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Hearing preservation outcomes using a precurved electrode array inserted with an external sheath

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Abstract

Objectives: Describe audiologic outcomes in hearing preservation cochlear implantation (CI) using a precurved electrode array inserted using an external sheath and evaluate association of electrode positioning and preservation of residual hearing.

Study Design: Retrospective review.

Setting: Tertiary otologic center.

Patients: Twenty-four adult patients who underwent hearing preservation CI with precurved electrode array.

Interventions: CI, intraoperative computed tomography (CT)

Outcome measures: Audiologic measures [Consonant-nucleus-consonant (CNC) words, AzBio sentences, low-frequency pure tone averages (LFPTA)] and electrode location (scalar location, electrode-to-modiolus distance ($\bar{M}$), angular insertion depth).

Results: Twenty-four adults with <80dB LFPTA with a precurved electrode array inserted using an external sheath; 16 underwent intraoperative CT. LFPTA was 58.5 dB HL preoperatively, with a 17.3 dB threshold shift at CI activation ($p=0.005$). CNC word scores improved from 6% preoperatively to 64% at 6 months postoperatively ($p<0.0001$). There was one scalar translocation and no tip fold-overs. The average angular insertion depth was 388.2 degrees, and the average $\bar{M}$ across all electrodes was 0.36 mm. Multivariate regression revealed a significant correlation

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CONFLICTS OF INTEREST TO DECLARE:

- Alejandro Rivas: Consultant for MED-EL, Advanced Bionics, Cochlear, Grace Medical, Stryker, and Cook Medical.
- Robert Labadie: Consultant for Advanced Bionics, Johnson & Johnson, MED-EL, and Ototronix.

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between CNC scores at 6 months and angular insertion depth ($p=0.0122$; $r^2=0.45$, adjusted $r^2=0.35$). Change in LFPTA was not significantly associated with angular insertion depth or $\bar{M}$.

Conclusions: A low rate of translocation allows a precurved electrode array inserted using an external sheath to maintain hearing preservation rates comparable to straight electrode arrays. With scala tympani insertion, angular insertion depth is a positive marker of improved speech performance postoperatively but may be a confounder variable based on individual cochlear size.

INTRODUCTION

Over the last two decades, hearing preservation electrodes, electric-acoustic stimulation (EAS), and minimally traumatic surgical techniques have expanded the indications for cochlear implantation (CI) to include patients with residual hearing. Preserving residual hearing during and after CI has been demonstrated to have a beneficial impact on post-operative audiological performance. There is a growing body of evidence that combining electric and acoustic stimulation contributes to improved sound localization, music appreciation, and speech recognition in complex hearing environments.¹⁻⁴ Preservation of residual hearing after CI is dependent upon patient factors, electrode insertion trauma, and electrode design.⁵⁻⁷ Despite technological and surgical advances, the degree of hearing preservation varies significantly across individuals.⁸⁻¹¹

In regard to minimizing surgical trauma, intracochlear electrode positioning has been determined to impact hearing preservation rates. Electrode arrays located completely within scala tympani have been associated with improved hearing preservation, while translocation of the electrode leading to scala vestibuli positioning has been associated with poorer hearing preservation outcomes.^{6,7,12} Additionally, closer proximity of the electrode to the modiolus has been associated with improved speech perception outcomes.¹³⁻¹⁶

Until recently, electrode designs focused on one of two goals: minimizing trauma to the modiolus or minimizing the electrode-to-modiolus distance. The straight electrode array was designed to accomplish the former. During insertion, these electrodes track along the lateral wall, which minimizes trauma to the modiolus by maximizing electrode-to-modiolus distance. Straight arrays have lower rates of translocation, resulting in better hearing preservation rates.¹⁷ Conversely, precurved electrode arrays were designed to minimize electrode-to-modiolus distance when ideally positioned. Although decreased electrode-to-modiolus distance has been achieved, precurved arrays have higher rates of scalar translocation¹⁷ and associated poorer hearing preservation as compared to straight arrays.^{7,12,18}

One manufacturer of CIs, Cochlear Limited (New South Wales, Australia), currently offers a precurved electrode array inserted using an external sheath (CI532), which combines both a precurved electrode design with an insertion device designed to minimize scalar translocation and intracochlear trauma. The first clinical report documented decreased translocation (0/44) but a high rate of tip fold-over (2/44)¹⁹. Prior study populations for this electrode had profound pre-operative hearing loss and little could be gleaned about hearing preservation rates.²⁰ The current study describes audiologic outcomes in hearing

preservation CI using the CI532 electrode and evaluates the association of electrode positioning and preservation of residual low-frequency acoustic hearing.

