Sensitivity and Costs of Intraoperative Trans-Impedance Matrix Recordings, Spread of Excitation Functions, and X-ray Imaging in Detecting Cochlear Implant Tip Foldovers

*†Viral Tejani, *†Robin Piper, *†Gail Murray, ‡Nauman F. Manzoor, *†Sarah Mowry,
*†Maroun Semaan, and *†Alejandro Rivas

*Department of Otolaryngology–Head and Neck Surgery, University Hospitals Cleveland Medical Center, Cleveland, Ohio; †Department of Otolaryngology–Head and Neck Surgery, Case Western Reserve University School of Medicine, Cleveland, Ohio; and ‡Department of Otolaryngology–Head and Neck Surgery, Virginia Commonwealth University, Richmond, Virginia

Objective: Evaluate the sensitivity and financial costs of Trans-Impedance Matrix recordings, Spread of Excitation functions, and x-rays in detecting cochlear implant tip foldovers
Setting: Tertiary academic medical center
Patients: 113 ears of 108 patients
Interventions: Following cochlear implantation and before concluding surgery, intraoperative Trans-Impedance Matrix recordings, Spread of Excitation functions, and x-rays were conducted to evaluate presence of tip foldover.
Main Outcome Measures: Presence of tip foldover; recording time necessary for and costs of Trans-Impedance Matrix, spread of excitation, and x-rays.
Results: There were six tip foldovers. Trans-Impedance Matrix showed 100% sensitivity, 100% specificity, 100% positive predictive value, and 100% negative predicative value in detecting tip foldovers. Spread of excitation showed 29% sensitivity, 99% specificity, 67% positive predictive value, and 95% negative predicative value. Trans-Impedance Matrix recordings were completed significantly faster than spread of excitation and x-rays. Elimination of x-rays from our intraoperative workflow results in a twofold cost reduction.
Conclusion: Trans-Impedance Matrix recordings have potential great clinical utility in evaluating proper CI placement intraoperatively and reducing costs of surgery while not compromising patient care. Given the low tip foldover rate, a multicenter study is in progress to evaluate the sensitivity, specificity, positive predictive value, and negative predicative value of Trans-Impedance Matrix in a larger dataset. This can provide better guidance to cochlear implant clinics interested in evaluating the impact of using Trans-Impedance Matrix on patient care as well as the economics of reducing use of intraoperative imaging.

Key Words: Cochlear implant—Electrophysiology—Tip foldover—Trans-Impedance Matrix.

Otol Neurotol **45:**e763–e771, 2024.

INTRODUCTION

Cochlear implants (CIs) have become a successful surgical intervention for patients with significant hearing loss and limited benefit from hearing aids. Regardless of CI manufacturer, there are generally two dominant types of electrode arrays. Perimodiolar electrode arrays are placed closer to the modiolus, whereas straight electrode arrays generally are closer to the lateral wall of the cochlea. There are differing philosophies regarding specific electrode array designs, and the choice of electrode array/CI manufacturer is a multifaceted decision involving the patient, audiologist, and surgeon. Cochlear Ltd. offers a portfolio of two straight arrays (CI 622, CI 624) and two precurved arrays (CI 612, CI 632).

A key component of CI surgery is the proper insertion of the electrode array into the cochlea. Precurved electrode arrays (particularly older generation models) have a higher risk of scalar translocation, which leads to poorer outcomes

---

Address correspondence and reprint requests to Viral Tejani, Au.D., Ph.D., University Hospitals Cleveland Medical Center: UH Cleveland Medical Center, 11100 Euclid Ave, HORT 103, Cleveland, OH 44106; E-mail: viral.tejani@UHhospitals.org

Viral Tejani, https://orcid.org/0000-0001-7585-9619

Investigator Initiated Research (IIR) award funded by Cochlear Ltd.

Sources of support and disclosure of funding: Funding for this study was provided by Cochlear Ltd under an Investigator Initiated Research (IIR) grant awarded to V.D.T. However, study design, data collection, data analysis, and manuscript preparation were completed solely by the authors without outside influence from Cochlear Ltd. V.D.T. is co-chair of the 2024 ACIA Conference Committee, consultant for iotaMotion, inc., Cochlear Americas, and Objective Hearing, LLC. S.M. is a consultant for Medtronic, Cook Medical, and Cochlear Americas. She is also a PI on an unrelated clinical trial sponsored by Cochlear Americas. A.R. is a consultant for Cochlear Americas, Grace Medical, Stryker, and Cook Medical. He is also a PI on an unrelated clinical trial sponsored by Cochlear Americas.

DOI: 10.1097/MAO.0000000000004361

(1). The Slim Modiolar Electrode (CI 532/CI 632) improves upon this design, showing proper placement in the scala tympani in almost all patients (2–4). However, a tip foldover can occur in that the most apical electrode contact folds over and collapses onto itself during the insertion of the electrode array. There is a higher risk of tip-foldover with precurved arrays compared with lateral wall arrays (5), with about 6% of cochlear implant cases using the slim modiolar array resulting in a tip foldover when collapsed across studies (2,6–9). Tip foldovers are easily corrected intraoperatively when imaging (e.g., x-ray, fluoroscopy, CT scan) is performed immediately after insertion to confirm proper electrode placement. If warranted, the surgeon can explant and reimplant the same electrode array or a different electrode array to correct device placement.

Intraoperative imaging is highly effective in identifying tip foldover, but it also exposes the patient to radiation (albeit a small dose), results in longer anesthetic time, and incurs additional cost. The use of electrically evoked compound action potentials (ECAPs) has been proposed as an alternative method of identifying tip foldovers via analysis of ECAP Spread of Excitation functions. ECAPs are neural responses that arise from electrical stimulation of the auditory nerve (10). When measured in response to sequential stimulation of two different electrodes (“probe” and “masker” electrode), the resulting response is used to construct Spread of Excitation functions (11). Typically in intraoperative settings, one would select a few probe electrodes to measure SOE functions. Measuring SOE functions takes 1 to 2 minutes per probe electrode and involves no radiation; however, their hit rate to identify foldovers has been questionable (12,13). Additionally, it is clinically time prohibitive to measure SOEs for all 22 probe electrodes; thus, only a few probe electrodes can be tested.

