Speech Recognition Outcomes in Adults with Slim Straight and Slim Perimodiolar Cochlear Implant Electrode Arrays

Running Title: Speech Outcomes 522 vs. 532

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ABSTRACT

Objective: To compare differences in audiologic outcomes between slim modiolar electrode (SME) CI532 and slim lateral wall electrode (SLW) CI522 cochlear implant (CI) recipients.

Study Design: Retrospective cohort study

Setting: Tertiary academic hospital.

Methods: Comparison of postoperative AzBio sentence scores in quiet (% correct) in adult CI patients implanted with SME or SLW matched for preoperative AzBio sentence scores in quiet, aided and unaided pure tone average (PTA).

Results: Patients implanted with SLW (n=52) and patients with SME (N=37) had similar mean (SD) age [62.0 (18.2) vs. 62.6 (14.6) years, respectively] mean preoperative aided PTA [55.9 (20.4) (SLW) vs. 58.1 (16.4) (SME) dB; p = 0.59], mean AzBio score [11.1 (13.3) (SLW) vs. 8.0 (11.5) (SME) % correct; p = 0.25]. At last follow-up [9.0 (2.9) (SLW) vs. 9.9 (2.6) months (SME]), postoperative mean AzBio scores in quiet were not significantly different [70.8 (21.3) (SLW) vs. 65.6 (24.5) (SME) % correct; p = 0.29] and data log usage was similar [12.9 (4.0) (SLW) vs. 11.3 (4.1) (SME) hours; p = 0.07]. In patients with preoperative AzBio <10% correct, the 6-month mean AzBio scores were significantly better with SLW than SME [70.6 (22.9) vs. 53.9 (30.3) % correct; p = 0.02]. The intraoperative tip rollover rate was 8% for SME and 0% for SLW.

Conclusions: Cochlear implantation with SLW and SME provide comparable improvement in audiologic functioning. SME do not exhibit superior speech recognition outcomes compared to SLW.

INTRODUCTION

Severe-to-profound hearing loss impacts a significant portion of the United States population[1,2]. While cochlear implants (CI) are widely accepted for treatment of moderate to profound sensorineural hearing loss[3], several modifiable factors influence postoperative audiological results including surgical approach, intra-scalar positions and electrode design among others. However, the effect of intra-scalar electrode position remains controversial. Slim lateral wall electrode (SLW) arrays, such as the CI522 cochlear implant device (Cochlear Ltd, Sydney, Australia) released March 2015, can be inserted through the round window (RW) and reside along the lateral wall (LW) of the cochlea (**Figure 1A and B**). Because spiral ganglion neural elements emanate from the modiolus, it is theorized that having the electrodes closer to the neural elements and modiolus will improve sound perception and speech recognition. In addition, the distance from the LW electrode to the neural elements may result in overlapping stimulation due to voltage spread[4,5]. Thus, Perimodiolar (PM) electrode arrays were developed in an attempt to improve speech recognition[6]. Studies have shown higher rates of scalar translocation—which itself has been associated with worse speech understanding scores—during insertion of certain PM arrays, however, particularly with the use of cochleostomy[7,89,10].

The slim perimodiolar electrode (SME), CI532 (Cochlear Ltd, Sydney, Australia), released September 2016, is a pre-curved electrode designed for insertion through the RW rather than a cochleostomy, which traditional pre-curved electrodes require, with the use of an insertion sheath. After insertion and removal of the sheath, the electrode wraps closely to the modiolus of the cochlea (**Figure 1A and B**).

To our knowledge, this is the largest cohort study comparing the audiologic speech recognition outcomes of the SLW (CI522) and the SME (CI532) cochlear implants in sequential post-lingual adult patients with severe-to-profound sensorineural hearing loss.

METHODS

Institutional Review Board Approval

Indiana University institutional review board (IRB) approval was obtained prior to retrospective collection of deidentified data.

