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Tip fold-over in cochlear implantation: case series

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Abstract

Objective—To describe the incidence, clinical presentation, and performance of cochlear implant (CI) recipients with tip fold-over.

Study design—Retrospective case series.

Setting—Tertiary referral center.

Patients—CI recipients who underwent postoperative CT scanning.

Intervention(s)—Tip fold-over was identified tomographically using previously-validated software that identifies the electrode array. Electrophysiologic testing including spread of excitation (SOE) or electric field imaging (EFI) was measured on those with fold-over.

Main outcome measure(s)—Location of the fold-over; audiological performance pre and post selective deactivation of fold-over electrodes.

Results—303 ears of 235 CI recipients had postoperative CTs available for review. Six (1.98%) had tip fold-over with 5/6 right-sided ears. Tip fold-over occurred predominantly at 270° and was associated with pre-curved electrodes (5/6). Patients did not report audiological complaints during initial activation. In one patient, the electrode array remained within the scala tympani with preserved residual hearing despite the fold-over. SOE supported tip fold-over, but the predictive value was not clear. EFI predicted location of the fold-over with clear predictive value in one patient. At an average follow-up of 11 months, three subjects underwent deactivation of the overlapping electrodes with two of them showing marked audiological improvement.

Conclusions—In a large academic center with experienced surgeons, tip fold-over occurred at a rate of 1.98% but was not immediately identifiable clinically. CT imaging definitively showed tip fold-over. Deactivating involved electrodes may improve performance possibly avoiding revision

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CONFLICT OF INTEREST:

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surgery. EFI may be highly predictive of tip fold-over and can be run intraoperatively, potentially obviating the need for intra-op fluoroscopy.

Keywords

cochlear implant failure; electrode tip fold-over; cochlear implant revision

Introduction

Cochlear implants (CIs) are surgically implanted neural prosthetic devices used as a rehabilitation option for severe-to-profound hearing loss. This concept has evolved since it was first introduced, and nowadays multiple variables have been identified as factors that may impact hearing outcomes. These include the surgical approach (cochleostomy versus round window approach), the electrode used (lateral wall versus perimodiolar), and the final electrode position within the cochlea (scala tympani and/or scala vestibuli).¹⁻⁷ However, very few works have described the incidence of electrode array malposition, specifically, tip fold-over.

Tip fold-over has conventionally been identified using intraoperative imaging, most commonly fluoroscopy.⁸ While the concept of using fluoroscopy seems straight forward, application of the technique requires experience to optimally align the view and limit radiation exposure to the patient and intraoperative personnel. Furthermore, while standard audiological testing is frequently performed intraoperatively in order to determine the electrode functionality, many times these measures can be normal in the setting of electrode arrays that underwent a fold-over (e.g. those electrodes that curl in rough approximation of the cochlea).^{8,9} Previous works have investigated the utility of other particular telemetric responses in order to detect the presence of tip fold-over. These responses include primarily spread of excitation (SOE) and electric field imaging (EFI). While the spread of excitation depicts the selectivity of neural excitation fields around each electrode, the EFI looks at the electrical impedance and voltage change between each combination of pairs of intracochlear electrodes. In both scenarios, the working hypothesis is that in the context of an electrode fold-over, an additional response is present given the presence of the overlapping electrodes.

Lassig and colleagues observed in 58 CI recipients a rate of problems pertaining to electrode array positioning of 13%.¹⁰ Hence, the use of different intraoperative imaging modalities along with different electrophysiologic measures emerged in order to monitor and confirm adequate placement of the electrode array. In their series of 72 CI recipients, Grolman et al. obtained EI, ECAP, and SOE.¹¹ They observed 4 CI electrode fold-overs, and in all four patients the SOEs revealed an upward second curve or maxima suggestive of tip fold-over. More recently, Cosetti et al confirmed these SOE findings in one patient with fold-over.⁸ Both studies reported the capability of successfully identifying the failure in electrode positioning (fold-over) intraoperatively, with subsequent correction by reinsertion or use of a backup device. The present study reports the incidence of tip fold-over in a large population of CI recipients who received a post-operative CT scan as part of a separate research study. We also report on initial clinical presentation and CI performance both before and after deactivation of electrodes involved in the fold-over.

