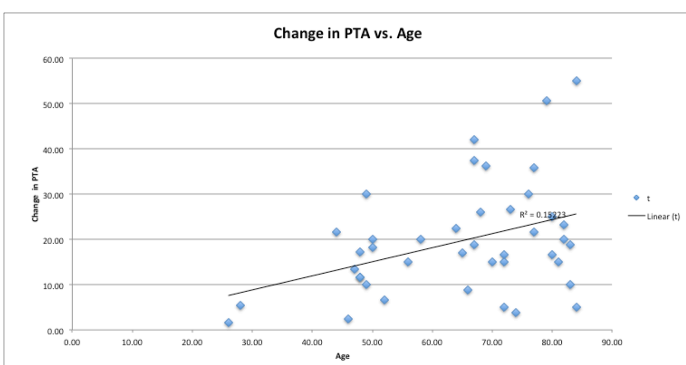

Figure 7.7: Updated distribution of the change in PTA versus age. Changes in hearing appear to increase with age.

A common underlying etiology of hearing loss in the elderly is presbycusis, which is primarily the progressive dysfunction and aging of the cochlea (Lin et al., 2012). The audiologic configuration for presbycusis follows similar criteria for hearing preservation candidates of cochlear implantation. Perhaps, the aged cochlea is unable to sustain trauma induced by electrode insertion. Nelson and Hinojosa studied 21 temporal bones of individuals with presbycusis. Four cochlear elements were examined and counted, the outer hair cells, inner hair cells, stria vascularis and spiral ganglion. The number of remaining structures for all four elements correlated with the degree of hearing loss based on the pure tone average at 500, 1000 and 2000 Hz. The strongest correlation existed with the inner and outer hair cells. Interestingly, inner and outer hair cell count was not associated with the slope of the hearing loss (Nelson & Hinojosa, 2006). Peripherally, poor outcomes may be due to neuronal survival. Shucknecht and colleagues classified types of hearing loss based on cochlear health (Schuknecht & Gacek, 1993) and are shown in table 7.3.

Type	Audiometric Pattern	Histopathology
Sensory	Abrupt high tone loss	Hair cell loss
Neural	Diminished word discrimination	Spiral ganglion cell loss
Strial (metabolic)	Flat loss	Stria vascularis atrophy
Cochlear conductive (mechanical)	Gradual descending pattern	No morphologic findings (presumed stiffening of basilar membrane)
Mixed	Combinations of flat, sloping, and abrupt high tone loss	Combinations of hair cell, ganglion cell, and stria vascularis loss
Indeterminate	Flat and/or abrupt high tone loss	No morphologic findings (presumed impaired cellular function)

Adapted from Nelson EG, Hinojosa R. Presbycusis: a human temporal bone study of individuals with flat audiometric patterns of hearing loss using a new method to quantify stria vascularis volume. *Laryngoscope* 2003;113: 1672–1686.

Table 7.3: Histopathology of different types and configurations of hearing loss. Spiral ganglion cell loss shows a relationship with poor word discrimination scores.

Based on the above classification, the spiral ganglion cells contribute most to word understanding. The other possibility would be the tremendous central integration that is necessary to process acoustic and electric stimuli. Little has been studied on the effects of age on cochlear implant outcomes, but it has been well documented the effects of age on central auditory processing and memory. We looked at the change in pre- and post-operative CNC scores and compared it to the age of the patient. The graph is shown in figure 7.8.

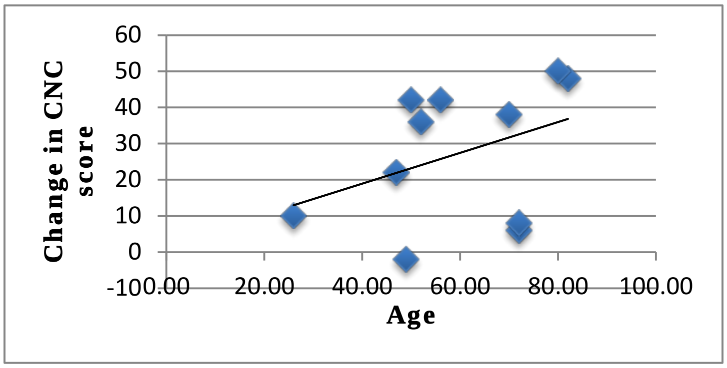

Figure 7.8: The change in CNC scores before and after cochlear implantation as a function of age. There is no clear relationship between age and changes in word discrimination abilities.

Change in CNC scores do not appear to be affected by age of the patient. Some of the largest improvements were seen in the oldest patients. Perhaps, the duration of deafness may play a role with this finding. The graph also tells us that age can affect individuals differently. Central processing capabilities are dependent upon time, pitch and intensity characteristics of the sound (Freigang et al., 2011). The inability to differentiate between different signals heavily affects the way sounds are processed. Freigang et. al. comprised a test of just noticeable differences (JNDs) between signals, which integrated the properties of central auditory processing. Fifty-nine subjects, aged 65-89, were tested and compared to a younger group, aged 20-29. Results indicate that the older population consistently requires increased JNDs in all three areas, time, pitch and intensity (Freigang et al., 2011).

Hearing loss is caused by a number of factors, some of which are unknown. The indications for cochlear implantation are dependent upon the benefit gained from amplification; however, outcomes will continue to vary upon patients and patient populations. The health of the peripheral and central mechanisms will determine the outcomes for the individual patient, which at this time cannot be predicted. Further studies of objective measures of the auditory pathway, beyond the auditory brainstem, may give insight as to how effectively the electric signal will be delivered and interpreted in the brain. Other attempts to evaluate outcomes, especially in the elderly, may involve tests for dementia or other central processing deficits.

Conclusion

As seen in the above studies, electrode placement within the cochlea can have differing effects on hearing preservation and outcomes. Hearing preservation can be preserved with either short or long electrodes. Insertion depth does not appear to affect the damage to the cochlea. Intraoperative monitoring using electrocochleography (Choudhury et al., 2012)could potentially guide the surgeon to place the electrode in the most optimal position with the least amount of damage. Preserved cochlear structures and the addition of low frequency acoustic input to electric stimulation leads to optimal speech understanding abilities.

Cochlear implants have been a successful treatment for many patients who do not benefit from traditional amplification; however, outcomes continue to vary. Several factors including electrode design, mapping parameters, health of the cochlea and health of the recipient must be considered to achieve the optimal outcomes for each patient. With differing anatomies and neuronal survival, more customizable coding strategies may be warranted. Frequency bands may need to be altered for each electrode to reduce the place/pitch mismatch. Intracochlear position determines what pitch is perceived and is dependent upon the rate of stimulation. It may be beneficial to lower the rate of stimulation in the apical channels to provide better pitch discrimination.

The eCAP provides some insight as to how the nerves are responding to electric stimulation. Running objective measures in addition to sentence comprehension tasks prior to implantation may provide information regarding the health of the cochlea. If we can correlate spiral ganglion or hair cell survival with objective measures, it may aid in selection of the electrode design to ensure maximal stimulation of the surviving nerves. Beyond the cochlear neurons, additional objective measures, including the ABR, middle latency responses and late cortical responses may help determine the health of the auditory pathway and if sounds are reaching the cortex efficiently. Knowing this information prior to implantation could provide better counseling tools and more predictable outcomes.

Cochlear implantation with hearing preservation shows many advantages; however, the elderly population may not consistently achieve the same benefits seen in younger groups. It is well known that the risk of hearing loss increases with age. Perhaps the status of the elderly cochlea is more fragile and less tolerant to trauma induced from electrode insertion. Outcomes may tend to vary more with the elderly as central processing disorders increase with age. It is necessary to evaluate both the peripheral and central processes of a patient in order to provide the best expectation. Objective measures can offer more than peripheral health, but also central health. Measuring the later auditory potentials of current implant patients and comparing to their speech discrimination scores may show some differences in the amplitude or latency of the responses.

Changes and improvements in electrode design will continue to evolve as will the criteria for cochlear implant candidacy. These “givens” will demands more understanding of the ear’s and brain’s responses to electric stimulation so that the maximal benefit of cochlear implantation can be achieved for the recipients of this technology.

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APPENDICES

Partial Deafness Cochlear Implantation at the University of Kansas: Techniques and Outcomes

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Abstract

Background: One of the most significant recent advances in cochlear implantation is the implantation of patients with residual hearing. These patients have a downsloping sensorineural hearing loss with poor speech discrimination and perform poorly with standard amplification. Studies using a variety of different electrode designs have demonstrated that it is possible to implant an inner ear and preserve residual hearing. Initial studies have demonstrated that a combination of residual acoustic hearing in the low frequencies with electrical stimulation in the mid- to high frequencies resulted in superior hearing performance in background noise.

Purpose: The objective of this study was to determine the effect of electrode insertion depth on hearing preservation.

Study Sample: Eighteen patients with mild to severe hearing loss in the low frequencies combined with poor word recognition were recruited for the study.

Intervention: Cochlear implantation.

Data Collection and Analysis: Pre- and postoperative hearing test, Hearing in Noise Test, and consonant–nucleus–consonant testing. Data analysis was performed with Kruskal Wallis and Mann-Whitney testing.

Results: In our study of 18 patients implanted with a Med-El PulsarCI100 we demonstrated the ability to preserve residual hearing with implant insertion depths ranging from 20 to 28 mm, giving us the possibility of near complete cochlear frequency coverage with an implant array while preserving residual hearing. These patients performed well both in quiet and in 10 dB signal-to-noise ratio conditions.

Conclusion: Hearing preservation was achievable even with deep implant insertion. Patients performed well in combined acoustic and electric conditions.

Key Words: Cochlear implant, electroacoustic stimulation, hearing preservation, partial deafness cochlear implantation

Abbreviations: CNC = consonant–nucleus–consonant; EAS = electroacoustic stimulation; FDA = Food and Drug Administration; HINT = Hearing in Noise Test; PTA = pure-tone average; SNR = signal-to-noise ratio

It is estimated that more than 31 million Americans are hearing impaired, most of whom do not have profound sensorineural hearing loss (Kochkin, 2005). The most common form of hearing loss in adults is high-frequency sensorineural hearing loss, which makes it difficult to distinguish speech sounds, particularly consonants. Their hearing function deteriorates further in background noise. These patients are often frustrated with hearing aids or do not benefit from them due to poor word-understanding abilities. Cochlear implants have become a useful tool for the treatment and rehabilitation of severe to profound hearing losses.