Eligibility Criteria and Patient Selection

Audiological data from patients who underwent cochlear implantation at our institution with Cochlear implant devices (Cochlear Ltd, Sydney, Australia) were obtained from the electronic medical record between January 1, 2016 and June 30, 2019. Of this population, only those with either SLW CI522 electrodes or SME CI532 electrodes were evaluated. Patients were excluded if they were under the age 18 at time of preoperative testing, had incomplete preoperative or postoperative hearing function tests, or had undergone explantation/reimplantation. For patients who received bilateral cochlear implant surgery and complete pre- and postoperative speech recognition testing for each ear, both insertions were included in the study as separate entries if the prior implantation fell within the study period. Determination of electrode choice was made by the operative physician prior to surgical intervention based on anatomical factors of the size of the facial recess and angle of the round window after removal of the niche bony overhang.

Surgical Approach

All surgeries were performed by the study's coauthors (RFN and CWY). A standard trans-mastoid trans-facial recess approach to the cochlea was employed in all cases. Electrode insertion into the cochlea was categorized as RW insertion, extended round window, or cochleostomy. Patient records were evaluated for any complications related to CI including intraoperative tip rollover, facial nerve injury, and postoperative infection. All postoperative X-rays were viewed intraoperatively to evaluate for complete insertion or tip rollover.

Demographic and Clinical Data

Data were compiled for pre-implantation duration of deafness, etiology of hearing loss, age at time of implantation and surgical complications. Preoperative audiologic testing included aided and unaided threshold at 500 Hz (dB), low frequency (250 and 500 Hz) pure tone average (LFPTA, measured in dB), aided and unaided pure tone average (PTA) (dB) and AzBio speech recognition (SR) score in quiet (% correct). Postoperative AzBio SR scores in quiet were obtained at 6-, 9-, and 12-months. Last follow-up score was the most recent score for an individual patient within the postoperative 12-months.

Statistical Analysis

Means and standard deviations for pre-implantation duration of deafness, etiology of hearing loss, age at time of implantation, surgical complications, preoperative audiological function tests, and postoperative audiological function tests were calculated using Microsoft Excel (Microsoft Corp, Redmond WA).. Further statistical analysis was completed with SPSS software (version 24, IBM Corp., Armonk, NK). Independent t-tests were used to compare differences between means. Sample size calculation was determined using a type 1 error of 0.05 and a power of 80%. We assumed a clinically meaningful difference in performance outcomes would be 12% difference in mean % correct with AzBio sentences (67% vs. 54% correct) based upon a previous study[11]. We assumed a standard deviation of 20%. This provided a sample size calculation of approximately 38 patients. Additionally, analysis of covariance (ANCOVA) was performed to compare outcomes in the two cohorts while accounting for potential effects of covariates. ANCOVA testing followed a bivariate Pearson Correlation test to ensure there was no strong correlation (defined as $r>0.8$) between the covariates of interest. Statistically significant differences were determined using a p value <0.05.

RESULTS

Patient Demographics

As shown in Table 1, a total of 76 patients underwent 89 implantations with either SLW electrode insertion (n=52) or SME electrode insertion (n=37). When compared to patients with SLW, patients implanted with SME have similar mean (SD) age [62.0 (18.2) vs. 62.6 (14.6) years], but an overall shorter mean (SD) duration of hearing aid use [21.7 (14.4) vs. 14.3 (12.2) years; $p < 0.01$] (**Table 1**). All patients used a hearing aid on the affected ear prior to insertion of the cochlear implant electrode.

The etiology of hearing loss included noise exposure, congenital/hereditary, trauma, Meniere’s disease, otosclerosis, autoimmune, cochlear hydrops, and for many patients the cause was unknown. Most patients from both cohorts presented with severe-to-profound hearing impairment of unknown origin (n=17 CI522 [32.7%] and n=16 CI532 [43.2%]). As shown in **Table 1**, males comprised 55.8% (29 of 52 electrodes) of the SLW electrode recipients and 46.0% (17 of 37 electrodes) of SME recipients. Left and right ears were implanted with similar proportions for SLW and SME groups as right ears accounted for 53.8% and 54.1%, respectively (**Table 1**).

