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Assessment of Electrode Placement and Audiological Outcomes in Bilateral Cochlear Implantation

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Objective: The goal of this study was to use highly accurate nonrigid algorithms to locate the position of cochlear implant (CI) electrodes and correlate this with audiological performance.
Patients: After obtaining institutional review board approval, adult patients who had bilateral CIs were identified, and those with preoperative temporal bone computed tomographic scans were asked to return for a postintervention computed tomography. Sixteen adult patients agreed. Demographics, cause of deafness, length of auditory deprivation, and audiological performance were recorded.
Intervention: Using a nonrigid model of the shape variations of intracochlear anatomy, the location of the basilar membrane was specified in relationship to the electrode array. The number of electrodes within each compartment of the cochlea was correlated with hearing in noise and consonant-noun-consonant scores for the known confounding variable: length of deafness.
Main Outcomes: Mann-Whitney *U* tests of differences were used to compare the hearing performance resulting from implants completely in the scala tympani (ST) versus those not completely in the ST.
Results: Of all implants, 62.5% were fully inserted in the ST; 34.4% were partially inserted into the ST and 3.1% was fully inserted in the scala vestibuli. Controlling for the known contributing variable of length of auditory deprivation, our results show that the location of electrodes in relationship to the scala is not predictive of audiological performance.
Conclusion: We have assessed electrode placement and correlated it with audiological outcome. The presence of the electrodes solely in the ST was not predictive of outcome. We estimate that it would take analyzing data of thousands of CI patients before any valid correlations can be made. **Key Words:** Cochlear implants—Consonant-noun-consonant—Hearing in noise—Scala tympani—Scale vestibule.
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Numerous studies have identified significant predictive factors for hearing outcomes in patients with cochlear implants (CIs) (1–3). These include duration of deafness (4), level of preimplant speech recognition (5), prelingual/postlingual status (6), and electrode programming configuration (7,8). Recipient age does not seem to have an effect on hearing outcomes in elderly candidates (9).

As studies done by Shepherd et al. (10) reported that the scala tympani (ST), at least from a dimensional standpoint, is the ideal place for electrode placement, a number of recent studies have proposed that electrode location within the scala vestibuli (SV) may be an important determinant of audiological outcome (11–14). Skinner et al. (11) and Finley et al. (13) used rigid registration methods, which are based on aligning structures from postoperative to preoperative computed tomographic scans and use of a high-resolution cochlear atlas to overcome the inability to positively identify the basilar membrane on clinically applicable temporal bone computed tomographic scans. Such rigid registration using a cadaveric model of the cochlea is a good technique if the model can be scaled by stretching, rotating, and skewing to fit the patient's anatomy. If anatomical

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The software described herein has been copy written. Authors Jack H. Noble, Benoit M. Dawant, and Robert F. Labadie may benefit financially from future licensing agreements.

Supplemental digital content is available in the text.

differences other than scaling exist, for example, a more acute basal turn in the patient versus the model, rigid registration imparts error on where the basilar membrane is depicted. Aschendorff et al. (14) relied on postoperative rotational tomography to determine whether the electrodes stayed in ST or crossed into SV.

We have developed and applied nonrigid methods to predict the location of the basilar membrane on clinically applicable computed tomographic scans. To do this, we created a model of the shape variations of intracochlear anatomy using micro–computed tomographic scans of 6 cadaveric temporal bones. We have successfully validated its predictive accuracy on cadaver models (15). The method is semiautomated, dramatically reducing the labor involved in analyzing individual specimens. With validation of this technique, we are able now to accurately locate the position of CI electrodes in relation to the basilar membrane in CI patients who have undergone computed tomography of the temporal bones before and after CI. For the first clinical testing, we chose to study adults who had bilateral implants such that potential confounding variables, with the exception of length of deafness, would be eliminated.

The goal of this study was to use the nonrigid algorithms we have developed to locate the position of CI electrodes in relationship to the basilar membrane in adults who had bilateral implants and correlate such with audiological performance.