An alternative electrophysiologic method of determining tip foldover is the measurement of voltage spread at all electrode locations, which are then used to calculate impedance measures. These potentials are known as Trans-Impedance Matrix (TIM; Cochlear Corporation), Electric Field Imaging (EFI; Advanced Bionics), or Impedance Field Telemetry (IFT; MED-EL), depending on the manufacturer. As the implants for the current study are Cochlear Corporation devices, we use the term Trans-Impedance Matrix for the rest of this manuscript. However, the concept of voltage spread and impedance measure is quite similar regardless of electrode array manufacturer. One electrode is stimulated, and the resulting voltage at that electrode and all other electrodes are recorded. The resulting voltage is used to calculate impedance via Ohm's Law ($\text{Resistance} = \frac{\text{Voltage}}{\text{Current}}$) and plotted. One advantage of Trans-Impedance Matrix recordings is that they can done for all 22 probe electrodes in the span of 2 to 3 minutes, whereas only 1 to 2 probe electrodes can be tested for SOE functions in the same time frame. The use of Trans-Impedance Matrix recordings have shown great promise in identifying tip foldovers in recent years (9,13–15). Although the Trans-Impedance Matrix has only been available as a research patch within Custom Sound EP (clinical cochlear implant software), it has now been incorporated into the “Placement Check” feature of the commercially available Cochlear Nucleus SmartNav system. The SmartNav system offers several tests to be used intraoperatively during CI surgery: insertion speed to evaluate speed of insertion, depth of insertion, placement check to check for tip foldover, impedance telemetry, electrically evoked stapedius reflex threshold testing, and ECAP threshold assessment via AutoNRT (neural response telemetry).

The present study has two goals:

1) Evaluate the sensitivity and specificity of Trans-Impedance Matrix functions, ECAP Spread of Excitation functions, and intraoperative x-rays, in identifying tip foldovers. No study has compared all three measures in one clinical population.
2) Evaluate the costs of the use of Trans-Impedance Matrix functions, ECAP Spread of Excitation functions, and intraoperative x-rays, which also has not been done in prior studies.

It is hypothesized that the Trans-Impedance Matrix will be as effective as an x-ray in detecting tip-foldover and that both Trans-Impedance Matrix and x-rays will be better than ECAP Spread of Excitation functions in detecting tip foldovers. It is also expected that Trans-Impedance Matrix recordings will be the most cost-effective means for detecting tip foldovers.

MATERIALS AND METHODS

This study was approved by our Institutional Review Board under STUDY20211662

Subjects were both pediatric and adult cochlear implant recipients with normal cochlear anatomy undergoing cochlear implantation between 9/2021 and 12/2022, with some being sequential bilateral implantation. Normal cochlear anatomy was confirmed via a preoperative CT or MRI. The age ranges of our pediatric and adults subjects were 0.8–16.1 years (4.7 ± 4.0 yr) and 21.7–88.2 years (67.61 ± 13.32 yr), respectively. A total of 113 cochlear implant surgeries were performed using three types of cochlear implant arrays (CI 612, 632, 624). The majority of our caseload was the CI 632 slim modiolar electrode array (n = 99), followed by the CI 612 (n = 12), and CI 624 (n = 2).

Cochlear implantation was performed by authors A.R.C., S.M., M.S., and N.M. using standard surgical protocols. Once the surgeon was ready to implant the array, audiology commenced the SmartNav insertion speed recording. Subsequently after insertion was completed, audiology proceeded to perform placement check, impedance, and AutoNRT recordings. SmartNav by defaults performs AutoNRT on all electrodes. After SmartNav recordings were completed, Custom Sound EP was used to perform impedance, ECAP Spread of Excitation, and AutoNRT recordings. ECAP Spread of Excitation was performed on one basal, one middle, and one apical electrode. AutoNRT was performed on nine electrodes spaced throughout the array. (Note that AutoNRT can be performed on 3, 5, 9, or all electrodes. We have clinically favored the use of 9-

electrode AutoNRT as it provided a balance of providing a sufficient ECAP threshold profile throughout the array in a timely manner.) Upon completion of both SmartNav and Custom Sound EP procedures, an x-ray was used to confirm proper electrode placement.

The time it took to complete each procedure was also documented. For SmartNav, the total time taken for completing insertion speed, placement check, impedance, and AutoNRT recording was documented. For Custom Sound EP, the time it took to complete impedance, ECAP Spread of Excitation function, and AutoNRT was documented. For x-ray, the time at which x-ray was called to the time at which the x-ray was read was documented.

In cases where SmartNav placement check determined the presence of a tip foldover, an x-ray was completed to confirm tip foldover. In addition, a Trans-Impedance Matrix recording was conducted (if possible) using Custom Sound EP to obtain more granular data on which electrode contacts were affected by the foldover, as the SmartNav placement check does not display the raw electrophysiologic tracings. All tip foldovers were corrected intraoperatively, and proper placement was confirmed by x-ray in addition to additional Trans-Impedance Matrix/SmartNav recordings.

Sensitivity, specificity, positive predictive value, and negative predictive value of using ECAP Spread of Excitation and Placement Check to identify tip foldovers were calculated as follows

$$\text{Sensitivity} = \frac{\text{True Positive}}{\text{True Positive} + \text{False Negative}}$$

$$\text{Specificity} = \frac{\text{True Negative}}{\text{False Positive} + \text{True Negative}}$$

$$\text{Positive Predictive Value (PPV)} = \frac{\text{True Positive}}{\text{True Positive} + \text{False Positive}}$$

$$\text{Negative Predictive Value (NPV)} = \frac{\text{True Negative}}{\text{True Negative} + \text{False Negative}}$$

True positives indicate the number of cases where a test correctly identifies a foldover. True negatives indicate the number of cases where the test correctly identifies proper placement of the CI. False positives indicate the number cases where a test incorrectly identifies a foldover for a properly inserted CI. False negatives indicate the number cases where a test incorrectly identifies normal placement when the CI does have a tip foldover. A good test should have both high sensitivity and high specificity.