Preoperative Audiologic Testing

In comparing SLW to SME groups by univariate analysis, we found no significant difference in mean (SD) of preoperative unaided PTA [SLW: 88.9 (20.1) vs. SME: 90.2 (16.8); $p = 0.75$], aided PTA [55.9 (20.4) vs. 58.1 (16.4) dB; $p = 0.59$] and the mean (SD) AzBio score in quiet [11.1 (13.3) vs. 8.0 (11.5) % correct; $p = 0.25$] (**Figure 2; Table 1**). Low frequency hearing was also similar between SLW and SME with no significant differences in the mean (SD) preoperative unaided 500 Hz (dB) hearing threshold values [SLW: 79.5 (21.5) vs. SME: 81.2 (19.2); $p = 0.70$) and mean (SD) preoperative aided 500 Hz hearing threshold [49.1 (20.3) vs. 51.5 (17.6); $p = 0.56$] (**Table 1**). Mean (SD) LFPTA was in the severe range in both groups and was 75.5 (20.9) and 78.3 (17.9) for SLW and SME (p=0.51), respectively.

Surgical Outcomes

Electrode insertion through the RW or extended RW was chosen in 96.2% of the SLW patients and 100% of the SME patients (**Table 2**). Extended RW insertion was used in 16.2% of the SME cases and none of the SLW cases. Intraoperative dexamethasone (10 mg/ml) was placed in the middle ear during and after electrode insertion in 21.1% of SLW cases (n=11) and no SME cases (**Table 2**) based upon physician preference and individual discernment for use.

All patients underwent intraoperative X-ray to assess coiling in the cochlea of the SME and SLW electrodes (**Figure 3A and 3B**). Among all patients undergoing cochlear implantation, the only complication that occurred among all patients was tip rollover in 3 patients receiving SME electrodes (8.1% rate) (**Figure 3C**). All tip rollovers were corrected intraoperatively. No patients receiving the SLW electrode experienced tip rollover. No additional complications occurred among all patients, including no facial nerve injury or postoperative infection.

Audiologic Outcomes

Postoperative audiologic speech perception was evaluated with AzBio SR scores in quiet obtained at 6-, 9-, or 12-months follow-up. There was no significant difference in AzBio SR scores 6-months postoperatively between the SLW and SME patients [SLW: 68.3 (21.6) vs. SME: 59.9 (26.9) % correct, respectively; ($p = 0.11$)], or at last follow-up

[70.8% (21.3) vs. 65.6% (24.5); (*p* = 0.29)], (**Figure 2; Table 3**). Time to last follow-up was also similar between the SLW and SME groups [SLW: 9.0 (2.9) vs. SME: 9.9 (2.6) months, respectively; (*p* = 0.14)] Additionally, there was no significant difference data log usage between the SLW and SME groups [SLW: 12.9 (4.0) vs. SME: 11.3 (4.1) hours, respectively; (*p* = 0.07) (**Table 3**).

To account for potential covariance with pre-operative characteristics, ANCOVA was performed with age at implantation, pre-operative PTA, and duration of deafness as potential covariates. Prior to ANCOVA testing, bivariate Pearson Correlation demonstrated no significant correlation between age at implantation and duration of deafness (p=0.115) or between duration of deafness and pre-operative PTA (p=0.130). There was a weak negative correlation between pre-operative PTA and age at implantation (r=-0.308, p=0.005). This indicated that with older CI patients tended to have less severe PTA at time of implantation.