Methods

A retrospective review of cases with pre- and postoperative temporal bone CT scans in our CI database was conducted at a tertiary referral center. 303 postoperative CT scans corresponding to the ears of 235 CI recipients were available for review. In this set of 303 cases, a total of 6 ears were identified to have a tip fold-over. The postoperative temporal bone CT scans for these subjects were obtained via a flat panel, volumetric computerized tomography (fpVCT) using a Xoran XCAT scanner (Xoran Industries, Ann Arbor, MI). The Voxel resolution ranged from $0.3 \times 0.3 \times 0.3 \text{ mm}^3$ to $0.4 \times 0.4 \times 0.4 \text{ mm}^3$. Of note, these CT scans were not performed as part of routine care in response to poor outcome, but rather were part of a CI CT imaging study.^{12–14} The range of hearing performance levels of participants in that study was representative of typical hearing performance outcomes seen across the general CI population. Hearing performance bias was avoided by designing the study such that there was neither a diagnostic nor a treatment component. The 6 tip fold-over cases were then included in this study for further analysis of clinical and audiological characteristics. In addition, in order to better determine the location of the tip fold-over within the cochlea, a previously-validated software that identifies the electrode array was used. This technique has been described in detail elsewhere.^{12,15–17}

Briefly, this image analysis sequence involves three steps: first, the intracochlear anatomy is localized in a preimplantation CT. Second, the electrode array is localized in a post-implantation CT. Third, the two results are merged by bringing both sequences into alignment. Of note, anatomical structures are localized in the preimplantation CT to avoid the metal-related artifact that the CI array creates in the post-implantation CT. After a statistical shape model is fitted to the external walls of the patient's cochlea, the electrode array is localized in the post-implantation CT as previously described by Noble et al.¹² In this approach, a curve is fitted to the image in order to estimate the centerline of the electrode array, after which a surface model of the electrode array is mapped to the extracted centerline. Finally, the results from the electrode and anatomical localization processes are merged, bringing the two images into global alignment.¹⁷

Intraoperative electrophysiologic testing, i.e. electrode impedance (EI) and neural response telemetry (NRT), was available for review in all cases. In addition, some individuals underwent spread of excitation (SOE) or electric field imaging (EFI) testing postoperatively. While the spread of excitation depicts the selectivity of neural excitation fields around each electrode, the EFI looks at the electrical impedance between each combination of pairs of intracochlear electrodes. These recordings have been described previously.^{18,19} Briefly, SOE is obtained as a function of electrically evoked compound action potential (ECAP) measured with an NRT system.⁹ After a stimulus is delivered, intracochlear potentials are recorded using telemetry, and subsequently the responses are measured in the speech processor. Spatial distributions are then obtained by moving the masker electrode to different positions from base to apex.⁹ When there is more than one peak amplitude, there is concern for a folded electrode. At present, EFI measurement is available only for implants by Advanced Bionics Corporation (Sylmar, CA). Briefly, the testing encompasses a stimulating intracochlear electrode that is then connected to an independent current source, a coupling capacitor, and a reference electrode that is larger than the intracochlear electrodes and is

fixed to the receiver/stimulator package placed along the mastoid bone.¹⁸ The amplifier is connected to another electrode that measures the local potential in the perilymph created by the stimulating electrode. By varying the stimulating and measurement electrode, the EFI mode ultimately allows one to build an intracochlear potential map resulting from the stimulation of each contact from apex to base.¹⁸ This allows the analysis of relative intracochlear electrode position (i.e. the spatial arrangement of the electrodes with respect to each other).¹⁹

Finally, some patients underwent image-guided programming of their CI, with selective deactivation of the overlapping electrodes. Previous studies have described this reprogramming strategy in detail.¹³ Briefly, spatial information is integrated by image-processing techniques to decrease cross-electrode electric field channel interactions.²⁰ This process is intended to reduce the cross-electrode neural stimulation site overlap. Electrodes that are likely to cause stimulation overlap are deactivated assuming that each electrode best stimulates spiral ganglion cells that are closest to it. Of note, this approach does not conflict with existing signal processing strategies, and thus reprogramming does not require major processing changes.

The above mentioned measurements were performed under IRB approval.