RESULTS

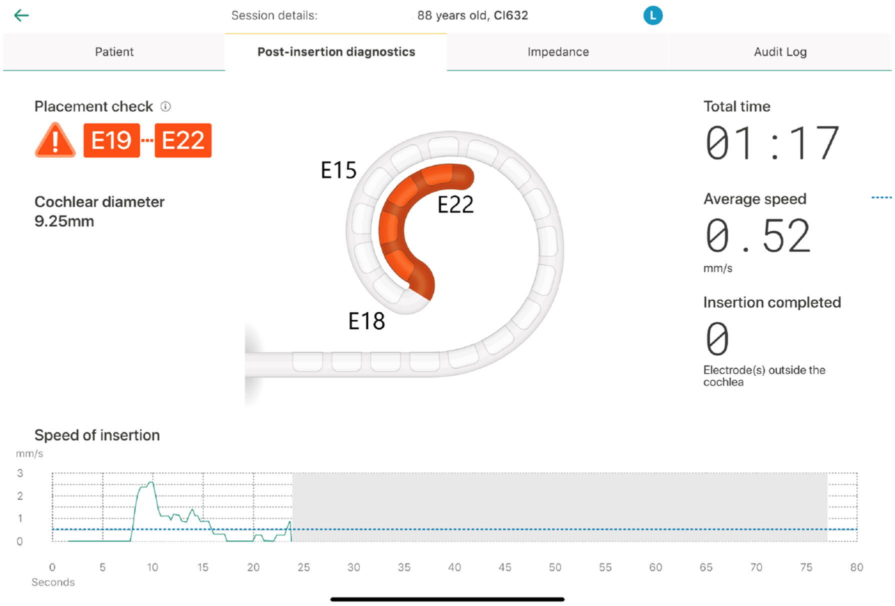
Intraoperative Findings

Out of 113 cochlear implantations performed, there were six tip foldovers, leading to a 5.3% tip foldover rate. All six foldovers were detected via the SmartNav placement check, and four were visually confirmed intraoperatively via x-ray. The intraoperative x-ray done for the fifth foldover was initially read to be normal (false negative), though later reread to be a foldover. The sixth foldover was not confirmed via x-ray as the surgeon noted that the electrode array kinked upon insertion and that surgeon was not surprised when Placement Check indicated foldover. Only two foldovers were detected via the ECAP Spread of Excitation function. There was also one ECAP Spread of Excitation function which was misinterpreted by audiology to be a tip foldover. In this case, both x-ray and SmartNav placement check confirmed proper placement and no tip foldover.

Figures 1–5 represent results from one subject with a tip foldover. Figure 1 shows the SmartNav Placement Check results signifying a tip foldover via a red cochlear implant array icon on the software. This figure indicates that electrodes 19–22 are affected by the fold-over. (Note that for Nucleus implants, electrode 1 corresponds to the most basal electrode and electrode 22 corresponds to the most apical electrode.)

Recall that Placement Check identifies tip foldover via measurement of the Trans-Impedance Matrix, but the Placement Check does not display the raw electrophysiologic tracings. A Trans-Impedance Matrix was recorded using Custom Sound EP to obtain granular data beyond the SmartNav Placement Check. The raw data show how voltage spread (and corresponding impedance) is affected by a tip foldover. The left panel of Figure 2 shows the Trans-Impedance Matrix for all 22 electrodes. Each stimulus electrode is signified by a unique color/symbol combination. For example, the leftmost black circle represents recordings when electrode 1 is stimulated and the resulting impedance is recorded on electrodes 1–22. In a normal case, a peak is expected when the stimulus electrode and the recording electrode are the same, and there is a steady decay as the recording electrode is further away from the stimulating electrode. The right panel is the same data as the left panel, but it only shows the resulting impedances when electrode 22 was stimulated rather than all electrodes. Although there is an expected impedance peak at electrode 22, there is an additional peak at electrode 15/16 signifying a tip foldover.

The raw data shown in Figure 2 are plotted as a heat map in Figure 3, where the y axis shows the recording electrode and the x axis shows the stimulus electrode. This heat map is displayed in Custom Sound EP via the Trans-Impedance Matrix Research patch. The highest impedance is expected where the stimulus and recording electrode are the same (the dark diagonal line), whereas there is a steady decay as the recording electrode is further away from the stimulating electrode. When there is a tip foldover, a red "X" is expected that is consistent with where the folded-over apical electrodes are in close contact with the medial electrode



Session details: 88 years old, CI632

Placement check ⓘ E19 ··· E22

Cochlear diameter 9.25mm

Total time 01:17

Average speed 0.52 mm/s

Insertion completed 0 Electrode(s) outside the cochlea

FIG. 1. Placement check showing tip foldover. Note that electrodes 15, 18, and 22 were subsequently labeled via photo editing software to highlight the electrodes affected by the tip foldover.

(22 and 15/16, in this subject's case and as confirmed via the intraoperative x-ray discussed in the next section).

An intraoperative x-ray was performed to confirm the tip foldover (Fig. 4). The x-ray shows that electrode 22 seems to be in close contact with electrode 15/16, consistent with the Trans-Impedance Matrix.

