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Durability of Hearing Preservation after Cochlear Implantation with Conventional-Length Electrodes and Scala Tympani Insertion

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Abstract

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Disclosures

Competing interests: Alejandro Rivas, consultant for Advanced Bionics Corp, Cochlear Corp, MED-EL GmbH, Grace Medical, and Carestream; Marc L. Bennett, consultant for Oticon; Rene H. Gifford, Advanced Bionics, Cochlear, MED-EL; David S. Haynes, consultant for Advanced Bionics Corp, Cochlear Corp, MED-EL GmbH, Stryker, Synthes, Grace Medical, and Oticon; Robert F. Labadie, consultant for Advanced Bionics, Medtronic, and Otomix; George B. Wanna, consultant for Advanced Bionics Corp, Cochlear Corp, MED-EL GmbH, Grace Medical, and Oticon.

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Objectives—To analyze factors that influence hearing preservation over time in cochlear implant recipients with conventional-length electrode arrays located entirely within the scala tympani.

Study Design—Case series with planned chart review.

Setting—Single tertiary academic referral center.

Subjects and Methods—A retrospective review was performed to analyze a subgroup of cochlear implant recipients with residual acoustic hearing. Patients were included in the study only if their electrode arrays remained fully in the scala tympani after insertion and serviceable acoustic hearing (≤ 80 dB at 250 Hz) was preserved. Electrode array location was verified through a validated radiographic assessment tool. Patients with <6 months of audiologic follow-up were excluded. The main outcome measure was change in acoustic hearing thresholds from implant activation to the last available follow-up.

Results—A total of 16 cases met inclusion criteria (median age, 70.6 years; range, 29.4–82.2; 50% female). The average follow-up was 18.0 months (median, 16.1; range, 6.2–36.4). Patients with a lateral wall electrode array were more likely to have stable acoustic thresholds over time ($P < .05$). Positive correlations were seen between continued hearing loss following activation and larger initial postoperative acoustic threshold shifts, though statistical significance was not achieved. Age, sex, and noise exposure had no significant influence on continued hearing preservation over time.

Conclusions—To control for hearing loss associated with inter-scalar excursion during cochlear implantation, the present study evaluated patients only with conventional electrode arrays located entirely within the scala tympani. In this group, the style of electrode array may influence residual hearing preservation over time.

Keywords

cochlear implantation; hearing preservation; cochlear trauma; image guidance

Over the past 30 years, cochlear implants (CIs) have become the most reliable and effective therapeutic option for severe to profound sensorineural hearing loss. As the popularity of cochlear implantation has grown, new surgical techniques, device designs, and indications for implantation have emerged.^{1–3} One of the most noteworthy recent advances in the field of cochlear implantation has been the discovery that acoustic hearing can be preserved and utilized in some patients following implantation.^{4–8} Current evidence suggests that minimizing cochlear trauma during CI electrode array insertion is crucial to successful hearing preservation; consequently, the technical aspects of implant surgery and device design have been increasingly scrutinized in an effort to optimize outcomes.^{9–11}

In addition to trauma caused by cochleostomy and electrode array insertion, patient-specific factors have been shown to influence acoustic hearing preservation outcomes.¹² For example, advanced age has been found to inversely correlate with early and late postoperative hearing preservation, suggesting that the pathophysiology responsible for age-related hearing loss may negatively affect native cochlear function following electrode array insertion and use.^{13,14} However, confounding variables can be problematic when attempting

to isolate nonsurgical predictors of successful hearing preservation. Specifically, controlling for the effects of cochlear trauma during electrode array insertion is a complicated task. To aid in this endeavor, recent advances have allowed for accurate en vivo identification of electrode array scalar position following insertion,¹⁵ and subsequent evidence has suggested that interscalar excursion identified by this method carries a strong association with loss of residual hearing following surgery.¹⁶ In the current study, we present the long-term audiologic follow-up data for a cohort of patients with verified scala tympani electrode insertions who underwent CI and had initial preservation of serviceable hearing as measured at implant activation.

Subjects and Methods

Following Institutional Review Board approval (No. 090155) from Vanderbilt University, a retrospective review was conducted to assess the durability of acoustic hearing in patients who had initially successful hearing preservation and radiologically verified full scala tympani insertions. All patients who underwent cochlear implantation at a single tertiary otologic referral center between January 2011 and December 2013 were identified through the American Medical Association's *Current Procedural Terminology* code 69930. From this group, all consecutive subjects with pre- and postoperative temporal bone computed tomography were analyzed via a previously validated anatomic atlas^{15,17,18} to determine electrode scalar location and angular depth of insertion. Cases were excluded from the final analysis if (1) interscalar excursion was identified on the aforementioned computed tomography protocol, (2) <6 months of postoperative audiologic follow-up was documented, or (3) postoperative audiometry demonstrated a bone conduction pure tone threshold >80 dB at 250 Hz.