METHODS

Study Design

Following Institutional Review Board approval, a retrospective chart review was performed of all patients undergoing CI with a Cochlear CI532 electrode array from January 2016 to September 2018. Patients were included if they demonstrated functional residual low-frequency acoustic hearing on preoperative audiologic testing and if they had at least 6 months of postoperative audiologic follow-up. Hearing preservation candidates had residual hearing that was <80 dB low-frequency pure tone average (LFPTA; average of 125, 250, and 500 Hz thresholds). Of the 97 patients who underwent CI with the Cochlear CI532 electrode array during the study period, 25 were identified as adult hearing preservation candidates on preoperative testing. Overall, 24 adults were included for statistical analysis, as one patient was excluded for inadequate audiologic follow-up. Of the included 24 patients, 16 underwent intraoperative computed tomography (CT) imaging, as part of an intraoperative CT clinical trial protocol at our institution.

Audiologic Outcomes Reporting

Preoperative audiologic testing occurred within 8 weeks of CI. All patients had reported audiologic outcomes at CI activation (within 1 month of surgery), and 6 months postoperatively. Those patients with longer follow-up additionally had the results of the most recent audiologic testing reported. All CI outcomes are reported according to Adunka, et al. minimum reporting standards.²¹ Functional residual hearing was defined as a low-frequency pure tone average (LFPTA) <80 dB HL at 125, 250, and 500 Hz. Patients who experienced a postoperative LFPTA >80 dB HL were determined to have no functional residual hearing after surgery. Overall, 23 patients were included for overall threshold shift analysis (one patient was excluded for known translocation, see below).

Speech perception testing included consonant-nucleus-consonant (CNC) word recognition (50 word list)²², AzBio sentence recognition in quiet (20 sentence list)²³, and AzBio sentences in noise with +5 dB signal-to-noise ratio (SNR) for all adults. Speech perception testing was conducted in the electric only condition. Of the 24 adults included in the study, 4 were excluded from speech perception outcomes analysis. Exclusion criteria included the following: inadequate CI use (datalogging <3.5 hours per day, n=3) and translocation (n=1)). Ultimately, there were 20 adults included in speech perception statistical analysis at 6 months.

The Speech Spatial Qualities (SSQ) questionnaire assesses subjective hearing abilities across three listening domains: speech understanding, spatial hearing, and overall quality of speech using a visual analog scale ranging from 1 (poor) to 10 (perfect).⁴⁶ The overall score, which is an average of these three subscales, was reported. Of note, 12 adults with both preoperative and 6-month postoperative SSQ scores were included in this portion of the study.

Computerized Tomography

Of the 24 patients in the study, 16 underwent intraoperative CT at the time of CI using a Xoran XCAT or XCAT XL volumetric CT machine (Xoran Technologies; Ann Arbor, Michigan). Image processing took place as previously described^{24,25} and was used to assess electrode position within the cochlea including scalar location, average of each electrode's distance to the modiolus ($\bar{M}$), and angular insertion depth. This analysis revealed one case of translocation; the speech perception and LFPTA data associated with this case were excluded from multivariate regression statistical analysis given the trauma associated with translocation leading to loss of residual hearing. Multivariate regression evaluating the association between LFPTA and electrode location included 15 patients (1 translocation patient excluded). Multivariate regression evaluating the association between speech perception outcomes and electrode location included 12 adults (exclusions: 2 inadequate datalogging, 1 translocation, 1 prelingually deafened). Of the two patients with inadequate datalogging, one patient had persistent difficulty with hearing in noisy environments and thus did not use her CI consistently in situations with background noise. She also had a history of stroke associated with word-finding difficulty, which may impact outcomes. The second patient with inadequate datalogging initially experienced a "hissing" sound when using his processor, and thus did not use the CI consistently in the initial months. This was resolved with remapping, and future datalogging is likely to improve.

Statistical Analysis

Statistical analyses were performed with GraphPad Prism 7.0 (GraphPad Software, La Jolla, California) and Microsoft Excel (Version 16.23, 2019, Redmond, Washington, U.S.A.). Continuous variables were reported as averages with standard deviations when normally distributed and medians with ranges when not normally distributed. Student t-tests were used to compare preoperative and postoperative averages with normally distributed data, while Mann-Whitney tests were applied to medians with non-parametric values. When using multivariate linear regression, both r^2 and adjusted r^2 were reported. All tests used two-sided testing and P values with a value less than 0.05 considered statistically significant.

RESULTS

Patient Demographics

During the study period, 24 adults underwent hearing preservation CI with a precurved electrode array inserted using an external sheath. The median age at implantation was 67.7 years (IQR, 34.6 years) and 46% (n=11) of implantations were right-sided. None of the included patients had a history of prior ipsilateral otologic surgery or chronic ear disease; three patients underwent prior contralateral CI. Progressive sensorineural hearing loss was the most common cause of hearing loss (92%, n=22), followed by congenital hearing loss (4%, n=1), and hearing loss associated with Meniere's disease (4%, n=1).