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Those with good low-frequency hearing and poor high-frequency hearing were initially not considered cochlear implant candidates as preservation of residual hearing was not thought to be possible due to the trauma sustained from electrode insertion (Sohmer, 2007). However, with improved electrode designs and surgical technique, indications for cochlear implants have extended to those who have essentially good, or aidable, low-frequency hearing and severe high-frequency loss above 1000 Hz. With a less traumatic surgical approach, low-frequency hearing can be preserved, resulting in low-frequency auditory perception and mid- to high-frequency electric perception (Gantz and Turner, 2003; Adunka et al, 2004a; Adunka et al, 2004c; Gstoettner et al, 2004; Kiefer et al, 2004; Turner et al, 2004; Kiefer et al, 2005; Gstoettner et al, 2008; Gantz et al, 2009).

Several studies have shown that patients listening in the electroacoustic stimulation (EAS) condition perform better in background noise and have improved music appreciation as compared to those in the implant-only condition (Turner et al, 2004; Skarzynski et al, 2006; Baumgartner et al, 2007; Behr et al, 2007; Lorens et al, 2008; Gantz et al, 2009; Skarzynski et al, 2009). Gantz and colleagues used a short electrode to demonstrate the feasibility of hearing preservation in cochlear implantation. Traditional long electrode users have shown poor pitch perception as compared to normal-hearing persons, especially in complex tasks such as music perception. Acoustic low-frequency hearing is important for pitch and spectral resolution. In this initial study 13 volunteers were implanted to a depth of 6 to 10 mm from the cochleostomy (Gantz and Turner, 2004; Gantz et al, 2004; Gantz et al, 2006). Following implantation, their ability to recognize familiar melodies was significantly more accurate than that of standard cochlear implant users. Furthermore, they performed better in speech in noise than the standard implant users. Another study done by James and colleagues showed improved speech recognition in noise with the EAS approach. The Nucleus Contour Advance™ was implanted in 12 patients with insertion depths ranging between 17 and 19 mm. An in-the-ear hearing aid was fit in the ipsilateral ear to amplify the preserved low frequencies. They measured a 20% improvement with speech in quiet along with a 3 dB improvement in signal-to-noise ratio (SNR). Subjectively, patients were very satisfied with the bimodal hearing (James et al, 2005). Garcia-Ibanez and colleagues (2009) implanted the Nucleus Contour Advance up to 17 mm for the purpose of preserving residual hearing. They found that hearing thresholds were measurable postoperatively in 71–86% of their subjects. Thirty-six percent of these patients had preservation of thresholds within 10 dB of their preoperative thresholds, and approximately 67% had preservation within 20 dB HL of the preoperative thresholds (Garcia-Ibanez et al, 2009). Hearing preservation was thus attainable with a variety of different electrode designs with insertion depths to approximately the 1000 Hz region of the cochlea.

The purpose of our study was to evaluate the potential of deeper-insertion cochlear implantation. Potential benefits of this approach include increasing the frequency coverage of the cochlea while preserving residual structure. This may be beneficial in terms of ensuring survival of neurotrophin-producing cells in the cochlear apex and may preserve balance function in the implanted ear.

METHOD

Surgical Approach

The extended round window approach was used in all cases. After performance of a mastoidectomy and facial recess (posterior tympanotomy) approach to the middle ear, all bone dust was irrigated out of the wound. Hemostasis was obtained, and 0.5 cc of Decadron 10 mg/ml was applied to the round window niche. The bony overhang of the round window niche was then carefully removed with a 1 mm diamond burr, and the round window was clearly visualized by testing the round window reflex. For the extended round window approach the bone anterior inferior to the round window was removed, keeping the scala tympani endosteum intact. The wound was once again irrigated, and Healon™ was used to cover the round window and endosteum. The endosteum was then opened with a small pick, and the implant electrode was carefully inserted. For round window insertion, the implant was inserted through an incision in the anterior midportion of the round window (Fig. 1). All patients were implanted with Med-El PuslarCI100 using either the standard (H) or medium (M) electrode arrays. These electrodes have 12 contacts distributed over 28 or 24 mm, respectively. The opening into the scala tympani was sealed with a small piece of fascia, and the wound was closed. Depth of the electrode was confirmed radiographically.

Subjects and Outcomes Measures

A total of 18 implant candidates, 5 males and 13 females, with varying degrees of hearing loss were recruited. Ages ranged from 26 to 84, with a mean age 63.17. Thresholds ranged anywhere from normal sloping to profound to severe to profound. Word discrimination scores tested via the Hearing in Noise Test (HINT) sentence test fell within Food and Drug Administration (FDA) or Medicare guidelines for implantation in the best-aided condition. FDA guidelines state that understanding ability must be less than 50% in the ear to be implanted and no better than 60% in the contralateral

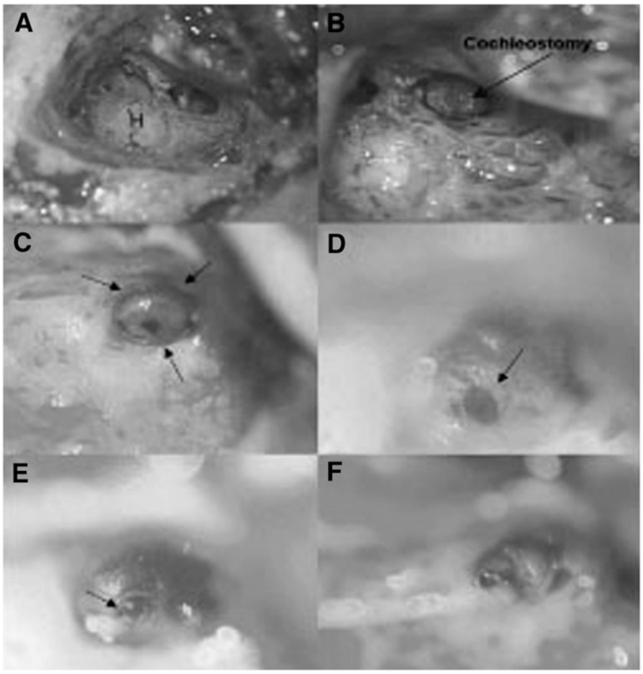

Figure 1. Comparison of standard cochleostomy to round window insertion of a cochlear implant. For all cochlear implant approaches, the middle ear is approached via a facial recess approach/posterior tympanotomy (A). The cochleostomy is placed anterior to the round window (B). To approach the round window, the posterior tympanotomy (arrows, C) needs to be significantly wider. Next the bony overhang over the round window niche is removed with a 1 mm diamond burr, allowing complete visualization of the round window (arrow, D). The round window is covered with a thin layer of hyaluronic acid, and a small slit is made with an arachnoid knife (E). Finally the electrode is inserted (F), and the niche is sealed with a tissue graft.

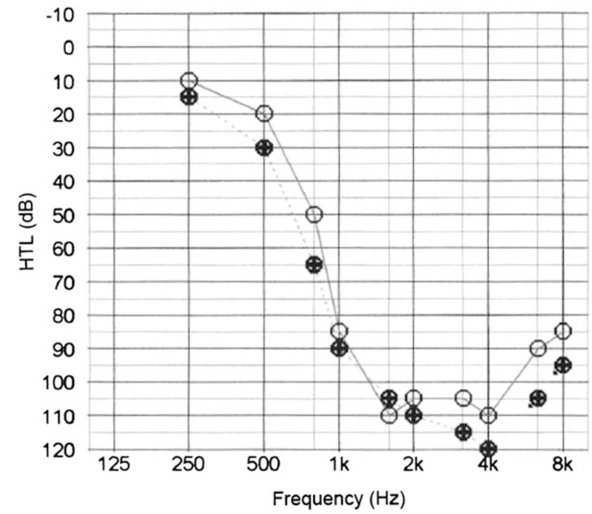

Figure 2. Example audiogram pre (open circle) and post 24 mm implant (crossed circles) performed with a Med-El standard electrode. Insertion was carried out via a round window approach and had remained stable over 18 mo.

ear. Medicare's criteria state that speech understanding must be less than 40% bilaterally (Huart, 2009). The etiology of the hearing losses for the participants is unknown. Prior to implantation, all patients underwent blood testing to screen for autoimmune inner ear disease and had an MRI scan to rule out retrocochlear losses. Laboratory work was negative for autoimmune inner ear disease for all patients. MRI scans were also negative for cochlear malformation or retrocochlear pathology. The participants further denied any family history of hearing loss.

Informed consent was obtained prior to testing, and the protocol was approved by the University of Kansas Medical Center human subjects board. Pure-tone thresholds were obtained before surgery and two weeks postoperatively using insert earphones. An example of a pre and post audiogram is shown in Figure 2. The HINT and consonant–nucleus–consonant (CNC) word tests were administered in order to evaluate word-discrimination and word-recognition abilities. Sentences and words were presented with the patient seated in a sound-treated booth at 0 degrees azimuth at 70 dB SPL via recorded voice. The tests were administered in three conditions: acoustic only, implant only, and electric plus acoustic (EAS) in the ipsilateral (implanted) ear. To ensure that the patient was only hearing with electric stimulation, both ears were plugged with an earplug to eliminate any acoustical hearing. The ipsilateral earplug was then removed for the EAS condition. A contralateral hearing aid was not used in any of the patients in order to isolate the implanted ear. HINT testing was also performed in a +10 dB SNR in the electric and EAS conditions. After the sentences or words were presented, the patients were asked to repeat back any words that they may have understood and were encouraged to guess if unsure. Scores were based on words repeated back correctly in each sentence and divided by the total number of words possible.

Statistics

Outcomes were analyzed by Kruskal Wallis and Mann-Whitney testing administered using SPSS v. 17.0. Significance was set at $p < .05$.