PATIENTS

After obtaining institutional review board approval, adult patients who had bilateral CIs were identified, and a subset of patients who had preoperative temporal bone computed tomographic scans was asked to return to our facility to obtain a postintervention computed tomography. Sixteen adult patients agreed and are included in this report. These patients' demographics, cause of deafness, length of auditory deprivation, and audiological performance were recorded.

INTERVENTION

Computed tomography was performed using a Xoran XCAT flat-panel volume computed tomography machine (Xoran Technologies, Ann Arbor, MI, USA). After flat-panel volume computed tomography scanning, our nonrigid model-based algorithm was used to predict basilar membrane location in reference to the CI electrode array (details of this method can be found online) (16). Our recently reported results (15) show a high correlation between such predictions and histopathologic analysis. Hearing in noise (HINT) and consonant-noun-consonant (CNC) scores were recorded, and correlations between the location of electrode and audiological scores were made as described below.

MAIN OUTCOME MEASURES

Owing to the skewed nature of the hearing performance data, values were summarized using means, medians, and 25th to 75th interquartile ranges that represent the middle 50% of the values in a given distribution. Mann-Whitney *U* tests of differences were used to compare the hearing performance resulting from implants completely in the ST versus those not completely in the ST. Measures of association were made using Spearman rank correlations. Finally, analysis of covariance procedures were conducted to test for hearing performance differences between the sets of implants that controlled for length of auditory deprivation in the ear receiving the implant (covariate). The hearing and deprivations

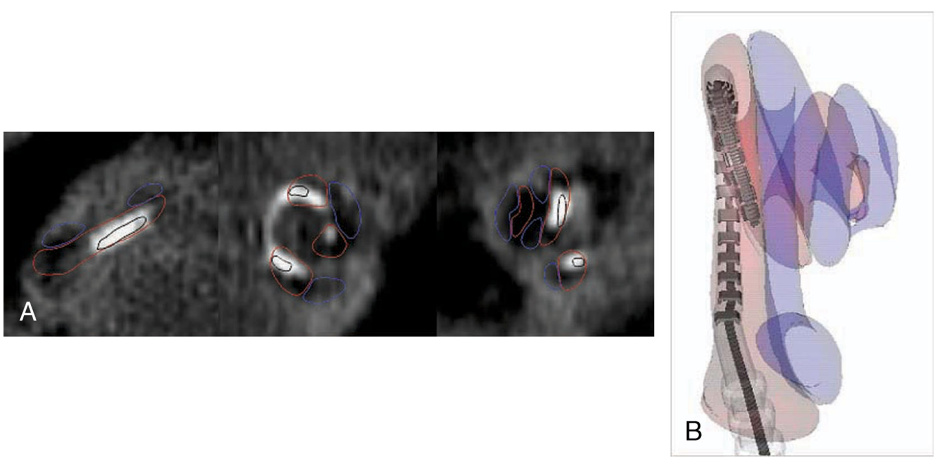

FIG. 1. *A*, Postoperative computed tomographic scan of a patient with full electrode insertion in the ST. Note that the ST is contoured by red and SV contoured in blue. *B*, Reconstructed computed tomographic scan in the same patient with full ST insertion. ST shadowed in *red*; SV shawdowed in *blue*.