An ECAP Spread of Excitation function was measured to determine if it was sensitive to the foldover. Figure 5 demonstrates how an ECAP Spread of Excitation function is constructed. The top panel shows the raw ECAP traces when probe electrode 11 is stimulated and the masker electrode is varied. The bottom panel shows the ECAP amplitudes as a function of masker electrode for probe electrode 11, as well as two other probe electrodes. In theory, an SOE with a singular peak is expected when there is no foldover, whereas an SOE with two peaks may signify foldover. In this case, for probe electrode 11, there is a steady decay in the ECAP response as the masker electrode is further away from the probe in the basal direction (toward electrode 2). However, there is a decay, followed by a rise, in ECAP amplitude as the masker electrode is further away toward the apical direction (toward electrode 22). The ECAP amplitude at masker 20 is 23.9 µV, whereas the ECAP amplitude at masker electrode 22 is 30.73 µV. This signifies a 6.83-µV increase. Given that the recording amplifier noise floor of the telemetry system is about 2 to 5 µV (16), the increase in ECAP is barely above the noise floor, but because it was above the noise floor, the SOE function was interpreted to have two peaks, indicative of a foldover. The two peaks are due to the close proximity of the apical electrodes and the medial electrodes that occurred from the foldover. When probe electrode 11 and masker electrode 22 were stimulated, similar regions of the cochlea were likely stimulated, resulting in a higher ECAP

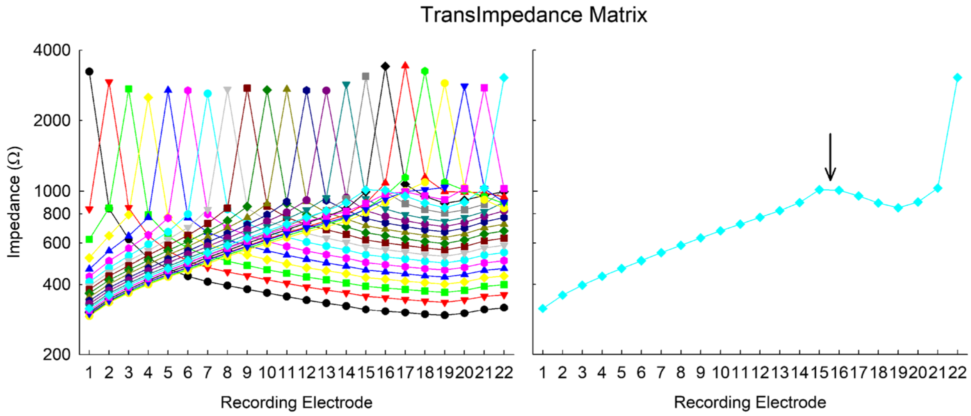


FIG. 2. Left panel shows the Trans-Impedance Matrix for all 22 electrodes. Right panel shows only electrode 22, with an arrow pointing to the second peak at electrodes 15/16 consistent with a tip foldover.

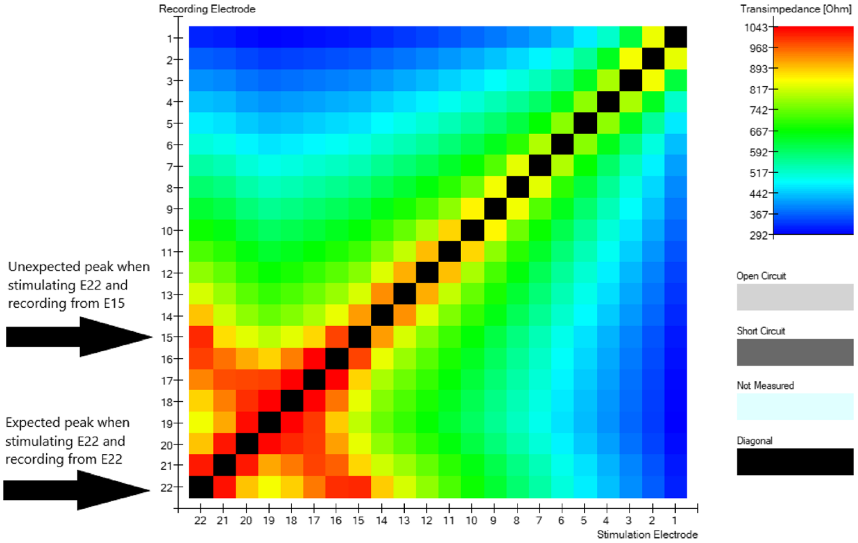


FIG. 3. Resulting heat map based on the TransImpedance recordings seen in Figure 2. The red X seen at the lower left portion of the plot reflects the double peaks and is indicative of tip foldovers.

response. The remaining two SOE functions (probe 3 and probe 22) do not show evidence of a tip foldover.

The tip foldover was corrected via removal and reinsertion of the electrode array. As shown in Figure 6, x-ray, Placement Check, TransImpedance, and SOE all confirmed appropriate placement after reinsertion. Note that the SOE function (Fig. 6D) for probe electrode 11 at first glance seems to indicate a foldover due to two peaks, but there were recording artifacts for probe 11/masker 8 and probe 11/masker 14 recordings that could not be readily solved intraoperatively. These recording artifacts contaminated ECAP traces and prevented meaningful interpretation.

Sensitivity/Specificity Analysis

Table 1 summarizes the sensitivity, specificity, positive predictive value, and negative predictive value for ECAP Spread of Excitation and SmartNav Placement Check. It is clear that the Trans-Impedance Matrix embedded in the SmartNav Placement Check algorithm identifies more tip foldovers correctly compared with ECAP Spread of

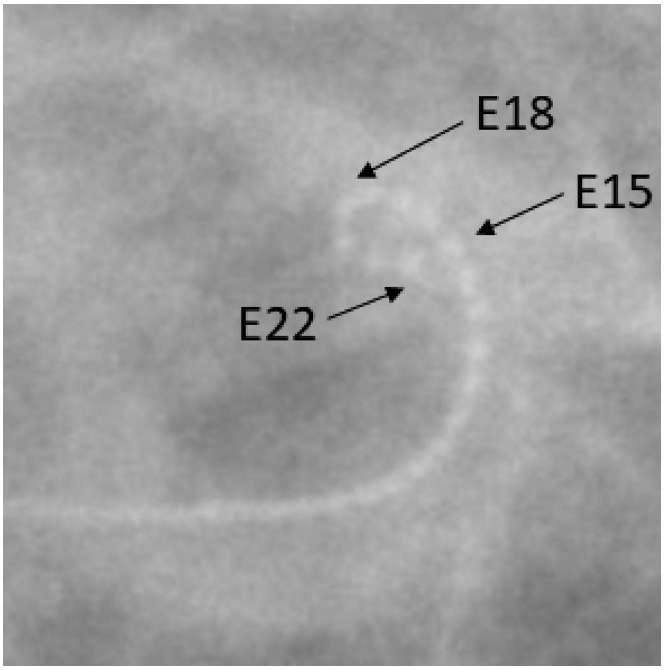


FIG. 4. Intraoperative x-ray showing tip foldover.