RESULTS

Residual hearing was preserved in all 18 patients. The change in pure-tone averages was calculated using 250, 500, and 750 Hz. This change was graphed as a function of insertion depth and is shown in Figure 3. There is no clear relationship between insertion depth and amount of hearing preserved, indicating that the apical region of the cochlea can be reached without compromising hearing thresholds ($r^2 = 0.091$). The advantage of residual hearing used in conjunction with electric

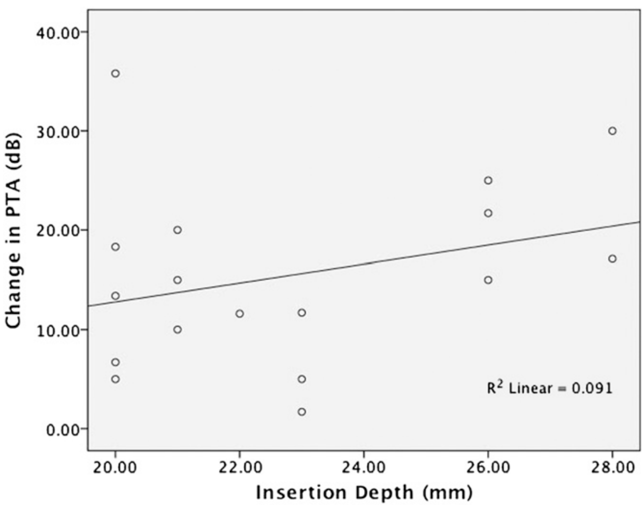

Figure 3. Effect of electrode insertion depth on postoperative change in hearing. Using a round window insertion approach, there was no clear relationship between implant insertion depth and change in postoperative pure-tone average (PTA). The PTA was chosen as an outcome measure since all of the patients we implanted had residual low-frequency hearing. This demonstrates that access to the low- to midfrequency region of the cochlea is possible with hearing preservation.

stimulation was measured using the HINT test presented in quiet and +10 dB SNR as well as CNC word lists. Outcomes for the quiet condition are graphed in Figure 4. The preoperative HINT score in quiet had a mean of 24.3% correct. When testing in the electric-only condition, the mean score improved to 75.3% correct. When presented in the acoustic plus electric condition, the mean score was 69.9% correct. This represents a significant difference in the aforementioned three conditions ($p \leq .001$). The Mann-Whitney test was then performed to find that there were statistical differences in the preoperative and electric-only conditions ($p \leq .001$) as well as the preoperative and EAS conditions ($p \leq .001$). There was, however, no statistical difference between the electric and EAS conditions ($p = .573$).

Patients tested in the +10 dB SNR condition showed preoperative scores of 25.7% correct. Mean scores improved to 64.33% correct in the electric-only condition and to 65.89% correct in the EAS condition. The Kruskal-Wallis test confirmed a significant difference between groups ($p = .001$). Similar to the electric-only condition, the Mann-Whitney test showed a significant difference between preoperative scores and postoperative HINT in the electric-only condition ($p = .001$) in addition to significant differences in preoperative and postoperative HINT scores in the EAS condition ($p \leq .001$). There was no statistical significance evident when the two postoperative conditions were compared ($p = .955$; Fig. 5).

Speech understanding outcomes were also measured using CNC word lists (Fig. 6). Preoperative mean scores were 16.67% correct out of 50 words. Scores improved to an average of 38% correct in the electric-only condition

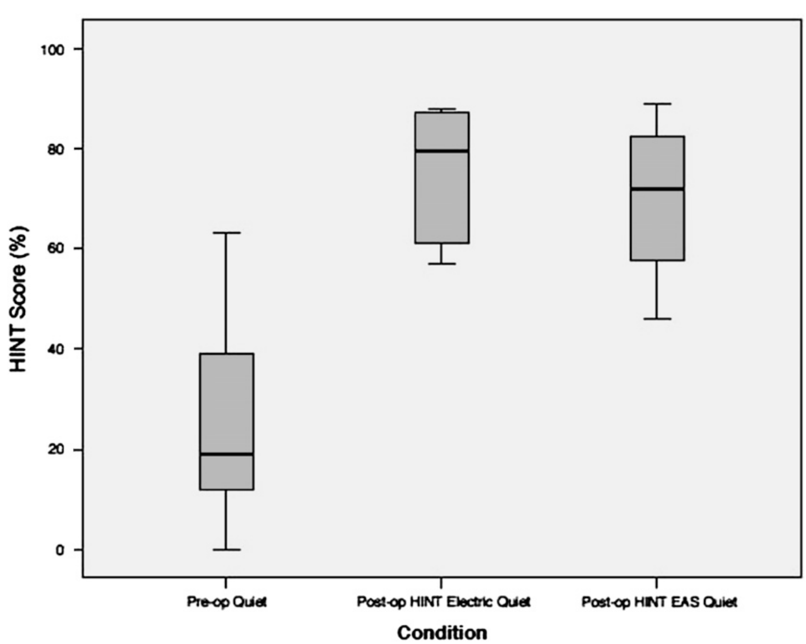

Figure 4. Postoperative performance in quiet. This box plot summarizes the preoperative and postoperative Hearing in Noise Test (HINT) scores recorded in two conditions: (1) electric only and (2) electroacoustic stimulation (EAS). The black line represents the median HINT score. The boxes represent the 25th through the 75th percentile, whereas the lower and upper lines represent the standard deviation. Preoperative HINT scores had a median of 19%. Postoperative activation of the implant resulted in significant improvement in HINT scores for both the electric-only and EAS conditions. Electric-only scores had a median of 79.5%, and EAS HINT scores averaged 72%. There is no statistical difference between the electric-only and EAS conditions.

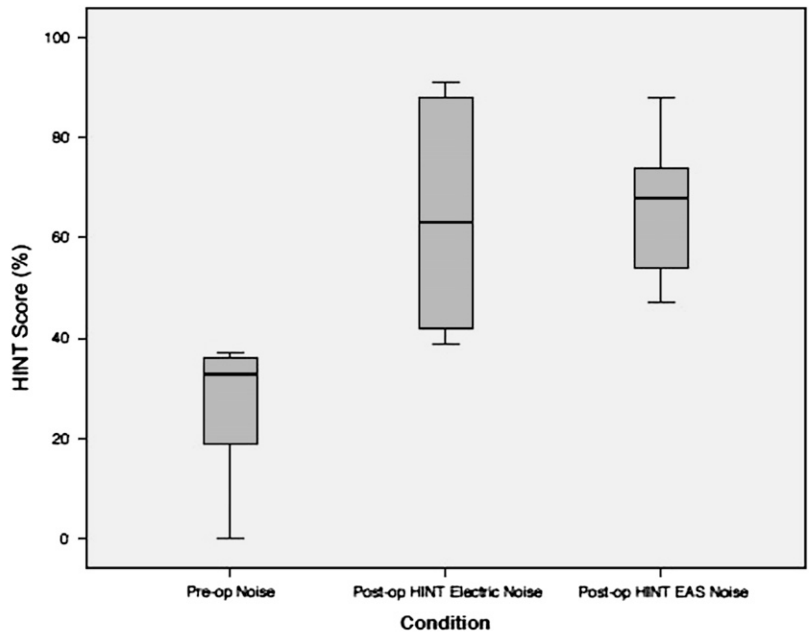

Figure 5. Postoperative performance in noise. The box plot summarizes the pre- and postoperative Hearing in Noise Test (HINT) scores when presented in +10 dB signal-to-noise ratio. Preoperative scores demonstrated a median of 33%. Postoperative median scores were 63% and 68% in the electric and electroacoustic stimulation (EAS) conditions, respectively. The black line represents the median HINT score. The boxes represent the 25th through the 75th percentile, whereas the lower and upper lines represent the standard deviation. There was statistical significance in preoperative scores and the electric condition and preoperative scores and the EAS condition; however, there was no statistical difference in the electric and EAS conditions.

and to 47.1% in the EAS condition. Using the statistical tests mentioned above, results were consistent in that a statistical difference was found when comparing preoperative scores to postoperative scores in the two different conditions: (1) electric only, $p = .004$; (2) EAS, $p = .000$. However, no statistical difference was found when comparing the two postoperative CNC scores ($p = .193$).

DISCUSSION

In our group of patients, insertion of a thin electrode array via a round window approach was able to achieve hearing preservation. In contrast to other studies, we were able to achieve insertions of up to 28 mm with preservation of residual hearing (Fig. 3). In temporal bone studies, insertions that extend beyond 360 degrees (about 20 mm) showed increased cochlear trauma (Adunka and Kiefer, 2006). This was not observed in this series of patients since preservation of hearing serves as a proxy for evaluation of damage apical to the implant. One potential advantage of a deeper implantation is the ability to stimulate apical regions of the cochlea should hearing deteriorate over time.

Although short electrodes have been shown to be beneficial for speech understanding, deep insertions also have advantages, even for hearing preservation candidates. With limited access to the apical regions, the implant may be less effective in the event that the residual hearing is lost. Frequency allocations may be reassigned to the apical end; however, Reiss and colleagues (Reiss et al, 2007; Reiss et al, 2008) suggest that it may require a significant amount of time for the users to adjust to the frequency shift.

Gstoettner and colleagues (2004) found that deeper insertions could be achieved with the Med-El electrode arrays. This is significant since implantation to 20 mm is predicted to give patients electrical hearing through the 1000 Hz range, leaving the apical, hearing portion of the cochlea intact. Twenty-one patients were implanted with insertion depths ranging from 18 to 24 mm. Hearing was successfully preserved in 85.7% of the patients. Compared to the electric-only condition, all patients performed better in the EAS condition. A key component to preserving hearing in these cases was found to be an atraumatic ("soft") surgical approach (Gstoettner et al, 2004).

Newer electrode designs have tried to combine thin, atraumatic insertion with implantation to at least 20 mm (Adunka et al, 2004b). Potentially even deeper insertion into the cochlea with limited damage is possible. Baumgartner and colleagues implanted 23 adults with a specialized flexible 31 mm electrode manufactured by Med-El. The electrode features five single contacts in the apical end and seven pairs across the rest of the array. With this design, the apical end is much thinner. Hearing preservation was achieved in four cases up to 12 mo. Improvements were seen with monosyllabic words as well as hearing in noise (+10 dB SNR), with mean scores of 54% and 57%, respectively.

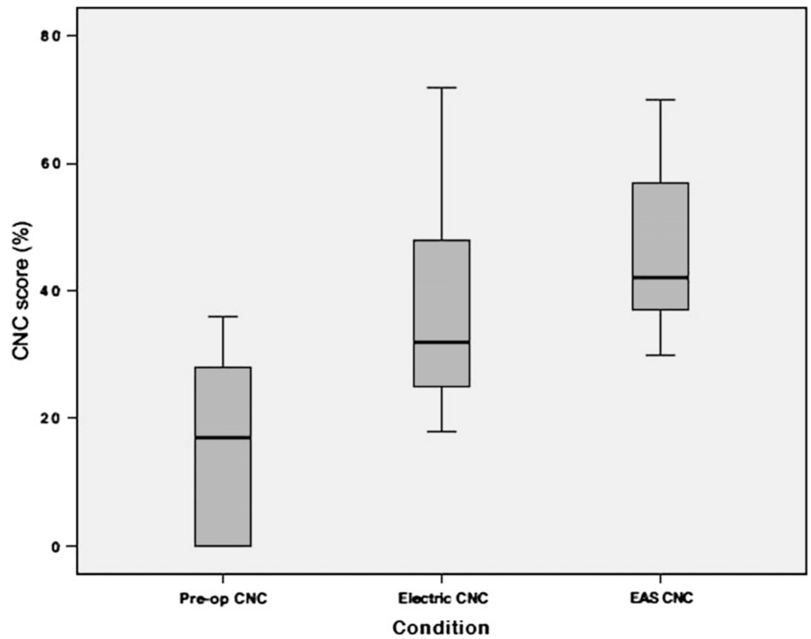

Figure 6. Change in consonant–nucleus–consonant (CNC) recognition after implantation. Preoperative scores had a median of 17% correct. Postoperative scores improved to a median of 32% correct in the electric-only condition and 42% in the electroacoustic stimulation (EAS) condition. The black line represents the median CNC score. The boxes represent the 25th through the 75th percentile, whereas the lower and upper lines represent the standard deviation. There is a significant difference in the preoperative score vs. both the postoperative electric-only and EAS conditions; however, there was no significant difference in the two postoperative conditions.