The primary outcome measure was durability of postoperative bone conduction pure tone thresholds at 125, 250, and 500 Hz relative to measurements at the time of implant activation. Acoustic thresholds were recorded prior to cochlear implantation, approximately 3 weeks later at the time of implant activation, and at any subsequent unaided threshold assessment beyond that point. Low-frequency pure tone averages (PTAs), when reported, were the mathematical mean of the thresholds at 125, 250, and 500 Hz. To quantify the maximum degree of hearing loss at a certain frequency, 125 dB was used when no response could be appreciated at the limits of audiometer output. C-value data from the last recorded implant programming session were used to calculate charge density per the formula provided in a recent report by Kopelovich et al.¹⁹ For the purposes of the present study, an "increasing" PTA/threshold over time indicates that hearing worsened, while a "decreasing" PTA/threshold over time indicates that hearing improved.

In addition to audiologic information, patients' medical charts were reviewed for the following data: age at the time of implantation, tobacco use within 1 year of the date of implantation, the electrode array manufacturer and type of electrode array (lateral wall or styleted/perimodiolar), the angular depth of electrode array insertion, the method of cochlear access (round window, extended round window, or anteroinferior cochleostomy separate from the round window membrane), the use of a perioperative or postoperative oral corticosteroid taper, a history of medical comorbidities (eg, coronary artery disease,

cerebrovascular disease, and hypertension), a history of noise-induced hearing loss, or a history of previous otologic surgery. Patients were considered to have coronary artery disease if they had a history of a myocardial infarction, coronary artery surgery, or unstable angina. Patients were considered to have cerebrovascular disease if they had a prior stroke or transient ischemic event. Tobacco use was considered to be significant if the patient reported a daily smoking habit that was ongoing within 1 year prior to the surgical date. With regard to corticosteroids, a 10-mg intravenous dose of dexamethasone was given prior to the surgical incision in all cases. Additional steroid tapers consisted of either a 16-day perioperative oral prednisone taper beginning 3 days prior to surgery (60 mg/d for 6 days, followed sequentially by 50 mg/d for 2 days, 40 mg/d for 2 days, 30 mg/d for 2 days, 20 mg/d for 2 days, and 10 mg for 2 days) or a postoperative methylprednisolone taper beginning on postoperative day 1 (24 mg for 1 day, followed sequentially by 20 mg for 1 day, 16 mg for 1 day, 12 mg for 1 day, 8 mg for 1 day and 4 mg for 1 day). Of note, devices were offered to patients from all 3 US Food and Drug Administration–approved manufacturers: MED-EL GmbH (Durham, North Carolina), Advanced Bionics Corporation (Valencia, California), and Cochlear Corporation (Denver, Colorado). Per institutional protocol, device selection was determined by patient preference, and electrode array type was determined by surgeon preference. All patients received the most current technology available at the time of surgery.

Continuous features were summarized with means, medians, and ranges; categorical features were summarized with frequency counts and percentages. Student's *t* test was used to compare population means. Correlation coefficients and coefficients of determination were used to estimate the relationships between different variables and residual acoustic hearing preservation. All tests were 2-sided, and *P* values <.05 were considered statistically significant.

Results

A total of 16 cases in 13 patients (3 bilateral) met inclusion criterion and were analyzed. The average age at the time of implantation was 65.6 years (median, 70.6; range, 29.4–82.2), and 8 patients (50.0%) were women. Ten cases (62.5%) involved a history of hypertension; 6 cases (37.5%), a history of noise-induced hearing loss; and 5 (31.3%), a history of tobacco use. Nine patients (56.3%) received an oral steroid taper that was either a perioperative prednisone taper (4 patients, 25.0%) or a postoperative methylprednisolone taper (5 patients, 31.3%), per surgeon preference. One patient (6.3%) had diabetes mellitus type 2, and 1 patient had a history of coronary artery disease. No patient had a history of cerebrovascular disease or prior ear surgery (Table 1).

The surgical procedure in all cases involved a limited mastoidectomy with access to the middle ear and cochlea through a posterior tympanotomy. A round window insertion was performed in 12 cases (75.0%), an extended round window approach in 3 (18.8%), and an anteroinferior cochleostomy in 1 (6.3%). A perimodiolar styled electrode was used in 4 cases (25.0%), while lateral wall electrode arrays were used in the remainder (75.0%). The mean angular depth of insertion for all arrays was 431 degrees (median, 453.5; range, 277–567).