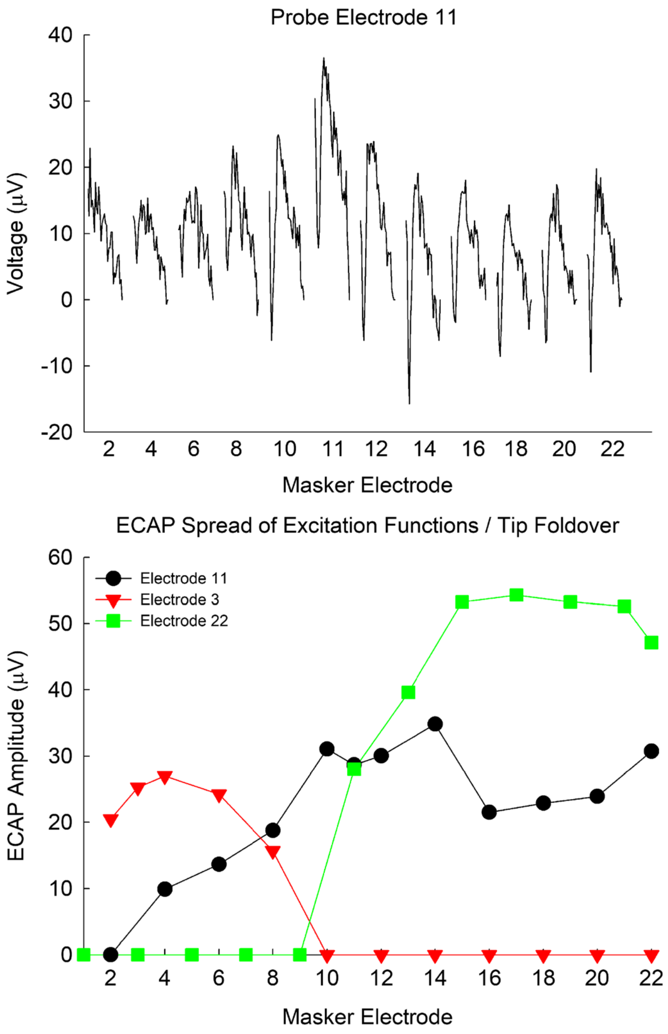


FIG. 5. Top panel shows the raw ECAP responses for probe electrode 11 as the masker electrode was varied. ECAP amplitudes were measured and used to construct the SOE functions on the bottom panel. Bottom panel shows the SOE functions for probe electrode 11, as well as two more SOE functions for probe electrodes 3 and 22. The SOE for probe electrode 11 shows evidence of two peaks, consistent with a foldover.

Excitation functions. Note that ECAP SOEs could only be collected for 100 of the 113 cases. Those 13 missing cases generally had one of three issues: 1) poor morphology of the ECAP response preventing meaningful interpretation, 2) absent response, or 3) data not collected due to time limitations.

Time and Costs of ECAP SOE, Placement Check, and X-rays

Table 2 summarizes the time needed to complete Custom Sound EP recordings, SmartNav Recordings, and x-ray. Recall that Custom Sound EP recordings include impedance, ECAP Spread of Excitation function, and AutoNRT. SmartNav recordings include insertion speed, placement check, impedance, and AutoNRT. For x-ray, the time at which x-ray was called to the time at which the x-ray was read was documented.

A repeated-measures ANOVA shows a significant difference in the time it took perform all the tests ($F_{2,130} = 53.85$, $p < 0.001$), with post-hoc *t* tests showing that SmartNav was significantly faster than Custom Sound EP and x-ray ($p < 0.001$ in both cases), and Custom Sound EP was significantly faster than x-ray ($p < 0.001$).

We calculated the cost of each method of testing (SmartNav, Custom Sound EP, and x-ray) as follows:

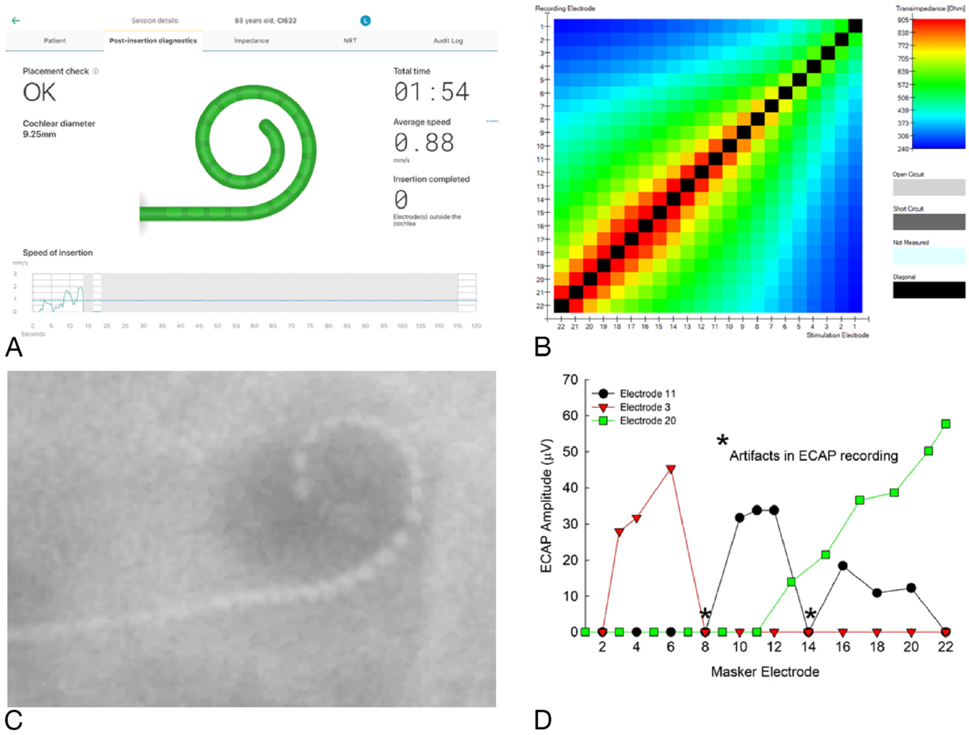
$$\mathrm{Cost}_{\mathrm{SmartNav}} = \left(\mathrm{Rate}_{\mathrm{OR}} * \mathrm{Time}_{\mathrm{SmartNav}}\right) + \left(\mathrm{Rate}_{\mathrm{Audiology}} * \mathrm{Time}_{\mathrm{Audiology}}\right)$$

$$\mathrm{Cost}_{\mathrm{CustomSoundEP}} = \left(\mathrm{Rate}_{\mathrm{OR}} * \mathrm{Time}_{\mathrm{CustomSoundEP}}\right) + \left(\mathrm{Rate}_{\mathrm{Audiology}} * \mathrm{Time}_{\mathrm{Audiology}}\right)$$

$$\mathrm{Cost}_{\mathrm{X-Ray}} = \left(\mathrm{Rate}_{\mathrm{OR}} * \mathrm{Time}_{\mathrm{X-Ray}}\right) + \mathrm{Cost}_{\mathrm{HeadX-ray}} + \mathrm{Cost}_{\mathrm{RadiologyRead}}$$

Table 3 lists the rates for the above charges that our institution incurs. The SmartNav, Custom Sound EP, and x-ray

Intraoperative Placement Check / TransImpedance, X-Ray, and Spread of Excitation After Reinsertion



Session details: 88 years old, CI632

Placement check: OK

Cochlear diameter: 9.25mm

Total time: 01 : 54

Average speed: 0.88 mm/s

Insertion completed: 0 Electrode(s) outside the cochlea

FIG. 6. *A*, Normal placement check after reinsertion of the electrode array. *B*, Normal Trans-Impedance Matrix plot with one dark diagonal. *C*, Intraoperative x-ray showing appropriate placement and coiling of the electrode array. *D*, Spread of Excitation functions showing singular peaks for E3, E11, and E20. Note that the SOE function for probe electrode 11 at first glance seems to indicate a foldover due to two peaks, but there were recording artifacts for probe 11/masker 8 and probe 11/masker 14 recordings. These recording artifacts contaminated ECAP traces and prevented meaningful interpretation.

times were previously listed in Table 2 and are relisted for clarity in Table 3, and reflect the average time needed for each test modality. For the cost of audiology time, at least an hour is blocked from the audiology clinical schedule to ensure that audiology is available at the time of intraoperative testing, though in reality, more time is blocked off to prevent patients from being added to the clinical schedule and to account for variances in OR scheduling (e.g., earlier starts times than planned). For the purposes of these calculations, we assume an hour of audiology time. Based upon the rates detailed in Table 3, we determined the total costs to be $1,496 ± $339, $1,254 ± $373, and $2,240 ± $871 for Custom Sound EP, SmartNav, and x-ray test modalities. This means that, on average, x-ray is $986 more expensive than using SmartNav, and $744 more expensive than using Custom Sound EP.

TABLE 1. *Sensitivity, specificity, positive predictive value, and negative predictive value of SOEs and placement check*

	ECAP SOE	Placement Check
True positive	2	6
False positive	1	0
True negative	92	107
False negative	5	0
Sensitivity	29%	100%
Specificity	99%	100%
Positive predictive value	67%	100%
Negative predictive value	95%	100%

As previously noted, the Trans-Impedance Matrix was made available as a research patch within Custom Sound EP under a research contract to our clinic. A simplified adaptation of the Trans-Impedance Matrix is incorporated into the “Placement Check” feature of the commercially available Cochlear Nucleus SmartNav system. We note that Cochlear Americas presently charges $4,500 to purchase the SmartNav system (list price of SmartNav shared with permission from Cochlear Americas). Our institution purchased four SmartNav systems for use among our four surgical locations, resulting in an upfront cost of $18,000. Because the use of SmartNav is $986 lower than the use of x-rays, it takes our institution 19 surgical cases to make up for the upfront costs ($18,000/$986). In addition, the Placement Check algorithm was able to identify one foldover that was not initially identified in the intraoperative x-ray, which speaks to the potential of electrophysiologic testing to prevent a false negative and possible revision surgery if poor auditory and surgical outcomes are seen. Thus, there are

TABLE 2. *Time required for intraoperative test procedures*

	Custom Sound EP	SmartNav	X-ray
Time (min)	10.36 ± 2.63	8.48 ± 2.89	15.90 ± 6.75

TABLE 3. *Cost calculations*

Service	Rates	
Rate_{OR}	129	\$/min
$\text{Rate}_{\text{Audiology}}$	160	\$/hour
$\text{Cost}_{\text{X-ray}}$	179	\$/x-ray
$\text{Cost}_{\text{Radiology Read}}$	9.23	\$/x-ray
$\text{Time}_{\text{SmartNav}}$	8.48	minutes
$\text{Time}_{\text{CustomSoundEP}}$	10.36	minutes
$\text{Time}_{\text{X-ray}}$	15.90	minutes
$\text{Time}_{\text{Audiology}}$	1	hour
Test Modality	**Total Cost**	
Custom Sound EP	1,496	\$
SmartNav	1,254	\$
X-ray	2,240	\$

both patient care outcomes and financial implications (costs of revision surgery) to consider when using electrophysiological testing.