Across all patients, regardless of group, increased age was significantly associated with worse SR scores 6-months postoperatively and at last follow up (p=0.001 for each). In addition, lower (worse) pre-operative PTA was associated with higher (better) SR score at last follow-up (p=0.005), but not at 6-months (p=0.084) (**Table 4**). Duration of deafness was not significant at either time point. Accounting for these variables through ANCOVA, there was no significant difference in SR scores between the SLW and SME groups 6-months postoperatively (p=0.362) or at last follow-up (p=0.628) **(Table 4**)**.**

We performed post-hoc, subgroup analysis of patients with the most severe preoperative AzBio scores in quiet defined as <10% correct. This subgroup included 32

SLW insertions and 25 SME insertions (**Table 3**). Of the patients with preoperative AzBio <10% correct, SLW resulted in improved 6-month mean (SD) AzBio scores [SLW: 70.6% (22.9) vs. SME: 53.9% (30.3); p = 0.02] (**Figure 2; Table 3**). A greater proportion of patients with SLW electrode insertions in the profound hearing loss subgroup ultimately achieved AzBio >80% correct in comparison to the SME subgroup (SLW: 47% vs SME: 28%). However, the differences between SLW and SME average AzBio scores at last follow-up [SLW: 69.8% (24.50) vs. SME: 61.8% (26.9); p = 0.25] were not statistically significant (**Figure 2; Table 3**). Mean data usage was also not significant between the SLW and SME profound hearing loss subgroups [SLW: 12.6 (4.73) hours vs SME: 10.8 (4.04) hours, respectively; (p = 0.13)] (**Table 3**).

DISCUSSION

The present study provides a direct comparison of audiologic outcomes between cohorts preoperatively matched by for preoperative PTA and LFPTA receiving SME and SLW electrodes. No significant difference in speech recognition in quiet was found between SME and SLW at last follow-up. Furthermore, our ANCOVA analysis demonstrates that, while age and pre-operative PTA may have some effect on postoperative AzBio scores across all patients, even when accounting for these factors, there is no significant difference in 6-month post-operative or last follow-up AzBio scores between the SLW and SME cohorts. That lower pre-operative PTA was associated with worse last follow-up SR scores is counter-intuitive and is likely the result of a weak (r=-0.308), but significant (p=0.005), negative correlation between pre-operative PTA and age at implantation in the study population. Recently, Holder et al. performed a similar comparison between 29 slim perimodiolar (CI532) patients with a cohort of 29 slim straight (CI422 and CI522) patients from a clinical database which also found no statistical difference in AzBbio sentence outcomes[11]. While CNC testing was not included in our analysis due to lack of available data, previous studies have demonstrated that AzBio scores are highly correlated to CNC scores,[12] Therefore, we do not feel the absence of CNC scores negatively impacts our conclusions.

Many institutions have a propensity to choose LW electrodes for patients with greater residual preoperative hearing[13,14]. Although their study did not match for some per-operative and intraoperative characteristics, Fabie and colleagues, showed that after statistically controlling for preoperative hearing, there was no difference in postoperative speech recognition between LW, stylet-containing PM and midscalar electrodes[13]. It has been theorized that for patients with little to no residual hearing, a PM electrode should be chosen to provide greater electrode apposition to the spiral ganglion neurons, less energy usage and greater overall speech understanding[13]. Prior studies have demonstrated that a LFPTA <80 dB is the postoperative threshold indicative of preserved low frequency hearing[15]. As our subjects tended to have poor preoperative LFPTA [mean (SD): 75.5 (20.9) and 78.3 (17.9) for SLW and SME, respectively] very few patients in our cohort would have qualified for hearing preservation. It has been theorized that PM electrodes would allow for lower stimulation thresholds, improved dynamic range and decreased stimulation of adjacent neural elements when compared to LW electrodes and result in improved audiologic performance[16,17]. Indeed, in both adult and pediatric patients, PM electrode designs have been associated with decreased stimulation thresholds compared to LW electrodes. However, the use of PM electrodes has not been found to be consistently correlated with improved audiologic outcomes in either population[18,19].