The average duration of hearing loss without benefit from amplification was 2.7 years (SD, 2.4 years). The average audiologic follow-up duration was 12.0 months (SD, 7.4 months). Fourteen patients had at least 12 months of postoperative follow-up, with a median of 15.1

months (IQR, 9.5 months). Notably, there were no intraoperative or postoperative surgical complications; there were no instances of CI failure or revision surgery.

Electrode Positioning Outcomes

All patients underwent a mastoidectomy and facial recess approach. The majority of patients had entry into the cochlea via the round window (83%, n=20), followed by extended round window (13%, n=3), and cochleostomy (4%, n=1). Sixteen patients underwent intraoperative CT at the time of CI. All electrode arrays were fully inserted, and there were no instances of tip fold-over. There was one instance of electrode array translocation; electrodes 1-11 were located within the scala tympani, however, electrodes 12-22 were located within the scala vestibuli.

The average angular insertion depth was 388.2 degrees (SD, 43.1 degrees). $\bar{M}$ across all electrodes was 0.36 mm (SD, 0.15 mm); the apical, middle and basal region $\bar{M}$ was 0.21 mm (SD, 0.15 mm), 0.45 mm (SD, 0.29 mm), and 0.44 mm (SD, 0.21), respectively [Figure 1]. It should be noted that range of $\bar{M}$ was limited to 0.14mm-0.60mm; the small range restricts further trends associated with electrode-to-modiolus distance.

Residual Hearing Outcomes

On average, patients had a preoperative LFPTA of 58.5 dB HL (SD, 13.9 dB) and an activation LFPTA of 75.8 dB HL (SD, 15.1 dB, p=0.004) [Table, Figure 2]. At the time of activation, the threshold shifts in hearing level at 125, 250, and 500 Hz were 17.2 dB, 17.9 dB, and 17.3 dB, respectively (ANOVA, p=0.78). At all timepoints, the lowest frequency, 125 Hz, had the smallest changes in hearing level. With a preoperative average LFPTA of 58.5 dB HL, 70% of patients had preserved residual hearing (<80 dB HL LFPTA) at activation, and 60% had preserved residual hearing at 6-month follow-up.

Although there was a significant threshold shift between the time of preoperative evaluation and CI activation, there was no significant difference between LFPTA at the time of CI activation and after 12-month follow-up (80.6 dB HL, p=0.36; n=14). Multivariate regression did not reveal a significant correlation between change in LFPTA with angular insertion (p=0.24) depth or $\bar{M}$ (p=.12; $r^2=0.31$, adjusted $r^2=0.18$) at 6 months after surgery (n=18).

Speech Perception Outcomes

Speech perception scores as related to residual hearing outcomes are summarized in Figure 3. The median AzBio sentence score improved from 6% (IQR, 18%) preoperatively to 86% (IQR, 26%) at 6 months postoperatively (p<0.0001; n=20), and 87.5% (IQR, 19%) after 12 months postoperatively (n=12). Similarly, the median CNC word score improved from 6% (IQR, 14%) preoperatively to 64% (IQR, 26%) at 6 months postoperatively (p<0.0001; n=20), and 66% (IQR, 20%) after 12 months postoperatively (n=13). The SSQ improved from a preoperative median of 0.91 (IQR, 2.8) to 6.1 (IQR, 2.4) at 6-month follow-up (p<0.001; n=12).

Multivariate regression was used to evaluate for a correlation of speech perception outcomes with angular insertion and $\bar{M}$. CNC scores at 6 months were statistically significantly correlated with angular insertion depth ($p=0.0122$) but not $\bar{M}$ ($p=0.42$; $r^2=0.45$, adjusted $r^2=0.35$; $n=12$) [Figure 4]. AzBio scores at 6 months were not statistically significantly correlated with angular insertion depth ($p=0.06$) or $\bar{M}$ ($p=0.72$; $r^2=0.32$, adjusted $r^2=0.18$; $n=12$).

DISCUSSION

The CI532 electrode array is a precurved electrode array inserted using an external sheath and was designed to both minimize electrode-to-modiolus distance while minimizing intracochlear trauma in an effort to maintain residual hearing. Our analysis indicates that both were achieved with $\bar{M} = 0.36 \pm 0.15$ mm and average LFPTA shift of 17.4 dB threshold shift at CI activation. Speech perception outcomes revealed significant improvement postoperatively with median CNC scores of 64% and AzBio scores of 86% at 6-month follow-up.

Scalar translocation occurred in 1 of 16 patients which is much lower than internally styleted precurved electrode arrays which demonstrate translocation rates between 30 and 50%.^{26–28} While the external sheath may be key in preventing translocation, it is also possible that the rigidity of the electrode itself plays a role. In this group of 16, no tip fold-overs were identified. However, prior reports indicate a fold-over rate of 4.5%¹⁹ – an incidence consistent with our overall experience with the CI532 electrode array (4/97 tip fold-overs in imaged CI532 ears to date).