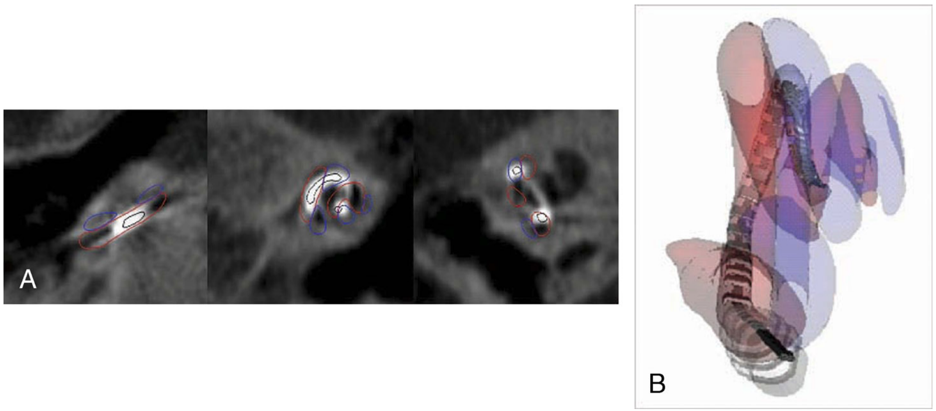

FIG. 2. *A*, Postoperative computed tomographic scan of a patient with the electrode crossing from ST to SV. ST contoured in *red*; SV contoured in *blue*. *B*, Reconstructed computed tomographic scan in the same patient with the electrodes starting in the ST and then crossing to the SV at approximately 180 degrees. ST in *red*; SV, *blue*.

duration values were rank transformed to meet the assumptions of analysis of covariance.

RESULTS

All 3 U.S. Food and Drug Administration–approved CI manufacturers were represented in the study. Of the 32 implants, 20 (62.5%) were fully inserted in ST. Figure 1 shows a computed tomographic scan and corresponding reconstructed image of Patient 1 where the implant is fully inserted in the ST. Of the 32 implants, 11 (34.375%) were partially inserted into the ST and partially in the SV. All the implants that crossed from the ST to the SV did so at approximately 180 degrees. Figure 2 shows a computed tomographic scan and a reconstructed image of Patient 3 where the implant is crossing from the ST to the SV. One implant (3.125%) was fully inserted in the SV.

Results are summarized in Tables 1 and 2 (see Supplemental Digital Content at http://links.lww.com/MAO/A46) where Table 1 includes patients who were simultaneously implanted (n = 9) and Table 2 included patients who were sequentially implanted (n = 7). Figure 3 graphically shows the results comparing CNC scores in the group with the electrodes fully inserted in the ST versus the group where the electrodes cross from the ST to the SV, and Figure 4 (see Supplemental Digital Content at http://links.lww.com/MAO/A55) shows the HINT scores in these groups. The distributions of hearing performance were subjectively similar for the 2 groups, and differences were not statistically significant (Mann-Whitney *U* tests, HINT score: $z = 0.117$, $p = 0.907$, CNC score: $z = 0.370$, $p = 0.711$). Although it seemed that auditory deprivation had been slightly longer for the group with implants partially inserted in the ST versus those fully inserted in the ST, the difference was not statistically significant (Mann-Whitney *U* test: $z = 1.426$, $p = 0.154$). The association of auditory deprivation with hearing performance as measured by the HINT was at a meaningful, albeit not statistically significant, level in this sample ($r_s = -0.309$, $p = 0.097$). The association of length of auditory deprivation with CNC