Findings from our study indicated a significant improvement in speech understanding with the use of a cochlear implant in patients with residual hearing compared to their performance with standard hearing aids. Interestingly, the residual acoustic hearing did not improve speech discrimination scores significantly over electric hearing alone. These results are contrary to the literature that suggests that electric acoustic hearing is superior to electric hearing alone. It is important to note that there was a large range in scores whereby some individuals did perform as well in the EAS condition as compared to other studies that have been published. Several variables may have played a role in speech discrimination, for example, whether the patient was properly fit with standard hearing aids and whether the ear was properly stimulated prior to surgery. Age may have also played a role, in that the geriatric population may have more difficulty in distinguishing and adjusting to the mixed signals. Our age range was quite large, which may have influenced the mean scores.

Additional theoretical benefits include the potential for the preservation of structures apical to the implant. Recent temporal bone histopathology studies have demonstrated degeneration of both supporting cells and spiral ganglion neurons apical to the tip of an implant when compared to the contralateral, unimplanted side (Khan et al, 2005). If an implant electrode migrates through the scala media to the scala vestibule, as suggested by Finley and colleagues (2008), the resulting inflammation may result in degeneration of residual functioning portions of the cochlea and poorer outcomes. Some animal studies have also suggested that traumatic insertions affected spiral ganglion survival (Leake et al, 2008). Lack of hearing loss with deeper insertions suggests that it is possible to maintain the apical structures of the cochlea while being able to electrically stimulate very low frequencies.

CONCLUSION

Atraumatic cochlear implantation has shown benefit in preserving hearing. Contrary to other studies we have not seen a difference in the performance of our patients in the electric-only versus the EAS condition in background noise. This is mainly due to our patients' excellent performance in the electric-only condition. Future studies will focus on understanding the physiological differences that affect performance in these different groups.

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Expanding cochlear implantation to patients with residual mid and high frequency hearing

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Aim. **Cochlear implantation has long been indicated to restore profound hearing loss and is the most effective intervention for patients who do not benefit from standard amplification. Recent innovations in implant design and surgical technique have expanded and allowed implantation with preservation of residual hearing for those patients with ski-slope hearing loss and poor discrimination. In these cases the goal is shallow to mid depth implantation in order to restore as much hearing as possible while preserving apical low frequency acoustic hearing.**

Methods. **We report a series of ears with up sloping hearing loss deeply implanted with custom thin electrodes in which residual hearing is preserved. These patients were poor hearing aid users and required restoration of hearing in the low frequencies.**

Results and conclusion. **This represents a change in the previous practice of avoiding implantation of areas with residual hearing. These cases demonstrate the feasibility of preservation of acoustic hearing in all frequency regions and represent an opportunity to further expand cochlear implantation to novel patient populations.**

Key words: Cochlear implantation - Hearing loss - Hearing loss, high-frequency.

Cochlear implantation was devised and traditionally used as a means to restore hearing to individuals with profound hearing loss who could not benefit from hearing aids. More recently, there has been a push towards implanting patients with ski slope hearing losses while preserving residual acoustic hearing. In order to preserve their residual hearing, surgical techniques and cochlear implant electrodes have been devised to inflict minimal trauma to the more apical regions of the cochlea where deeper tones are processed.[1-3] These patients are then rehabilitated using acoustic input for the residual low frequency hearing and electrical input for the middle to high frequencies. The combined input is referred to as electro acoustic stimulation (EAS) and represents a significant change in how we approach patients with residual hearing since prior to the establishment of these techniques, cochlear implantation resulted in loss of all residual hearing in the ear being implanted.

While cochlear implant patients may perform reasonably well in quiet environments, patients using EAS have the advantage in environments with competitive speech. EAS patients are able to recognize and suppress the competitive speech by their ability to process lower frequency speech sounds. This is referred to as glimpsing,[4] which has also resulted in better music appreciation as compared to traditional cochlear implant (CI) users. Alternate approaches to improving speech understanding is the use of novel coding strategies such as fine structure speech processing (FSP) which have also shown increased perception of speech.[5-8] Use of these strategies requires an implant that can stimulate the apical third of the cochlea.

Key components of successful hearing preservation are surgical technique and surgeon experience.

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Hearing preservation can be achieved through a carefully placed cochleostomy,[9] however round window insertion instead of a cochleostomy appears to be gaining widespread acceptance.[10, 11] Theoretical benefits to this approach have been described. Decreased necessity for drilling likely lowers acoustic trauma, infection rate, leakage of perilymph, and entrance of bone dust into the cochlea. In addition, the round window niche provides ease of sealing the cochleostomy around the electrode. Other techniques described in soft CI surgery include deferring the cochleostomy until immediately before electrode insertion, no suctioning of perilymph, gentle electrode insertion, and potential use of a lubricant to facilitate insertion.[12, 13] Although these are elegant techniques and provide obvious theoretical limits to cochlear damage, they lack evidence for superior outcomes. Rather it seems that duration of deafness and patient age may be predictors of success.[14] Introduction of blood into the cochlear environment is another concern during cochlear implant. Intrascalar administration of blood into guinea pig ears has been shown to result in both transient and permanent hearing loss.[15]

Application of these techniques has made hearing preservation a feasible outcome after cochlear implantation in multiple centers. Initial studies with 20 mm insertion depth had an 85% success rate of preserved low frequency hearing in 21 cochlear implant patients with shallow electrode devices and since then these results have been replicated in multiple centers.[16-20] Insertion depth appears not to increase the incidence of hearing loss,[21-23] opening the possibility of preserving hearing in most types of hearing loss. In this paper we report the use of the aforementioned techniques to implant a series of ears with rare upsloping hearing loss. These patients had significant residual hearing above 4000 Hz. The goal in these cases was to achieve an implantation that could take advantage of fine structure processing (FSP), while preserving sound awareness in the high frequencies.

Materials and methods

Patient selection: Patients were identified with up sloping hearing losses that met standard implant selection criteria (PTA>70 dB; SD<60% in better hearing ear, <50% in the ear to be implanted reference). Preoperative testing included a MRI with gadolinium of the brain and internal auditory canals; full pure tone audiometry, and speech testing in the best aided condition using HINT, CNC andAZ Bio tests performed in quiet and in noise. Postoperative testing using the same test battery was performed at 3, 6, 9 and 12 months after implantation.

Surgical approach

The extended round window approach was used in all cases. After performance of a mastoidectomy and facial recess (posterior tympanotomy) approach to the middle ear, all bone dust was irrigated out of the wound. Hemostasis was obtained and 0.5 cc of decadron 10 mg/mL was applied to the round window niche. The bony overhang of the round window niche was then carefully removed with a 1 mm diamond burr and the round window clearly visualized by testing the round window reflex. For the extended round window approach, the bone anterior and inferior to the round window was removed, keeping the scala tympani endosteum intact. The wound was once again irrigated and Healon™ was used to cover the round window and endosteum. The endosteum was then opened with a small pick and the implant electrode is carefully inserted so that the 12th contact is inside the round window membrane (Figure 1). All patients were implanted with the MedEl Sonata$_{TI}$100 using custom made electrode arrays designed for these patients. These electrodes have 12 contacts distributed over 26.5 mm in a 31.5 mm long array. The apical 5 electrodes are single contacts with an electrode diameter of 0.5 x 0.8 mm. The opening into the scala tympani was sealed with a small piece of fascia and the wound closed. All patients underwent intraoperative imaging to ensure that there were no hairpin turns or kinks in the array. Depth of the electrode was determined by imaging as previously described.[24] All patients were discharged the same day with oral antibiotics and a 10 day course of methylprednisolone. Patients were activated 1 month post operatively and programmed with the FSP speech coding strategy.

Results

Case 1

The patient is a 48-year-old female with a longstanding history of bilateral non- syndromic hearing loss. There was no family history of hearing loss. Her