Although translocation rates are decreased with this precurved electrode, prior studies and our experience suggest a steep learning curve associated with implanting the CI532.²⁹ Unfurling of the electrode array occurs in the opposite direction from internally styleted arrays with the 532 electrode unfurling towards the grip of the external sheath. Additionally, the unfurling direction is not consistent requiring the surgeon to visualize the unfurling with respect to the sheath for each individual case. Furthermore, insertion depth is generically indicated by three markers distal to the last active electrode and a tap which rests either medial or lateral to the facial nerve. As other groups have orally reported, surgeons tend to over-insert the CI532. Most likely secondary to the availability of an intraoperative CT scanner at our facility, the surgeons who routinely implant CI532 electrodes have obtained intraoperative feedback on their insertions in real time, which has resulted in subtle modifications of insertion technique to improve intracochlear electrode positioning. This technique often involves slightly pulling the electrode back after insertion to seat it against the modiolus as evidenced by the low $\bar{M}$ reported. The homogeneous perimodiolar positioning makes it difficult to extract trends related to $\bar{M}$ as there is not a wide variation of the independent variable.

The homogeneous perimodiolar positioning also has implications regarding angular insertion depth. Given a fixed length electrode array and consistently tight perimodiolar positioning, deeper angular insertion depth implies smaller cochlear size and broader frequency coverage with the implant. Such broader frequency coverage likely explains the

positive association between angular insertion depth and audiological outcomes seen in Figure 4. Future studies will aim to correlate cochlear duct length with these outcomes.

Importantly, some patients did have further decline in residual hearing between CI activation and 6-month follow-up, however, this was statistically insignificant. Postoperative acoustic hearing loss typically falls into two categories: immediate and delayed. Immediate-onset hearing loss that is detected at the first postoperative appointment is commonly attributed to surgical trauma or an acute inflammatory process.^{30–32} Aside from natural progression of hearing loss, the causes of delayed-onset hearing loss have yet to be elucidated, but it has been hypothesized that a foreign body reaction to the electrode array may be involved.³⁰ Consequently, the long-term residual hearing outcomes in this study may be impacted by both inflammation and natural disease process unrelated to the electrode array. Future studies will continue to monitor these patients and expand the patient population with long-term outcomes.

CONCLUSION

The precurved electrode array inserted using an external sheath has residual hearing preservation potential while maintaining close proximity to the modiolus. A greater angular insertion depth is associated with improved speech outcomes at 6-month follow-up. Future studies will further evaluate this relationship with consideration to the individual cochlear size.

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Figure 1.

Average Electrode-to-modiolus Distance ($\bar{M}$) across electrode array. Note: average is represented by thicker black curve, with standard deviation bars at each electrode. Electrode #22 is closest to the cochlear apex. For comparison, $\bar{M}$ is 0.48 ± 0.15 mm in precurved arrays and 1.16 ± 0.16 mm in straight arrays.¹³

Figure 2. Low-frequency Threshold Shifts. A) Low-frequency pure tone average (LFPTA) threshold shift by frequency over time. B) LFPTA threshold shifts at activation and 6-month follow-up per individual.

Figure 3. Speech perception scores over time. A) AzBio sentence and B) Consonant-nucleus-consonant word speech perception scores preoperatively, 6 months postoperatively and after 12 months postoperatively. Abbreviations: LFPTA, low-frequency pure tone average; HL, hearing level; CNC, Consonant-nucleus-consonant.

Figure 4. CNC Multivariate Regression Line Fit Plots. (A) Angular insertion depth was correlated with postoperative CNC scores at 6 months, while (B) electrode-to-modiolus ($\bar{M}$) plot did not ($r^2=0.45$, adjusted $r^2=0.36$).

Table.

Average Preoperative and Postoperative Low-Frequency Pure Tone Average (LFPTA). Standard deviations are represented in parentheses; 'Change in HL' compares preoperative and 12-month postoperative thresholds.

	Frequency (Hz)			
	125	250	500	LFPTA
Preoperative, dB HL	47.8 (19.3)	56.9 (16.0)	70.2 (16.0)	58.5 (13.9)
Activation, dB HL	65.0 (18.7)	74.8 (16.2)	87.7 (17.6)	75.8 (15.1)
6 months Postoperative, dB HL	69.2 (21.0)	79.6 (18.3)	92.3 (18.6)	80.3 (17.0)
12 months Postoperative, dB HL	70.0 (18.2)	79.3 (17.9)	93.6 (14.6)	80.6 (14.6)
Change in HL, dB	22.2	22.4	23.4	22.6