Park et. al. examined audiologic outcomes of fourteen children who received bilateral cochlear implants at different times, where one ear received a LW electrode and the other received a PM electrode[20]. Though a significant difference was noted in speech perception between ears, this difference was attributable to the time interval between implantations and not the device itself or the surgical technique used[20].

Previous studies have demonstrated that traditional stylet-containing PM electrodes increase the risk of insertion trauma due to their larger size and more rigid nature with a reported translocation rate of 26-40%, resulting in worse audiologic outcomes than electrodes remaining in the scala tympani[21,22]. Importantly, the SME

(CI532) design seems to have improved translocation rates (<10%) and residual hearing preservation when compared to the previous (i.e. CI512) designs [23-26].

There were no tip rollovers in the SLW group and only 3 incidents of tip rollover in the SME group (8%) which is in agreement with prior studies[23,26-28].

Intraoperative dexamethasone was not administered in any SME cases while it was used in 11 SLW cases. The choice to use intraoperative dexamethasone is based on surgeon preference. Unfortunately, measurements of residual hearing were not available for many patients in our cohort so the effect of dexamethasone cannot be assessed.

There was also no significant difference in daily CI usage between the SLW and SME groups, suggesting similar patient experience with each design. The clinical default pulse duration with the CI522 (37 µs) is longer than that of the clinical default pulse duration for CI532 (25 µs). However, our results suggest that the difference in pulse duration does not alter the audiologic outcomes. All of our patients used a maxima of 8.

What factors could account for the lack of a speech recognition outcome difference between CI532 and CI522? It is possible that the intracochlear location of the electrode varies from predicted (e.g. CI532 electrode is pushed against the lateral wall during insertion). A second possibility is that the distal end of the neural elements is close to the organ of Corti, which resides between the modiolus and the lateral wall. Thus, if the electrode remains in the scala tympani, there may not be any differences in audiologic outcomes. Thirdly, as the specificity of neural stimulation is limited by the relatively large contact size and stimulation within the ionic perilymphatic fluid, an electrode may still stimulate a broad territory despite resting close modiolus.

Our subgroup analysis of those patients with very poor preoperative AzBio scores demonstrates that patients implanted with SME did not outperform patients with SLW electrodes. In fact, we found statistically improved performance at 6-months in the subgroup cohort with SLW electrodes. The choice of a PM electrode for patients with no residual hearing does not appear to provide a clinically meaningful advantage long-term and may be inferior to lateral wall electrodes in the immediate postoperative period. However, these are preliminary findings and should be explored fully in well-powered study across different populations.

Finally, there are anatomic and technical aspects to consider when using the SME, including the size of the facial recess, orientation of the RW, or, rarely, the level of the jugular bulb[30]. If the angle of the round window is unfavorable, extending the round window may be required to prevent tip rollover with SME. However, placement of the SLW electrode is possible irrespective of the orientation of the RW. Additionally, it has been recognized that speed of electrode insertion is an important factor in hearing preservation. Faster rates of insertion have been shown to cause higher rates of osseous spiral lamina fractures and basilar membrane translocation in cadaveric temporal bone specimens. These complications occur at much lower rates with very slow insertion speeds and robotic insertion, although in its infancy and only trialed, to this point, with SLW electrodes, has been proposed as a way to minimize insertion trauma. Our results remain applicable to the Profile Plus (Cochlear Ltd, Sydney, Australia) 600 series electrode arrays as the primary difference between the CI522/532 and the CI622/632 nucleus is capability of undergoing magnetic resonance imaging without requiring removal of the internal magnet.

There are several limitations to this study. These include the retrospective nature of this study, heterogenous patient population, inability to stratify patients based on hearin gloss. While we performed postoperative X-ray to rule out tip foldover. CT imaging would be required to determine intracochlear positioning. Additionally, a larger sample size would increase confidence in our results. Finally, although AzBio sentence testing in quiet is commonly used to evaluate speech recognition outcomes, these sentence materials were not designed to detect other potentially subtle differences between electrodes or patients[31,32] .