DISCUSSION

The key finding of this study is that the Trans-Impedance Matrix tool as integrated in the SmartNav Placement Check correctly identified all six tip foldovers at our institution while correctly identifying proper placement in all remaining cases, giving rise to the 100% sensitivity and specificity rates. Recent studies are in line with our results (9,14,15). Klabbers et al. (9) evaluated 47 ears implanted with the CI632 slim modiolar electrode array; 3 of 47 ears had tip foldovers detected via Trans-Impedance Matrix and confirmed via x-ray fluoroscopy. Interrater reliability among surgeons/fellows/residents for interpreting x-rays were also lower than interpreting the Trans-Impedance Matrix, with causes for x-ray misinterpretation including image artifacts and skewed projections of the electrode array. A similar issue occurred at our institution where one intraoperative x-ray was initially read as normal but later interpreted to be a tip foldover, whereas the Trans-Impedance Matrix results indicated a tip foldover. Misinterpretations of x-rays can lead to unnecessary removal and reinsertion of the implant (for a misdiagnosed tip foldover) or leaving an improperly placed electrode in the cochlea (for a misdiagnosed proper placement). Kay-Rivest et al. (14) evaluated 117 ears implanted with a combination of CI 632, 612, 622, and 624 arrays. Three ears showed tip foldovers on Trans-Impedance Matrix, which were confirmed via plain film x-ray. They calculated a 100% sensitivity and 100% specificity rate. Hoppe et al. (15) evaluated 148 ears implanted with the CI 512 or 532 device, 4 of which had tip foldovers intraoperatively that were detected by Trans-Impedance Matrix and confirmed via CT/DVT imaging. The Trans-Impedance Matrix also incorrectly identified two ears as having a tip foldover where none was detected via imaging. This gave rise to a specificity of 98.64% (confidence interval, 95.80–99.76%), positive predictive value of 76% (confidence interval, 49–95%), and negative predictive value of 99.6 to 100%. A positive predictive value of 76% indicates that three of four cases with tip foldovers would be correctly identified (meaning one of four cases would be false positives). Hoppe et al. indicated a sensitivity of 100% based on temporal bone bench testing.

The above three studies (9,14,15) as well as our study show that the Trans-Impedance Matrix/SmartNav Placement Check has great clinical utility for intraoperative testing. A drawback of these studies, albeit a good drawback, is the low incidence of tip foldovers across all four studies, making it harder to calculate a good metric for sensitivity, specificity, positive predictive value, and negative predictive value. To address this drawback, we are currently engaged in a multicenter study to evaluate and compare the SmartNav Placement Check to intraoperative imaging across a larger population set. It is critical that a good metric of sensitivity, specificity, positive predictive value, and negative predictive value is established on a large patient population before considering changes in intraoperative workflow, which may include reduction of intraoperative imaging. One other drawback in using the SmartNav Placement Check is that the algorithm does not work when two open circuits or two short circuits are identified. Fortunately as a backup, our clinic is able to use the Trans-Impedance Matrix patch within Custom Sound EP to look at electrode placement in such cases. We recognize that most clinics will not have access to the Trans-Impedance Matrix patch.

Spread of Excitation functions correctly identified two of our six foldovers, which is lower than reported by Grolman et al. (12). That study implanted 72 ears with the Nucleus 24R(CA) and 24RE(CA) perimodiolar implants. Intraoperative ECAP Spread of Excitation measures were done on four electrodes spaced across the array. Four foldovers were identified via imaging, whereas three of the four tip foldovers were identified via ECAP Spread of Excitation. Assuming 3 true positive cases, 0 false positives, 68 true negatives, and 1 false negative, this gives ECAP Spread of Excitation a 75% sensitivity rate, 100% specificity, positive predictive value, and 98% negative predictive value, which are higher than our rates (Table 1). Given the small number of foldovers across this study and ours, it is tenuous to conclude that both studies vastly disagree with one another, as percentage calculations are easily skewed by the small numbers used to calculate sensitivity. Zuniga et al. (13) retrospectively analyzed 303 ears implanted with different manufacturers, with six foldovers identified on postoperative CT scans. Two of those patients underwent postoperative ECAP Spread of Excitation testing, with only one showing evidence of foldover on the ECAP Spread of Excitation function. Because only the foldover cases underwent Spread of Excitation, it is difficult to compare our results to Zuniga et al. (13) given the lack of a control group of non-foldover cases with ECAP Spread of Excitation.

In addition to adding to the growing evidence of the clinical utility of Trans-Impedance Matrix, the economic impact of electrophysiology testing was addressed in our current study, which was not addressed in previous studies. We quantified the reduction of intraoperative time, which resulted in significant cost savings without any impact to patient care. A recent cost–benefit analysis of intraoperative

CT at a large CI clinic with a similar tip foldover rate as our institution suggests that it takes about 5 to 10 years to financially breakeven when considering a CI caseload of 100 to 150 cases/year (17). These figures take into account the cost of revision surgery, institutional tip foldover rate, and the cost per surgical case of using intraoperative CT scan. The use of electrophysiological testing rather than intraoperative imaging would allow the breakeven point to be reached much quicker. It is important to note that our results on the use of electrophysiological testing to verify electrode placement are preliminary, and we do not make recommendations for or against exclusively relying on the use of electrophysiological testing or removing intraoperative imaging from the surgical workflow.