Audiometric follow-up data were available for analysis at a mean of 18.0 months (median, 16.1; range, 6.2–36.4). The mean preoperative PTA across all 16 cases was 57.5 dB (median, 58.3; range, 43.3–70.0). Implants were generally activated 3 weeks following surgery, at which time the first postoperative acoustic pure tone assessment was performed. The average PTA at the time of activation was 74.3 dB (median, 75.0; range, 58.3–86.7), and the mean PTA at the last recorded follow-up was 82.5 dB (median, 75.8; range, 58.3–125.0). An average PTA increase of 8.2 dB (median, 1.7; range, –15.0 to 43.3) was seen between the time of activation through the last recorded follow-up. In 7 cases (43.8%), either no PTA shift or a decrease in PTA was noted. The PTA shift was ≤ 10 dB in 4 cases (25.0%), >10 dB but <20 dB in 2 cases (12.5%), and >20 dB in 3 cases (18.8%). Serviceable residual hearing was noted at the last recorded follow-up in 11 cases (68.8%).

The PTA change between time of activation and last recorded follow-up was also analyzed as a function of different surgical and patient-specific variables. There was a moderately negative relationship between depth of insertion and PTA shift over time, though this was not statistically significant ($r = -0.39$, $P = .10$). A moderately positive relationship between the initial PTA shift measured at the time of activation and the shift measured over time was also observed but not statistically significant ($r = 0.39$, $P = .10$). There was no clear correlation between the amount of PTA shift over time and patient age ($r = 0.04$, $P = .88$), charge density ($r = -0.22$, $P = .42$), or preoperative PTA level ($r = -0.13$, $P = .62$; Figure 1). Styled electrode arrays were associated with a significantly greater degree of PTA shift over time when compared with lateral wall arrays (23.8- vs 3.5-dB increase, $P = .04$). There was no significant difference in PTA shift over time on the basis of patient hypertension ($P = .46$), noise-induced hearing loss ($P = .49$), sex ($P = .49$), tobacco use ($P = .44$), or steroid use (perioperative or postoperative, $P = .22$), though the initial PTA shift measured at the time of activation was significantly lower in patients who used perioperative or postoperative oral steroid tapers ($P = .02$). There was also no significant difference in PTA shift over time between the 2 oral steroid tapers ($P = .81$). Subgroup analyses comparing outcomes between cochleostomy and round window insertion as well as analysis of the respective impacts of coronary artery disease and diabetes were not feasible secondary to small patient numbers (Table 2).

Discussion

As efforts to understand the least traumatic insertion methods for CIs are ongoing, it is important to consider any element that could influence hearing preservation over time. In the present study, the impact of several patient comorbidities, demographic factors, and surgical variables on the continued preservation of serviceable acoustic hearing were analyzed from the time of implant activation through an average of 18 months following surgery. To control for the degree of insertion trauma associated with interscalar excursion, only patients with an electrode array in the scala tympani were included, as determined by a previously validated method of intracochlear electrode array localization.^{15,16} The findings from this study challenge the reliability of age as a predictive factor for durable hearing preservation and suggest that such preservation may have an association with the use of a nonstyled lateral wall electrode.

Identifying trauma during CI electrode array insertion and correlating it with a particular degree of hearing loss remains a difficult endeavor. Many of the physical mechanisms and patterns of insertion trauma have been described with histopathologic data acquired from postmortem analysis.^{20,21} Though it may now be possible to analyze the effects of interscalar electrode array excursion *en vivo*,¹⁶ the means are not available to consistently associate a distinct injury with either an immediate partial residual hearing loss or a progressive loss over time. However, in terms of the durability of initial hearing preservation outcomes, an evolving inflammatory response to insertion trauma could manifest as a continued postactivation hearing loss, and correlating continued threshold shifts over time with quantifiable surgical data might provide an indirect measurement tool. The correlation between early postoperative threshold shifts and greater degrees of long-term hearing loss may suggest that more significant damage at the time of implantation also has enduring effects. In consideration of the traumatic potential of a specific type of contemporary electrode array, recent evidence is not entirely clear.²² However, in the present study, lateral wall electrode arrays were associated with a lesser degree of hearing loss over time than what was seen with styletted arrays, which may be a trauma-related phenomenon. Another consideration is that the pressure of an actuated perimodiolar electrode array on the modiolus could create a relative compromise of venous return. Although the explanation of these findings is, unfortunately, speculative, it is certain that a reliable method for real-time feedback during insertion will help to clarify the causes and effects of cochlear insertion trauma. Recent data regarding intraoperative imaging and impedance measurements are encouraging.²³