CONCLUSIONS

SLW (CI522) and SME (CI532) both provide comparable improvement in speech recognition in post-lingual adult patients. In this data set, SME do not exhibit superior outcomes compared to SLW and SLW can be used even in patients with the most profound sensorineural hearing loss.

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Figure Legends:

Figure 1: Straightened configuration (A) and desired intracochlear position (B) of SLW (CI522) and SME (CI532) electrodes. Actual intracochlear position may vary. RW, round window.

Figure 2: (A) AzBio scores for all patients (B) AzBio scores for patients with preoperative AzBio <10% correct. Displayed as mean +/- SD with individual data points. NS = Not significant.

Figure 3: Postoperative X-ray of SLW (A), SME (B) and tip rollover SME (C)

Table 1: Preoperative Patient Characteristics

Characteristic	**CI 522 (SLW) (N=52)**	**CI 532 (SME) (N=37)**	***P***
Age at implantation, y (SD)	62.0 (18.2)	62.6 (14.6)	0.67
Gender, male (%)	29 (55.8%)	17 (46.0%)	
Side of implant, right (%)	28 (53.8%)	20 (54%)	
Race, white (%)	49 (94%)	37 (100%)	
Duration of hearing loss, y (SD)	27.7 (16.2)	20.8 (17.6)	0.06
Duration of HA use, y (SD)	21.7 (14.4)	14.3 (12.2)	**0.01**
LFPTA, dB (SD)	75.5 (20.9)	78.3 (17.9)	0.51
PTA Unaided, dB (SD)	88.9 (20.1)	90.7 (16.8)	0.66
PTA Aided, dB (SD)	55.9 (20.4)	58.1 (16.4)	0.59

y, years; SD, Standard Deviation; PTA, Pure Tone Average; Hz, Hertz; dB, decibel, LFPTA indicates low-frequency pure-tone average (250, 500 Hz)

Table 2: Operative Details

Detail	CI 522 (SLW) (n=52)	CI 532 (SME) (n=37)
Method of insertion		
RW, % (n)	96.2% (50)	83.7% (31)
Extended RW, % (n)	0 % (0)	16.2% (6)
Cochleostomy, % (n)	3.8% (2)	0% (0)
Intraoperative Dexamethasone, n (%)	11 (21.2%)	0
X-ray confirmation, n (%)	52 (100%)	36 (97.3%)
Complications (tip rollover)	0	3 (8.1%)*

RW = round window; n = number of patients, * = Tip rollovers corrected intraoperatively

Table 3: Speech Recognition Outcomes

PATIENTS (ALL)	**CI 522 (SLW) (n=52)**	**CI 532 (SME) (n=37)**	***P***
AzBio (preoperative), % correct (SD)	11.1 (13.3)	8.0 (11.5)	0.25
AzBio (6 month), % correct (SD)	68.3% (21.6)	59.9% (26.9)	0.11
AzBio (Last), % correct (SD)	70.8% (21.3)	65.6% (24.5)	0.29
Follow-up (Last), months (SD)	9.0 (2.9)	9.9 (2.6)	0.14
Data log usage, hours (SD)	12.9 (4.0)	11.3 (4.1)	0.07
Low Frequency PTA, dB (SD)			
PATIENTS (AzBio <10%)	**CI 522 (SLW) (n=32)**	**CI 532 (SME) (n=25)**	***P***
AzBio (6 month) % correct (SD)	70.6% (22.9)	53.9% (30.3)	**0.02**
AzBio (Last), % correct (SD)	69.8% (24.5)	61.8% (26.9)	0.25
Follow-up (Last), months (SD)	9.2 (3.0)	10.4 (2.3)	0.10
Data log usage, hours (SD)	12.6 (4.7)	10.8 (4.0)	0.13