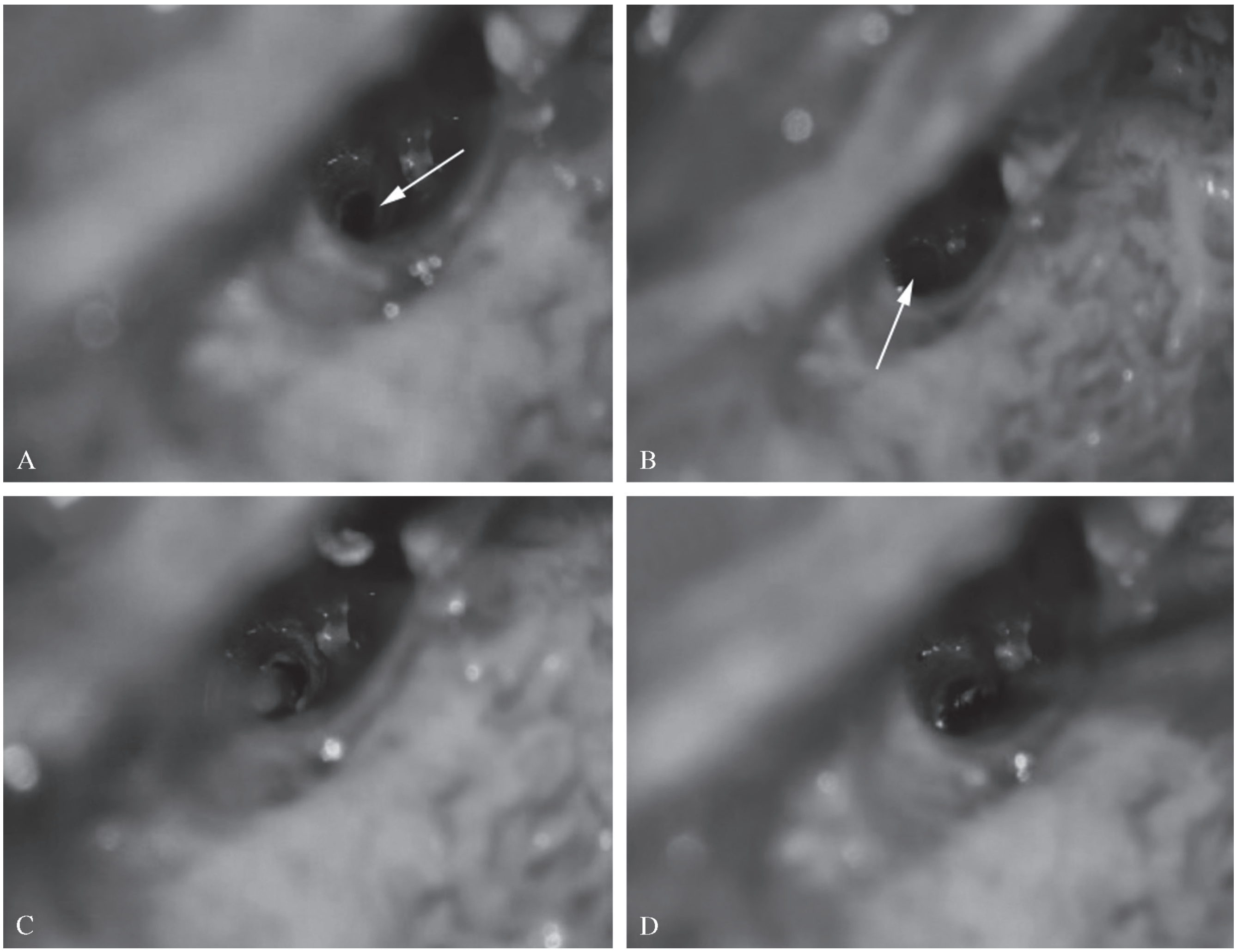

Figure 1.—Surgical approach for hearing preservation implantation. A wide facial recess is drilled exposing the round window niche (A, arrow). It is important to lower the facial ridge to the greatest degree possible so that the optimal insertion angle for the long electrode can be obtained. Care must also be taken to avoid contact with the incus while drilling. Using a 1 mm diamond bur the round window niche overhang is removed (B). Exposure of the round window is checked by palpating the stapes and looking for a round window reflex. This is not seen if there is still pseudomembrane over the round window. The round window is covered with hyaluronic acid (C) and opened. This allows the insertion of the electrode (D) with minimal contamination of the perilymph with blood.

initial audiograms revealed profound rising to moderate? up-sloping hearing loss (Figure 2A). Preoperative CNC score in then left ear was 5%, HINT in quiet 40% and HINT in noise (+10dB SNR) 0%. She underwent implantation with a custom Mel-El device with a thin electrode and soft surgery technique. Pre and postoperative audiograms are shown in Figure 2A, B. Thresholds remained stable throughout testing. At six months post implant activation HINT scores revealed 95% in quiet and 85% at +10 dB. CNC scores at six months were 90%. Interestingly, addition of a hearing aid in the contralateral ear (bimodal condition) did not result in improvements in scores (HINT 90%, HINT + 10dB 85%, CNC 85%). Scores and hearing thresholds have remained stable for 24 months post implantation. Analysis of CT scans (Figure 3) and reconstructed Stenvers view x rays at 1 year post implantation demonstrate that the electrode position has remained stable at a 680º insertion angle.

Case 2

After long term stable performance with her unilateral implant, the patient requested implantation in her contralateral ear. She underwent implantation using a similar device in the right ear again using soft surgery technique. Pre and postoperative audiograms are shown in Figure 2C, D. Similar to the left ear, the patient experienced substantial preservation of hearing across all frequencies. Only 20-15 dB loss occurred at frequencies less than 1500 Hz. Based on bone conduction thresholds, this appeared to be a conductive loss (Figure 2D). For her right implant alone CNC scores at 6 months were 84%, HINT in quiet =100%; HINT +10 dB=100%. Again using CT temporal bone to construct a three-dimensional image implant position was determined. Measurements for the right ear show rotational angle of 700 degrees. Figure 3 shows CT scans of both temporal bones after implant insertion.

Case 3

Patient presented with a >15 year history of non syndromic up sloping hearing loss. Preoperative CNC test showed a score of 26%; AzBio test =39%. Hearing tests at 1 months post implantation demonstrated preservation of hearing with the presence of a conductive hearing loss in the low frequencies (Figure 4B, C). Overall insertion depth based on estimation from imaging was 700^{O} (Figure 4A).

Discussion and conclusions

Hearing preservation cochlear implantation developed from the use of short (10 mm) electrodes that were implanted in the basal turn of the cochlea in attempt to preserve the residual low frequency hearing.[25] Several pioneering studies in the field demonstrated that 20mm insertions to the 1000 Hz region could be performed without sacrificing residual cochlear function.[26] In all of these cases the electrode array was inserted into the region of the cochlea that was devoid of residual hearing. Recent studies have demonstrated that there was no relationship between the depth of insertion and hearing preservation if flexible electrodes and soft surgery techniques were used.[21, 27] Following this logic, deep implantation in patients with atypical up sloping hearing loss should be feasible as demonstrated in the cases described above. An interesting observation in these cases is the 10-20 dB conductive hearing loss across the low frequencies observed in two of the three cases (Figures 2, 4). Potential causes could include contact between the implant and the ossicular chain versus a mechanical effect of the electrode within the scala tympani. We have not observed a similar degree of conductive hearing loss in patients implanted for ski slope hearing loss so the latter explanation is more likely.

Use of soft surgery techniques previously described coupled with custom thin electrode devices may provide the opportunity to safely preserve hearing in these atypical up sloping hearing loss patients. Several key factors have been identified as important in consistently achieving hearing preservation. Although hearing preservation has been described using the advanced off stylet technique in modiolar hugging implants, mechanical studies demonstrate that more flexible electrodes lead to lower degrees of insertion trauma.[28, 29] This is particularly important since there is some evidence that over insertion with less flexible electrodes can lead to poorer implant outcomes, even when considering electric only conditions.[30] Therefore, when targeting the low frequency regions of the inner ear for stimulation, a long and atraumatic electrode is required. We used a custom electrode that is based on the Med-El flex design. The apical 5 electrodes are single contacts that create a flexible atraumatic tip. The basal end to the electrode features? extra reinforcement to make it easier to advance into the apical third of the cochlea. Other important factors to consider are the surgical approach. We have implanted all of these electrodes via an extended? Round window approach. Variability in the orientation of the round window and the initial sharp turn the electrode needs to navigate the hook region, have been cited as potential disadvantages of using the round window as an entry point to the inner ear.[10, 11] A cochleostomy or removal of the bony ridge anterior to the round window have been advocated to overcome these obstacles. As with other hearing preservation cases, care was taken to avoid blood and bone dust from entering the inner ear. All patients also received intraoperative and post operative steroids since animal studies strongly suggest that the use of steroids can mitigate implant related damage.[31, 32]

Patients with significant residual hearing have previously faced a dilemma; implants offered electrical stimulation across all frequencies but at the price of

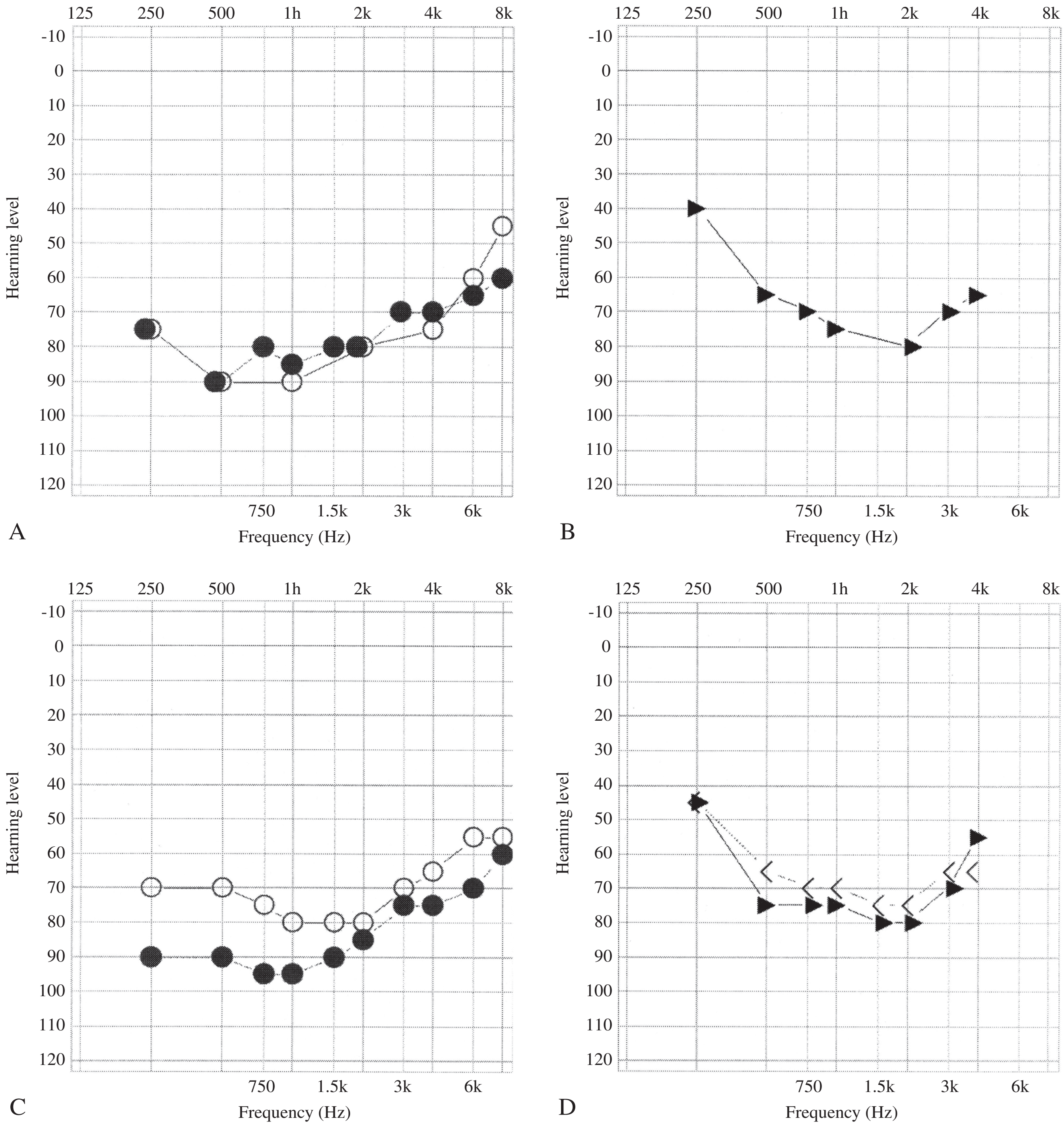

Figure 2.—Pre and postoperative audiograms for cases 1 and 2. Preoperative pure tone thresholds are shown as open circles. Post operative pure tone thesholds are shown as closed circles. As seen in Figure 2A, case 1 demonstrates excellent preservation of pure tone thresholds. Post operative masked bone conduction scores (B) demonstrate several suprathreshold responses in the low frequency region. Case 2 pre- and postoperative pure tone thresholds are seen in C. There is a 20 dB change in hearing in the low to mid frequencies. This is most likely a conductive hearing loss as demonstrated by the masked bone thresholds (D).