TABLE 1. *Patients simultaneously implanted (n = 9)*

Implant type	Sex	Side	Date of birth	Date of surgery	Cause	Duration, yr	HINT, %	CNC, %	Electrodes
Nucleus	Male	Right	10/3/47	7/23/08	Noise	8	99	80	Full ST
Nucleus	Male	Left	10/3/47	7/23/08	Noise	8	99	80	Full ST
Nucleus	Male	Right	2/26/30	8/26/02	Noise	6	66	20	Full ST
Nucleus	Male	Left	2/26/30	8/26/02	Noise	6	74	28	Full ST
Nucleus	Female	Right	12/29/55	12/5/08	Unknown	6	98	88	Full ST
Nucleus	Female	Left	12/29/55	12/5/08	Unknown	6	100	88	Full ST
Nucleus	Female	Right	7/29/47	3/27/09	Unknown	Unknown	95	74	Partial ST/SV
Nucleus	Female	Left	7/29/47	3/27/09	Unknown	Unknown	42	18	Full ST
Nucleus	Female	Right	5/8/31	4/23/09	Unknown	9	44	46	Full ST
Nucleus	Female	Left	5/8/31	4/23/09	Unknown	9	66	44	Partial ST/SV
ABC	Male	Right	2/22/49	5/10/07	Poisoned	37	80	60	Full SV
ABC	Male	Left	2/2249	5/10/07	Poisoned	37	86	58	Partial ST/SV
ABC	Female	Right	12/8/68	7/19/07	RA	5	88	40	Full ST
ABC	Female	Left	12/8/68	7/19/07	RA	5	90	40	Partial ST/SV
MedEl	Male	Right	7/14/37	2/6/09	Unknown	3	13	0	Full ST
MedEl	Male	Left	7/14/37	2/6/09	Unknown	3	99	50	Full ST
ABC	Male	Right	1/23/33	10/31/07	Unkown	5	0	0	Partial ST/SV
ABC	Male	Left	1/23/33	10/31/07	Unkown	5	0	0	Full ST

RA indicates rheumatoid arthritis.

TABLE 2. *Patients' sequential implanting (n = 7)*

Implant type	Sex	Side	Date of birth	Date of surgery	Etiology	Duration, yr	HINT, %	CNC, %	Electrodes
Nucleus	Female	Right	2/13/81	10/19/05	ECMO	1	94	70	Partial ST/SV
Nucleus	Female	Left	2/13/81	6/28/06	ECMO	1	100	86	Full ST
Nucleus	Female	Right	8/22/80	8/1/05	Genetic	24	87	20	Partial ST/SV
Nucleus	Female	Left	8/22/80	7/19/07	Genetic	20	90	20	Full ST
Nucleus	Male	Right	3/11/67	3/1/98	Cogan	7	94	78	Full ST
Nucleus	Male	Left	3/11/67	7/14/08	Cogan	10	96	76	Partial ST/SV
Nucleus	Female	Right	8/13/65	12/17/02	Genetic	32	63	24	Full ST
Nucleus	Female	Left	8/13/65	11/24/08	Genetic	40	43	30	Full ST
Nucleus	Female	Right	12/3/69	9/1/04	Unknown	21	75	38	Partial ST/SV
Nucleus	Female	Left	12/3/69	1/20/10	Unknown	35	95	60	Partial ST/SV
ABC	Male	Right	9/17/67	2/28/07	Ototoxic	39	22	0	Full ST
ABC	Male	Left	9/17/67	9/18/08	Ototoxic	40	11	0	Partial ST/SV
ABC	Female	Right	7/20/67	1/5/05	Genetic	3	94	58	Full ST
ABC	Female	Left	7/20/67	8/30/07	Genetic	5	92	68	Full ST

score was substantially smaller ($r_s = -0.129$, $p = 0.498$). When the length of auditory deprivation was included as a covariate in the analysis of the differences in hearing between the 2 groups, there were no statistically significant changes in the primary conclusions (HINT: $F_{1,27} = 0.110$, $p = 0.742$; CNC: $F_{1,27} = 0.003$, $p = 0.959$). This is shown in Table 3 (see Supplemental Digital Content at http://links.lww.com/MAO/A46).

CONCLUSION

Intracochlear position of the CI has been shown in previous studies to correlate with audiological outcome. Skinner et al. (11) presented 15 patients implanted with Advanced Bionics devices and determined that the position of electrodes within the SV is negatively correlated with audiological performance. Aschendorff et al. (12) used postoperative rotational tomography to determine the position of CI electrodes with respect to the basilar membrane. Results of speech tests demonstrated the best results after insertion in the ST with poorer results after dislocation from the ST to the SV. Finley et al. (13) continued the work of Skinner and demonstrated, in an additional 14 patients with Advanced Bionics implants, that poorer audiological outcomes could be predicted by the number of electrodes in the SV, the depth of electrode insertion, and the age at the time of insertion (13).