n, number of patients; SD, standard deviation

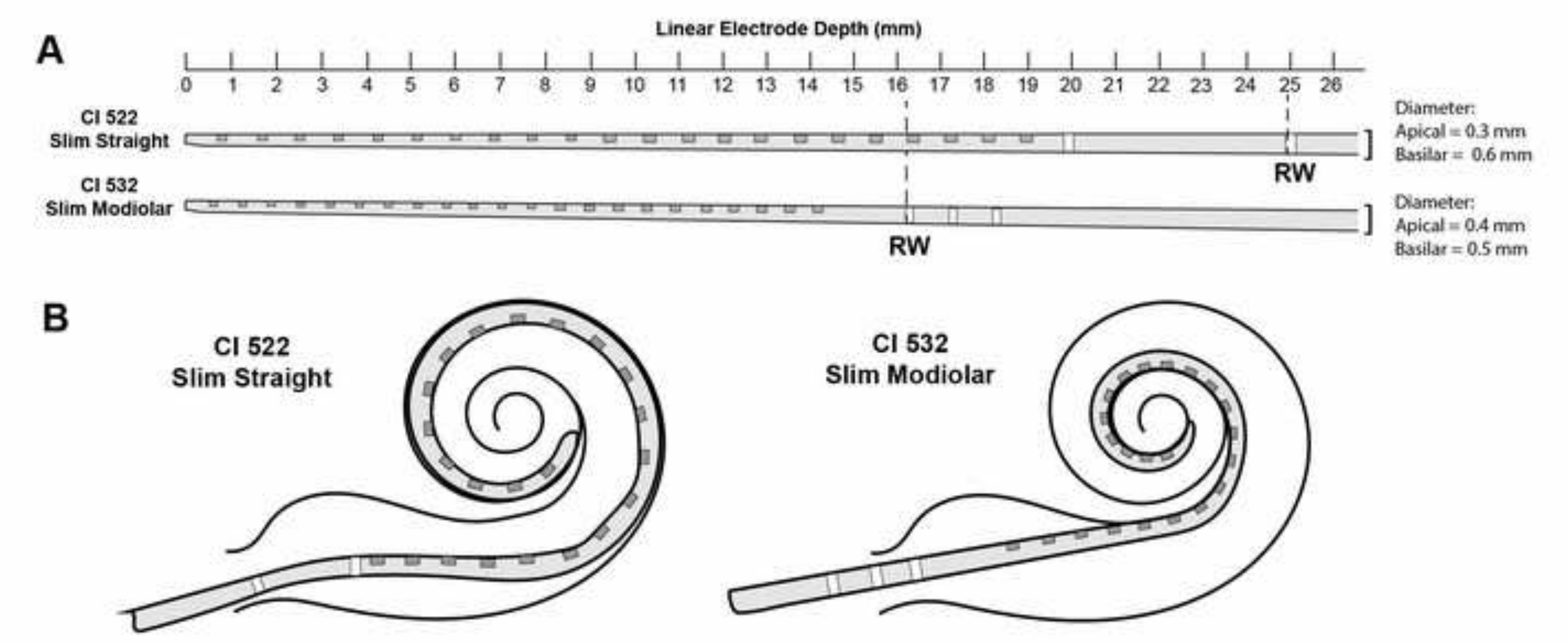
Table 4: ANCOVA results evaluating effect of cochlear implant type while accounting for age at implantation, pre-operative PTA, and duration of deafness.

	6-Month Post-Operative AzBio Score		**Last Follow-Up AzBio Score**	
Variable	**Proportion of Variance Accounted for (Partial η-squared)**	***P***	**Proportion of Variance Accounted for (Partial η-squared)**	***P***
Age at Implantation	17.8%	0.001	12.5%	0.001
Pre-operative PTA	4.8%	0.084	9.5%	0.005
Duration of Deafness	3.8%	0.125	3.8%	0.084
Cochlear Implant Type	1.4%	0.362	0.3%	0.628