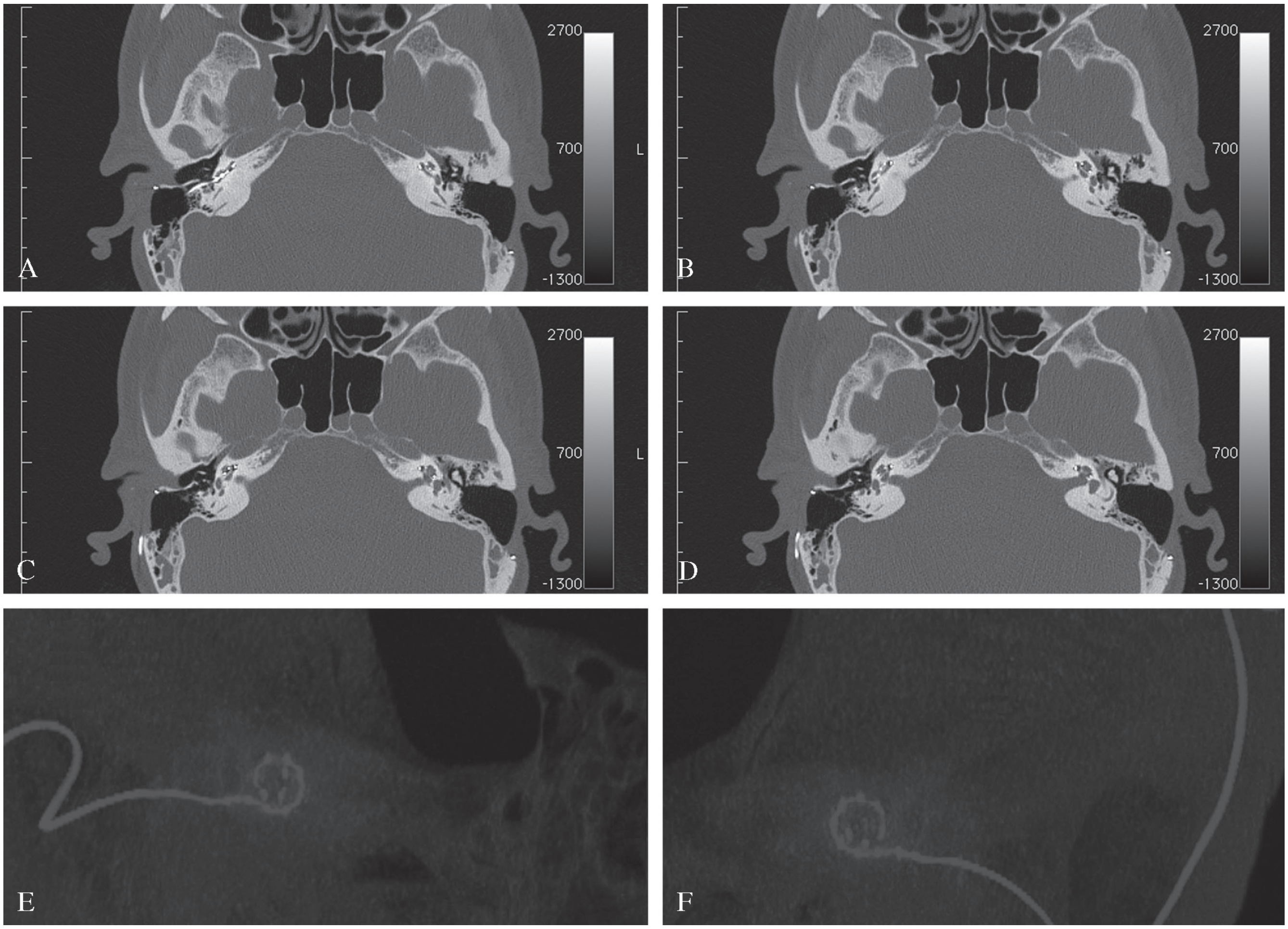

Figure 3.—Imaging of cases 1 and 2 using post operative CT (A-D) and Stenvers projections based on CT data for case 1 (F) and case 2 (E). As can be seen on the serial CT sections, the electrode contacts are distributed throughout the length of the cochlear. The individual DICOM data was then projected as Stenvers views using OsiriX software. These projections demonstrate a 680º insertion in case 1 (F) and a 700º insertion in case 2 (F).

loss of residual hearing. These cases may represent a step toward a solution for patients who are fearful of losing residual hearing or who want the benefit of acoustic hearing when they are not wearing their implant. This opens the possibility of implantation to a wide range of patients who have significant residual hearing but perform poorly with hearing aids. A key to identifying these patients is expanding the use of the minimum test battery and raising awareness of audiologists and physicians of current implant criteria. Additionally, deep implantation in up sloping hearing loss allows for the opportunity of examining pitch rate/place perception with electric/acoustic hearing across multiple frequencies in the same ear. Because the patients experience electrical stimulation in areas with acoustic hearing, the electrical stimulation can be precisely mapped. Variation in rate of stimulation can then be correlated with perceived pitch and the acoustic residual hearing can be used as a same ear control. Results from these studies may provide finer tuning of cochlear implant devices in the future.

Riassunto

Ampliamento dell'impianto cocleare in pazienti con residuo uditivo a media e alta frequenza

Obiettivo. Da molto tempo l'impianto cocleare è indicato per ripristinare la sordità grave ed è l'intervento più

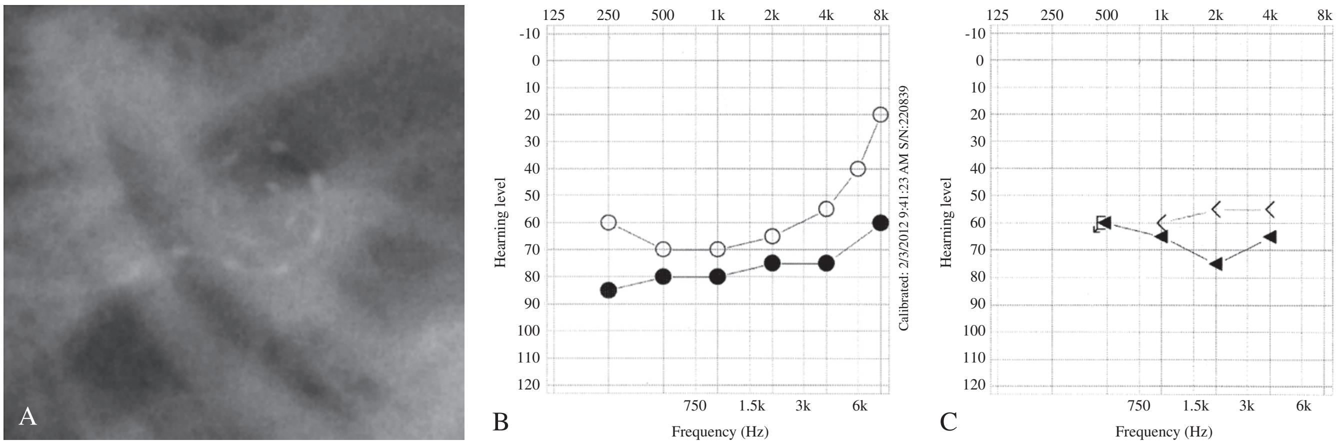

Figure 4.—The postoperative Stenvers view for case 3 can be seen in A. Full insertion of the custom 31.5 mm electrode results in a 700 degree distribution of the electrode contacts that are distributed over 28.5 mm of the electrode length. Pre and post operative pure tone thresholds show a 10 -20 dB hearing loss resulting from this insertion (B). Measurement of bone conduction thresholds (C), suggests that at least for 500-4000 Hz measurements the postoperative loss is predominantly a conductive loss.

efficace per i pazienti che non traggono beneficio dall'amplificazione standard. Le recenti innovazioni del design dell'impianto e della tecnica chirurgica hanno ampliato e consentito l'impianto, con conservazione del residuo uditivo, nei pazienti colpiti da perdita dell'udito in discesa e scarsa discriminazione. In questi casi, l'obiettivo è l'impianto a bassa-media profondità, allo scopo di ripristinare il più possibile l'udito, preservando l'udito apicale a bassa frequenza acustica.

Metodi. Riportiamo una serie di casi, con perdita dell'udito crescente, con impianto profondo di elettrodi sottili su misura, in cui si è conservato il residuo uditivo. Questi pazienti erano scarsi utilizzatori di apparecchi acustici e necessitavano del ripristino dell'udito alle basse frequenze.

Risultati e conclusioni. Questo trattamento rappresenta un cambiamento rispetto alla pratica precedente di evitare l'impianto di aree con residuo uditivo. Questi casi dimostrano la fattibilità di conservazione dell'udito acustico in tutte le regioni di frequenza e rappresentano un'opportunità per ampliare ulteriormente l'impianto cocleare a nuove popolazioni di pazienti.

Parole chiave: Impianto cocleare - Udito, perdita - Udito, perdita, alta frequenza.

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Electric to Acoustic Pitch Comparisons in the Same Ear: A patient with CI deep insertion and preserved residual hearing across multiple frequencies.

INTRODUCTION:

Numerous studies have documented changes in pitch perception with manipulations of stimulation parameters using electrical stimulation (Vermeire, 2008, Carlyon, 2010). In addition to the effects on pitch perception due to place of stimulation, increases in pulse rate have been shown to result in higher pitch percepts up to a few hundred pulses per second across the electrode array. Studies have also made comparisons of pitch elicited by electric stimulation to one ear compared to acoustic stimulation to the contra-lateral hearing ear (Dorman, 2007). In the cases of CI recipients without residual hearing, the studies have been restricted to procedures providing pitch estimates or scaling procedures that don't provide a measure of the overall range of percepts. (Boyd, 2011) and in the cases of comparing CI electrical stimulation to hearing in the contralateral ear results have been confounded by the ability of the subjects to compare the pitch of acoustic signals to the electrical signals of the CI.