Herein, our group reports use of a novel, proprietary, automated, nonrigid algorithm to predict CI electrode location in relationship to the basilar membrane. Accuracy of the three-dimensional reconstructions produced with this software were verified using anatomic microdissections, demonstrating that this method is highly precise and poised for clinical application (15). Reviewing the placement of electrodes for bilaterally implanted adults, we found that more than one third cross the basilar membrane and that this occurs universally at 180 degrees from the insertion site. Controlling for the known contributing variable of length of auditory deprivation and using a linear modeling approach to account for the effect of the type of surgery (sequential versus simultaneous), results from analysis of the 32 implants show that the location of the CI electrode in relationship to the basilar membrane (ST versus SV) is not predictive of audiological performance.

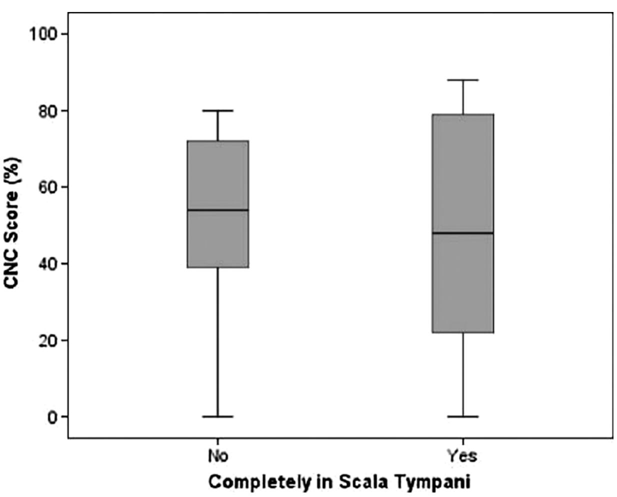

FIG. 3. Comparison of CNC word scores for bilaterally implanted patients with complete versus incomplete ST insertion. Data are shown as a horizontal median value with 25th to 75th percentiles shown in the *gray box*, and complete data are shown between the *whiskered lines*.

TABLE 3. *Primary conclusions (HINT: $F_{1,27} = 0.110$, $p = 0.742$; CNC: $F_{1,27} = 0.003$, $p = 0.959$)*

	Mean	Median	IQR
HINT, %			
Completely in the ST	71.2	89.9	44.8–98.8
Not inserted completely	72.9	86.5	68.3–94.8
CNC, %			
Completely in the ST	46.6	48.0	21.0–79.5
Not inserted completely	49.2	54.0	38.5–73.0
Auditory deprivation, yr			
Completely in the ST	11.3	6.0	5.0–10.0
Not inserted completely	20.1	21.0	5.0–37.0

IQR indicates the 25th to 75th interquartile range, representing the middle 50% of the values.

We know from surgical experience that patients who have revision CI surgery can have very good audiological outcomes. At the time of revision surgery, the cochlea is often filled with soft tissue as a pseudocapsule has formed around the electrode array, obliterating anatomical distinctions between the ST and the SV. Combining such clinical observations with the data presented herein, we propose that electrode array position—in reference to the basilar membrane—does not affect audiological performance. Note that we propose this only for traditional CI surgery and not hearing preservation/hybrid surgery.

A strategy for further testing of this hypothesis would be to conduct an equivalence trial of randomly selected patients with implants fully inserted in the ST and another randomly selected sample with implants that are at least partially outside the ST. A parallel group study designed to test the equivalence of mean CNC scores (i.e., true difference of 0%) would require 1850 patients per group to achieve 90% statistical power in testing equivalence limits within ±5% performance or less (using 1-sided α level of 0.05). Given all of the same assumptions, groups of 1455 patients each would achieve 80% statistical power to test the proposed equivalence limits of a mean difference of ±5% performance or less. Whereas this is a large task, (*a*) it is necessary to determine whether intracochlear position matters and (*b*) it can be accomplished using automated software such as that developed by our group.

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