PTA, pure-tone average

Figure

Click here to access/download;Figure;Figure1_Mockup.jpg



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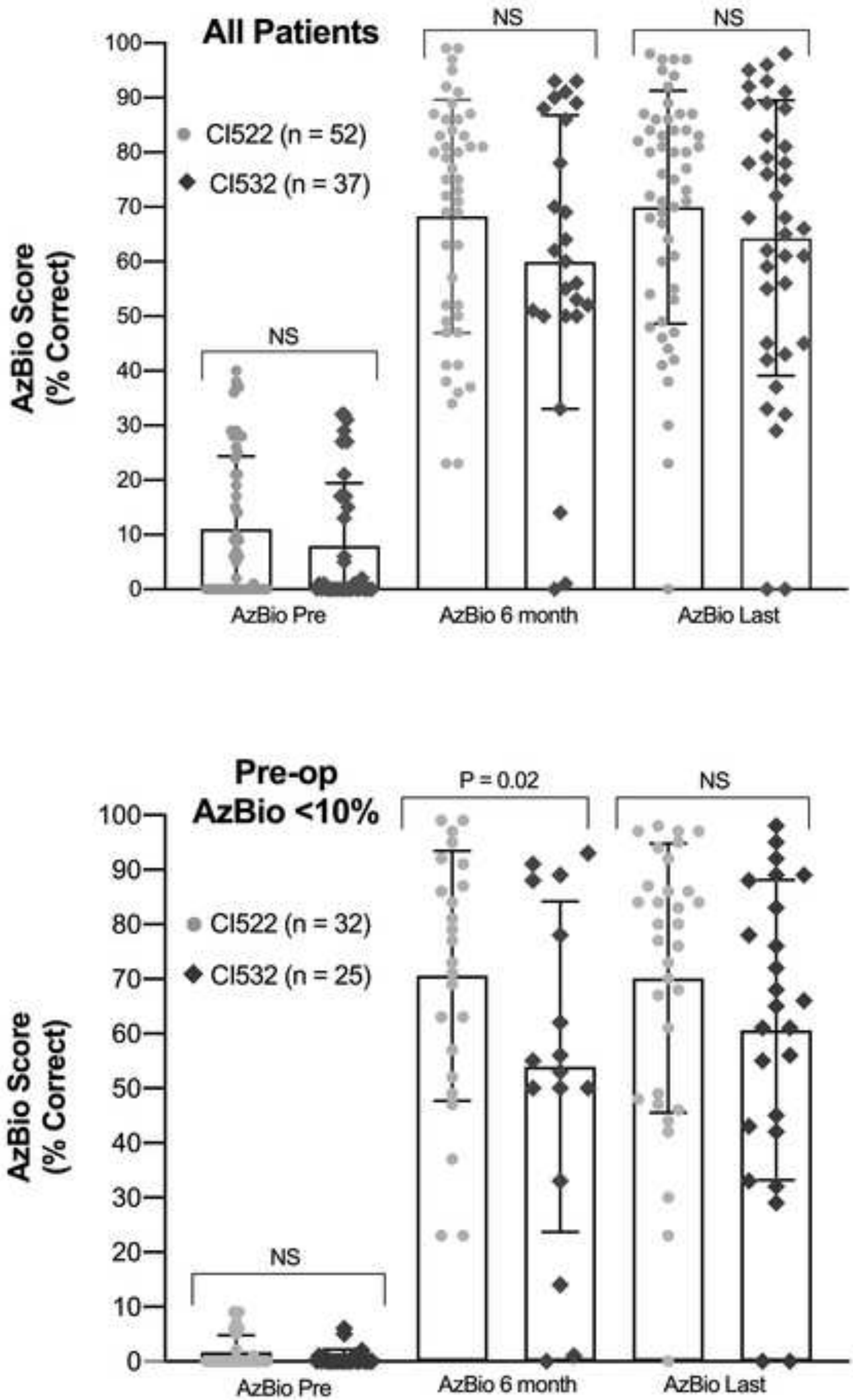

Figure

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