This study explored the rare opportunity of examining Pitch Rate/Place perception with electric/acoustic hearing across multiple frequencies in the same ear.

SUBJECT

The subject for this investigation met criteria for CI and underwent cochlear implantation using a MED-EL custom long electrode and a soft-surgery hearing preservation, round window technique. An insertion depth of 28 mm was achieved as seen with post-operative imaging and indicating an insertion angle of 700°. Audiometric thresholds, pre and post implantation are seen in Figure 1.

Figure 1

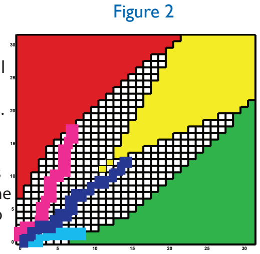
	250 Hz	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz	8000 Hz
Pre-op	75	90	90	80	75	60	45
Post-op	75	90	90	75	70	65	70

METHODS

Pure tone signals were generated in 100 Hz increments for the frequency range of 100-8200 Hz. Each tone had an onset and offset ramp of ~ 5 ms with a stimulus duration of 500 ms. Electrical pulse trains of 500 ms at a 60% loudness of the dynamic range and using stimulation rates of 100, 200, 300 and 1100 pps were loudness balanced to the pure tone(s) that best approximated the pitch elicited by the electrical signal. A sequential analysis pitch ranking procedure (Fig 2.) was then completed. Multiple pairs of electric and acoustic signals were tested simultaneously. Once statistical significance was reached on a particular pair, the acoustic signal was then adjusted in frequency in order to bracket the pitch percept of the electrical signal. This procedure was completed for each data point until a statistical match was found or the pitch was bracketed within a 100 Hz range.

The patient is presented with two signals in a randomized order and asked to indicate which has the higher pitch. This continues until a statistically significant outcome is achieved. Figure 2 illustrates the three possible outcomes. Each starts in the lower left-hand corner with a response noted as either to the right (green signal was higher) or upward (red signal was higher). For signals that are indistinguishable the responses would reach a trajectory falling into the yellow area. (Bross, 1952).

Figure 2

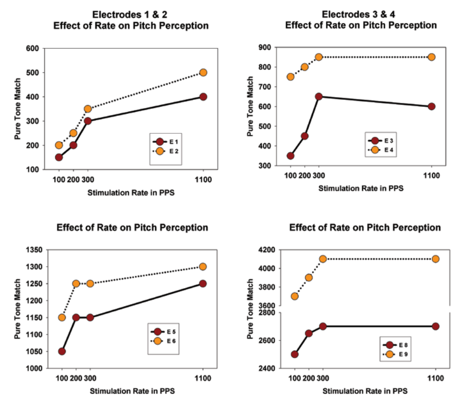


RESULTS

Decreases in the electrical stimulation rate resulted in decreases in pitch perception for each of the electrodes. For this subject, electrode pitch/rate saturation appears to occur at around 200 pps for electrodes 5 & 6. For the remaining electrodes, pitch/rate saturation appears at or above 300 pps as can be seen in Figure 3.

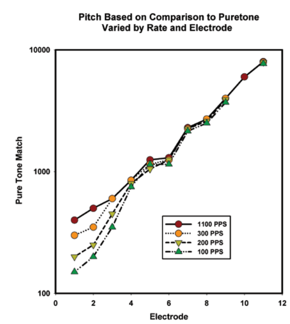
The decreases in pitch with decreasing rate are similar to those found by Baumann (2004) and Zeng (2002) however when provided with an acoustic match in the same ear, the amount of change in terms of cochlear position was much smaller than anticipated. Figure 4 shows the changes in pitch perception with changes in rate plotted against a log scale mimicking the cochlea. The results show that there is fairly close agreement between electrode position in the cochlea and place relating to Greenwood's map at stimulation rates above pitch/rate saturation. In addition, changes in pitch percepts due to decreases in stimulation rate are much more robust in the apical region of the cochlea.

Figure 3



Interestingly this patient subjectively reported that as stimulation rate was decreased on electrodes basal to E4, the sound acquired an increasing "buzzing sound" quality as opposed to the apical electrodes that remained tone like with decreases in rate. Preliminary testing on some of the apical electrodes revealed that the subject could not differentiate electric from acoustic stimulation independent of stimulation rate.

Figure 4



DISCUSSION

This subject presented a unique opportunity to compare both acoustic and electric pitch perception in the same ear and across a broad frequency spectrum. The results suggest that there is good agreement between Greenwood's map and electrode position within the cochlea as seen previously by Vermeire, (2008) and Carlyon (2010). The acoustic hearing in the same ear as the implant provided a quantifiable metric for establishing the size and spread of the perceptual intervals related to place and rate of stimulation. These results show that, for this subject, place pitch is the primary influence for pitch perception in the cochlear region basal to 1000 Hz and that both place and temporal cues result in changes of pitch perception in the apical region. The subject's report that electrical stimulation maintained a tone-like percept in the basal/mid cochlear regions only when signals were above pitch/rate saturation while changes in rate for the apical region did not adversely affect the tone quality provides some insight regarding the viability of temporal cues for different regions of the cochlea.

CONCLUSION

Electric place and temporal cues generate different pitch percepts depending on the region of the cochlea receiving the stimulation. Electrical stimulation exploiting the normal hearing process through the use of a long electrode array that extends deep into the cochlea coupled with stimulation strategies that can provide temporal and place cues can extend the range of pitch perceptions by CI recipients. The relationship of the electrode position to the Greenwood map further confounds the debate regarding dendritic vs. spiral ganglion cell stimulation as this patient has fairly robust survival of both cell populations as suggested by preserved residual hearing.

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Analysis of eCAP Growth Function and Speech Perception

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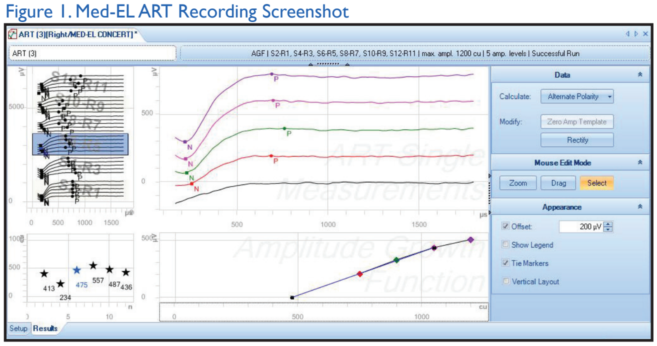
INTRODUCTION:

One of the prominent issues in cochlear implantation is determining the wide variability in performance amongst users. Candidates with similar history and implanted with the same device can demonstrate outcomes on both ends of the spectrum.[1] One may perform very poorly, while the other can understand open-set speech. Advances in surgical technique and electrode design allow for atraumatic insertions; however, the outcomes continue to vary significantly from one user to another. Despite age, longevity of deafness, surgical technique and device characteristics, more potential factors such as neuronal survival, electrode position and central processing abilities may contribute to the variance in speech perception.[1] Objective measures are becoming more widely studied to further understand the neural pathways of the auditory nerve and central nervous system.[2] Animal studies show significant correlations between the slope, amplitude and thresholds of the eCAP and spiral ganglion survival.[2,3] This is yet to be correlated in humans;[2,3] however, properties of the eCAP may have a direct relation to the surrounding neurons in the periphery to help determine the remarkable differences in speech perception scores. In this study, the electric compound action potential (eCAP) was recorded, analyzed and compared to speech perception using the consonant-nucleus-consonant (CNC) monosyllabic test. We hypothesize that the steeper the slope, the better the CNC score.

METHODS:

Twenty-five adults implanted at the University of Kansas Medical Center with either the Med-El Sonata$_{TI}$ 100 or the Concert multi-channel electrode were included. Each recipient underwent the "soft surgical" technique with insertion through the round window and has at least six months experience with the device. Auditory response telemetry (ART) was recorded on multiple electrodes via the Maestro software from Med-El, Inc. The minimum amplitude was 300 cu and the maximum was 1200 cu. Twenty-five iterations were recorded with a pulse phase duration of 30 microseconds. To reduce non-stimulus related artifact, the zero amplitude template[4] was applied to each electrode. The amplitude for each stimulus is shown individually and the corresponding amplitude growth function is plotted (Figure 1). The electrodes were grouped into four groups outlining different areas of the cochlea. Group 1 consisted of basal electrodes (10-12); group 2 included mid to basal electrodes (7-9); group 3 lower mid region (5-7) and group 4 was the apical electrodes (1-4). Recorded CNC lists were administered at 60 dB SPL with the patient seated at 1 meter from a loudspeaker at 0 degrees azimuth. Scores were recorded in percent correct. Pearson's correlations were used to assess the eCAP slope and CNC scores ($p<0.05$).

Figure 1. Med-EL ART Recording Screenshot



RESULTS:

In the most basal and apical group, no correlations existed between the slope of the eCAP and CNC score ($r = .068$, $p > 0.05$; $r = .18$; $p > 0.05$) as seen in Figure 2 and 5. However, there was a significant correlation between the two mid-region groups (group 2: $r = .62$, $p < 0.05$; group 3: $r = .52$; $p < 0.05$). Results are shown in Figures 3 and 4.