Mitigating posttraumatic inflammation may prove to be a helpful adjunct to hearing preservation following cochlear implantation. Although some manifestations of inflammation are relatively inhibited in the cochlea,^{24,25} the appearance of fibrosis and neo-ossification following electrode array insertion is well described, and the presence of either entity can dampen the propagation of sound energy.^{26,27} In addition to physical trauma, hypersensitivity to the electrode array²⁸ and infection²⁹ may contribute to an inflammatory response that can damage hearing. Furthermore, residual acoustic hearing may be threatened by excitotoxic damage to the cochlear nerve induced by the implant itself,¹⁹ though a clear relationship between charge density and PTA shift over time was not seen in the present cohort. The value of corticosteroids when combating these factors is unclear, but recent evidence has indicated that topical³⁰ and systemic^{31–33} corticosteroids at the time of implantation may help to mitigate some of the effects of implant-associated inflammation. In the present cohort, no significant difference in hearing loss was seen between activation and the last recorded follow-up when patients were compared on the basis of whether they received perioperative oral steroids or not. Despite this finding, the use of steroids in the management of sensorineural hearing loss may still support the beneficial effect of supplemental dosing when threshold shifts are identified over time.

Determining the relative influence of patient-specific comorbidities on hearing preservation will be a significant boon to predictive modeling. In theory, any condition that weakens cochlear structural integrity, vascular supply, or wound healing could have a negative impact on a hearing preservation attempt. When the pathophysiology of age-related hearing loss is considered,³⁴ it would seem that advanced age should be a negative prognostic factor.

Although the present data question the influence of advanced patient age on durable hearing preservation over time, the impact of age on hearing preservation attempts, in general, seems to be more established than that of other comorbidities.^{9,12,13,35} Arguments could also be made that tobacco use, vascular disease, diabetes, and noise-induced hearing loss could affect hearing preservation outcomes by affecting preoperative physiologic and structural resilience in the cochlea. Additionally, it is reasonable to consider that a more rapid trajectory of hearing loss leading up to implantation may be indicative of a pathologic process within the cochlea that would render durable hearing preservation less likely to be achieved. In our cohort, the audiogram prior to the preoperative audiogram was available for review in only 4 cases. An analysis of these 4 cases did not reveal statistically significant relationship between the trajectory of hearing loss and the durable preservation of acoustic hearing. In general, the evidence regarding comorbidities and confounding factors remains unclear, if not contradictory.^{12,16} The present study found no significant univariate relationship between any of these variables and durable hearing preservation over time. Further research will be necessary to reconcile these findings.

Several limitations of this study should be noted. In addition to the limitations inherent to a retrospective review, the statistical power of this analysis was weakened by the relatively small size of the cohort. Also, as previously noted, while controlling for interscalar excursion addresses one possible mechanism of insertion trauma, the fact that an electrode array remained in the scala tympani does not necessarily imply that insertion was entirely atraumatic.³⁶ Future efforts will focus on establishing a more comprehensive method of control in this regard.

Conclusions

Durable acoustic hearing preservation is an attainable goal for CI patients with significant residual hearing. Trauma at the time of electrode array insertion remains a threat to this endeavor, and the use of a stylet electrode array via round window or extended round window insertion may portend a poorer prognosis for continued preservation following activation. The mechanisms of postoperative loss beyond these points remain unclear, though the effects of chronic inflammation and electrical excitotoxicity should be considered in patients who experience sudden threshold shifts following an initially successful preservation.

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Figure 1. Hearing changes (pure tone average [PTA] shift) between activation and the last recorded audiogram.

Table 1

Demographic Information and Medical Comorbidities.

Variable	n
Patients	13
Cases	16
Hypertension	10
Steroids (postoperative or perioperative)	9
Noise-induced loss	6
Tobacco use	5
Coronary artery disease	1
Diabetes	1

^aMean age, 65.6 years; median, 70.6; range, 29.4–82.2.

Table 2

Pure Tone Average Shifts between Activation and the Last Recorded Follow-up Audiogram.

Variable	Yes, dB	No, dB	<i>P</i> Value
Stylet electrode array	23.75	3.5 ^a	.04 ^b
Hypertension	11.2	4.2	.46
Noise-induced loss	4.4	11.0	.49
Male sex	5.4	11.7	.49
Tobacco use	3.3	10.9	.44
Peri- or postoperative oral steroid use	3.7	14.8	.22

^a A lateral wall electrode array was used.

^b Statistical significance ($P < .05$).