We note that there is greater variance in the time it takes to perform x-rays compared with electrophysiologic recordings, as shown by the standard deviations in Table 2. This reflects the variable availability of x-rays; in some cases, x-ray was immediately available, and in other cases, x-ray was occupied by other OR cases. This unpredictability in availability significantly impacts OR efficiency. Additionally, greater cost savings may be realized if OR personnel are trained on use of the SmartNav platform. The platform uses wireless testing via a Kanso 2 processor and an iPad, and set-up and operation are designed to be intuitive. If OR personnel are trained, this frees up audiology for billable patient care. Lastly, patient care is enhanced. The patient benefits from reduction in exposure to unnecessary, albeit small, amounts of radiation, whereas resources (equipment and personnel) are freed for other patients.

Direct comparison of ECAP Spread of Excitation and Trans-Impedance Matrix in identifying tip foldover has not been previously conducted. The direct comparison conducted in our study suggests superiority of Trans-Impedance Matrix over Spread of Excitation in identifying tip foldovers. ECAP Spread of Excitation in previous studies also seems to have lower predictive values in identifying tip foldover compared with our Trans-Impedance Matrix results (12,13). One issue with using ECAP measures is that neural responsiveness varies along the cochlea and varies depending on how close or far the array is from the modiolus; thus, it is difficult to interpret if changes in ECAPs are due to a tip foldover or due to natural variations along the cochlea. Additionally, it is time prohibitive to test all combinations of electrodes when performing ECAP measures intraoperatively; thus, the dataset is limited.

Intraoperative imaging has been the gold standard in visually confirming proper placement of the cochlear implant before concluding surgery. As Klabbers et al. (9) showed, there is potential to misread imaging results whether it is due to surgical experience or due to artifacts in the image. Objective electrophysiological testing removes these subjective confounds.

CONCLUSION

The use of electrophysiologic voltage spread through the cochlea, whether it be TIM (Cochlear Corporation), EFI (Advanced Bionics), or IFT (MED-EL), shows promise in identifying tip foldovers. This reduces the need for intraoperative imaging/radiation exposure and improves economics of cochlear implant operations without negatively affecting patient care. Given the low rate of tip foldovers at our center and others, we are currently engaged in a multicenter study that will provide better data on sensitivity, specificity, positive predictive value, and negative predictive value of the SmartNav Placement Check in identifying tip foldovers.

Acknowledgments: Omotayo Agaja, Au.D.; Nicole Besse, Au.D.; Anna Braam, Au.D.; Abby Maurer Jayack, Au.D.; and Holly Yako, Au.D. collected a majority of intraoperative data. Cochlear Corporation provided the research patch to perform Trans-Impedance Matrix recordings via Custom Sound EP

REFERENCES

1. Wanna GB, Noble JH, Carlson ML, et al. Impact of electrode design and surgical approach on scalar location and cochlear implant outcomes. *Laryngoscope* 2014;124:S1–7.
2. Aschendorff A, Briggs R, Brademann G, et al. Clinical investigation of the Nucleus Slim Modiolar Electrode. *Audiol Neurootol* 2017;22:169–79.
3. Holder JT, Yawn RJ, Nassiri AM, et al. Matched cohort comparison indicates superiority of precurved electrode arrays. *Otol Neurotol* 2019;40:1160–6.
4. Liebscher T, Mewes A, Hoppe U, et al. Electrode translocations in perimodiolar cochlear implant electrodes: Audiological and electrophysiological outcome. *Z Med Phys* 2021;31:265–75.
5. Dhanasingh A, Jolly C. Review on cochlear implant electrode array tip fold-over and scalar deviation. *J Otol* 2019;14:94–100.
6. Friedmann DR, Kamen E, Choudhury B, Roland JT Jr. Surgical experience and early outcomes with a slim perimodiolar electrode. *Otol Neurotol* 2019;40:e304–10.
7. Shaul C, Weder S, Tari S, et al. Slim, modiolar cochlear implant electrode: Melbourne experience and comparison with the contour perimodiolar electrode. *Otol Neurotol* 2020;41:639–43.
8. Shew MA, Walia A, Durakovic N, et al. Long-term hearing preservation and speech perception performance outcomes with the slim modiolar electrode. *Otol Neurotol* 2021;42:e1486–93.
9. Klabbers TM, Huinck WJ, Heutink F, Verbist BM, Mylanus E. Transimpedance matrix (TIM) measurement for the detection of intraoperative electrode tip foldover using the slim modiolar electrode: A proof of concept study. *Otol Neurotol* 2021;42:e124–9.
10. Brown CJ, Abbas PJ, Gantz BJ. Preliminary experience with neural response telemetry in the nucleus CI24M cochlear implant. *Am J Otol* 1998;19:320–7.
11. Abbas PJ, Hughes ML, Brown CJ, Miller CA, South H. Channel interaction in cochlear implant users evaluated using the electrically evoked compound action potential. *Audiol Neurootol* 2004;9:203–13.
12. Grolman W, Maat A, Verdam F, et al. Spread of excitation measurements for the detection of electrode array foldovers: A prospective study comparing 3-dimensional rotational x-ray and intraoperative spread of excitation measurements. *Otol Neurotol* 2009;30:27–33.
13. Zuniga MG, Rivas A, Hedley-Williams A, et al. Tip foldover in cochlear implantation: Case series. *Otol Neurotol* 2017;38:199–206.
14. Kay-Rivest E, McMenomey SO, Jethanamest D, et al. Predictive value of trans-impedance matrix measurements to detect electrode tip foldover. *Otol Neurotol* 2022;43:1027–32.
15. Hoppe U, Brademann G, Stöver T, et al. Evaluation of a trans-impedance matrix algorithm to detect anomalous cochlear implant electrode position. *Audiol Neurootol* 2022;27:347–55.
16. Patrick JF, Busby PA, Gibson PJ. The development of the Nucleus Freedom Cochlear implant system. *Trends Amplif* 2006;10:175–200.
17. Mitchell MB, Labadie RF. Cost-effectiveness of intraoperative CT scanning in cochlear implantation in fee-for-service and bundled payment models. *Ear Nose Throat J* 2022;101:NP164–8.