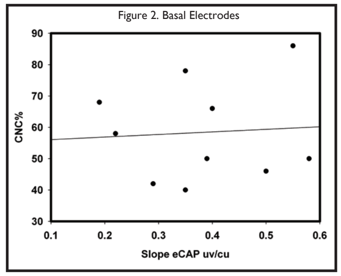


Figure 2. Basal Electrodes

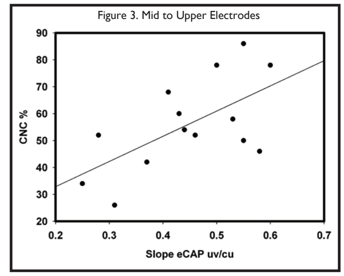


Figure 3. Mid to Upper Electrodes

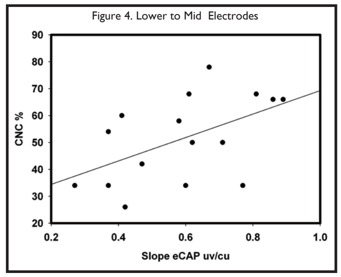


Figure 4. Lower to Mid Electrodes

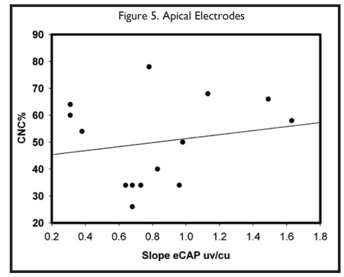


Figure 5. Apical Electrodes

DISCUSSION:

Uncertainty remains if the nerve count is directly correlated to speech perception, and if so, would most likely not relate linearly.[2] In fact, postmortem examination of cochlear implant users found that cochlea with the least amount of spiral ganglion performed the best on the NU-6.[5] Speech perception includes additional cognitive variables that bypass the auditory periphery. However, results from this study suggest that eCAP slope can correlate to speech perception outcomes based on its position in the cochlea. This is in agreement with findings from Kim et. al, 2010 in which they found a significant correlation between eCAP slope and CNCs with the Cochlear Nucleus Hybrid implant. This was compared to the standard Nucleus CI24M and CI24RE. No correlation was noted between the CI24M, and a weak correlation was noted with the CI24RE. The stronger correlation with the hybrid implant along with the results found from the current study indicate that the more intact auditory nerve and surrounding structures of the cochlea result in better speech perception. Although, the slope of the eCAP may not directly correlate to surviving neurons, perhaps it encompasses further information about the health of the nerve that may assist with predicting speech outcomes. Additional studies of the eCAP could possibly aid in calculating surviving spiral ganglion as seen in other animal studies.[6] Furthermore, speech outcomes are measured across the entire electrode array, not just a portion of the cochlea, which can lead to further variations in scores. Objective measures recorded beyond the auditory nerve may give further insight into the effects of electrical stimulation on the central auditory pathways and changes overtime. This could be compared amongst hearing preservation patients and traditional users. Those with more hearing preservation most likely produce more neurotrophins, which in turn, would lead to increased spiral ganglion survival. Increasing our understanding of the factors that improve speech perception can lead to better rehabilitation strategies or possibly intervention to improve spiral ganglion health.

CONCLUSION:

The eCAP amplitude growth function correlates with speech perception outcomes dependent upon position in the cochlea. Further research in this area is needed to understand electric stimuli on the auditory nerve and central nervous system with hopes to shape more individualized rehabilitation strategies.

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DISCLOSURE

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Is hearing preservation cochlear implantation in the elderly different?

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Key Words: cochlear implantation, hearing preservation, aging, presbycusis

Abstract: Hearing preservation cochlear implantation has become commonplace and give patients who are poor hearing aid candidates but have significant residual hearing an opportunity to take part in the hearing world. Hearing preservation cochlear implantation has been extended into pediatric populations yet little attention has been paid to geriatric implantation. In this presentation we review some of the factors that may affect outcomes in the elderly. In particular we focus on the potential role of mitochondria in hearing loss and discuss whether the elderly have similar hearing preservation outcomes as the general population.

Introduction: The recognition that preservation of residual low frequency hearing improved cochlear implant (CI) function has been widely described. Amongst potential patient populations, the elderly represent a population where down-sloping hearing losses with poor speech discrimination are common, and hence are a potential population from which potential hearing preservation CI patients may be recruited from. A key question is if the elderly have the same outcomes in terms of hearing preservation and outcomes as younger patients. To examine this we looked at change in hearing after implantation as a function of age and then examined the correlation between age and change in pure tone average and looked at cochlear implant outcomes as a function of age for hearing preservation patients. We discuss some of the potential causes of observed differences between patient populations.

Methods: Subjects and Outcomes Measures: Informed consent was obtained prior to testing, and the protocol was approved by the University of Kansas Medical Center human subjects board. A total of eighteen patients with residual hearing between 125 and 500 (5 males and 13 females) were implanted between 2009 and 2011. Ages ranged from 26-84 with a mean age 63.17. All candidates fell within Food and Drug Administration (FDA) or Medicare guidelines for implantation. Prior to implantation, all patients underwent blood testing to screen for autoimmune inner ear disease and had an MRI scan to rule out the presence of retrocochlear disease. Surgical Approach: The extended round window approach was used in all cases. After performance of a mastoidectomy and facial recess (posterior tympanotomy) approach to the middle ear, all bone dust was irrigated out of the wound. Hemostasis was obtained and 0.5 cc of decadron 10 mg/ml was applied to the round window niche. The bony overhang of the round window niche was then carefully removed with a 1 mm diamond burr and the round window clearly visualized by testing the round window reflex. The wound was once again irrigated and Healon™ was used to cover the round window (RW). The RW was then opened with a small pick and the implant electrode is carefully inserted. All patients were implanted with MedEl medium (M) electrode arrays. Pure tone thresholds were obtained before surgery and 2 weeks post-operatively using insert earphones.

Results: As seen in Fig 1 there was a linear relationship between age at implantation and change in hearing in the low frequencies (r^2=0.52; $p<0.05$). When arbitrarily divided at age 65, the average change in hearing for the younger patient group (Average age= 46.5) is 13.42 dB and the older patient (average age=74.5) group is 19 dB (p=0.12). As seen in the box plot of this data (Fig 2), the range of data distribution is broader for the older age group, resulting in a large standard deviation.

Discussion: The development of reliable approaches for hearing preservation cochlear implantation has led to a rapid expansion of cochlear implantation to novel patient populations(Skarzynski et al., 2010). The audiologic configuration that makes patient candidates for hearing preservation implantation is common in the elderly (Hoffman et al., 2012). A recent review of cochlear implantation in the elderly suggests that earlier implantation, when patients have less hearing loss may result in better hearing outcomes(Lin et al., 2012). Successful expansion of hearing preservation implantation into this population thus represents an important goal. Overall our data suggest that hearing preservation is feasible in the elderly and that on average hearing preservation outcomes are similar to younger patients (Fig 2). However, when examining the data more closely, the range of hearing loss after implantation is higher in older patients and regression analysis does suggest that with increasing age, the amount of hearing loss after implantation is increased (Fig 1). As we have previously reported we did not see any significant difference in implant function between our patients based on age (Prentiss et al., 2010), therefore despite slightly increased loss of low frequency hearing, hearing preservation implantation is still a valuable intervention. Accumulation of increased patient numbers may allow us to divide patients into 10 year cohorts, allowing us better risk stratification based on age.

The relationship between age and central auditory dysfunction have been well documented but little is known about the effects of age on the cochlea's sensitivity to damage. A potential source of age related sensitivity to damage is the function of mitochondria within the inner ear. Damage to mitochondrial DNA has been documented to occur in all regions of the inner ear with increasing age (Seidman et al., 2002; Yamasoba et al., 2007; Someya and Prolla, 2010; Crawley and Keithley, 2011). The accumulation of mitochondrial DNA damage can lead to sensitivity to further stress and subsequent induction of apoptosis(Fariss et al., 2005). This opens the possibility that completely different protective molecules that stabilize mitochondria could be applied to improve our hearing outcomes in the elderly.

Conclusion: Hearing preservation cochlear implantation is feasible in the elderly although slightly higher rates of hearing loss may be observed compared to younger patients.

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Figure 1: Scatter plot of change in pure tone average versus age. There is a linear relationship between the patients age at time of implantation and degree of hearing preservation.

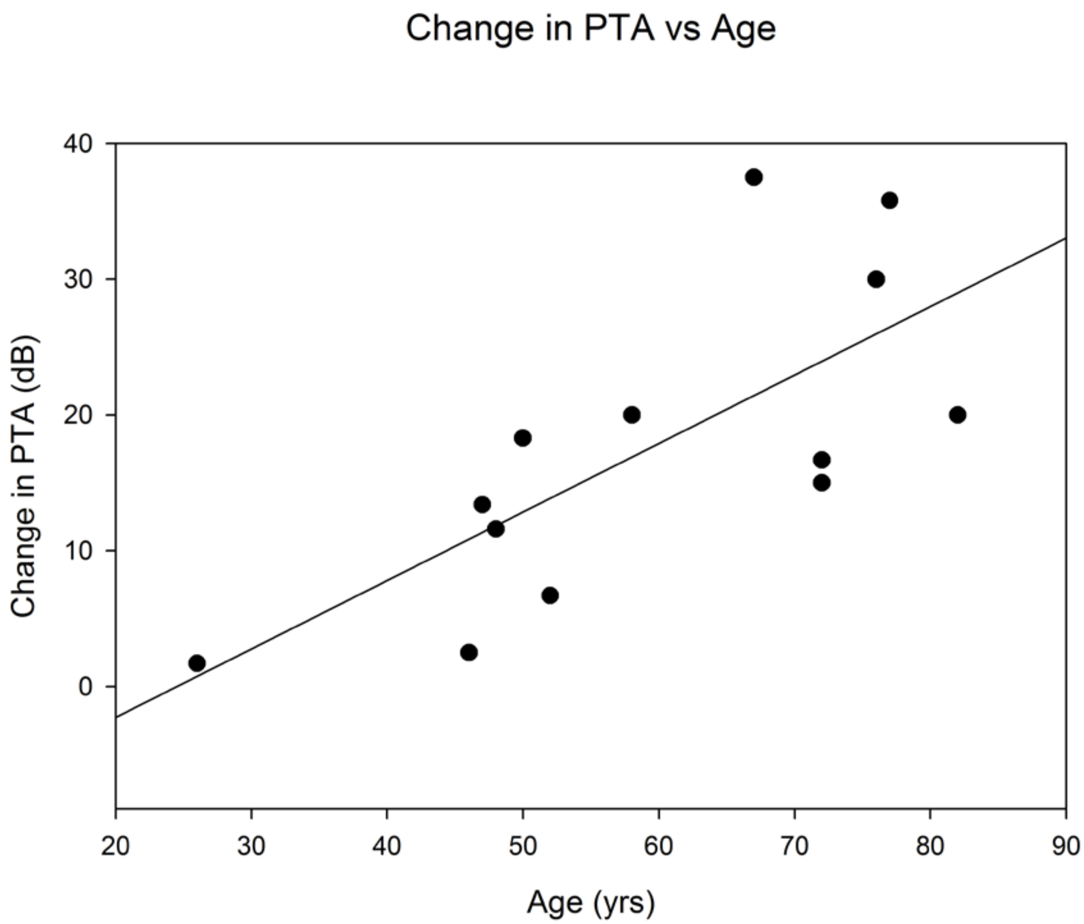

Figure 2: Box plot of average change in hearing for patients age less than and greater than 65. Younger patients tend to have slightly less change in hearing and older patients demonstrated a wider range in change in residual hearing after implantation. This was not statistically significant.

Effect of Age on Hearing Preservation