Results

Three hundred and three (303) ears of 235 CI recipients with postoperative CTs and detailed operative reports were available for review for the time period from January 2009–July 2015. Of these 303 cases, a round window approach was performed in 152 (50%), extended round window approach in 99 (33%) and a cochleostomy in 52 (17%). Fifty two percent of the cases were right-sided CI and in regards to the electrode used in the overall data set 48% were perimodiolar, 41% lateral wall and 10% mid-scala.

Six cases (1.98%) were identified to have tip fold-over based on CT imaging and these will be discussed in more detail in the present study. Table 1 summarizes demographic and clinical characteristics of these 6 patients. Three experienced cochlear implant surgeons were involved in performing the surgeries. The mean age of the patients at the time of implant was 52.3 years (range 8 years–75 years), with one (17%) pediatric patient and one female patient (17%). Five out of six (83%) cases were right-sided CI recipients, 4 of which were implanted with the surgeon's right hand. Three-dimensional reconstructions of the postoperative CT allowed identification of the electrode array within the cochlea (Figure 1). This revealed that tip fold-over of the electrode was found predominantly at 270° within the cochlea and was predominantly associated with a pre-curved electrode selection (5/6) (Table 1). Furthermore, surgical approaches consisted of a round window approach in 66.6% (4/6) of the cases and the remaining cases underwent an extended round window approach. Of note, one of these six patients (case #2) had a lodged electrode tip more than an electrode tip fold-over per se. In this case, an almost 90-degree turn was observed at the end of the electrode, unlike a full bent with electrodes overlapping onto each other that is characteristic of tip fold-over (Figure 1). This resulted in increased electrode proximity and interference

and for that reason that case was included in this group of patients, with the clarification of a *lodged* rather than a *fold-over* tip.

These patients did not report audiological complaints during initial electrode activation. Interestingly, one of the CI recipients underwent a successful hearing preservation protocol despite the fold-over (case #1). In this case, while the electrode is pushing against the basilar membrane, the electrode array remained within the scala tympani. The overall average follow up was 38.5 months (range 16–42 months).

As per our standard practice, all patients underwent intraoperative confirmation of adequate electrode function by means of electrophysiological testing, specifically electrode impedance (EI) and neural response telemetry testing (NRT). Of the reported cases, EI and NRT were present and considered normal. During the postoperative period and once patients were known to have tip fold-over of the electrode array, three patients underwent further electrophysiological testing in order to correlate the radiographic findings of the fold-over with a functional parameter. Hence, cases #1 and 2 underwent spread of excitation (SOE) testing and case #4 underwent electrical field imaging (EFI). Figure 2 depicts SOE of case #1, where the tip was folded at its most distal aspect. For probe electrodes 8–14, more than one local maximum in SOE were observed, suggesting tip fold-over involving these electrodes. Figure 3 depicts SOE of case #2, a case where the tip of the electrode array was lodged. In this case, while there is no obvious presence of more than one local maximum in SOE, which is typical of tip fold-over, a flat or reduced response involving electrodes 17–22 was observed. Such a flat response is suggestive of a lodged electrode tip rather than a completely folded over electrode tip. Finally, EFI in case #4 (figure 4) revealed more than two local maxima involving electrodes 1–8, consistently identifying all the overlapping electrodes resulting from the fold-over.

At an average follow-up of 11 months, all patients showed an objective postoperative improvement in their hearing performance compared to their pre-CI performance (table 2). In addition, three subjects (50%) underwent deactivation of the overlapping electrodes with two of them showing marked audiological improvement (table 2).

Discussion

Previous work conducted by Lassig and colleagues identified that up to 13% of 58 CI recipients may experience problems pertaining to electrode array positioning.¹⁰ Consequently, different studies have focused their efforts on intraoperative confirmation of proper electrode position without tip foldover. These works have made use of a combination of imaging modalities and/or electrophysiological measures that reflect proper electrode array functioning.^{8,9,11,19} For example, Grolman et al. obtained electrophysiological measures of electrode impedance (EI), evoked compound action potential (ECAP) and spread of excitation (SOE) in 72 CI recipients.¹¹ Using a 3D imaging technique, they identified four CI electrode fold-overs that also showed an upward second curve or maximum in SOEs, a finding suggestive of tip fold-over. Of note, ECAPs and EIs did not yield obvious abnormalities in any of these four cases. A more recent study by Cosetti et al. reviewed a total of 277 cases of CI recipients and also identified that patients with tip fold-

over (n= 5, 1.8%) depict abnormalities in SOEs.⁸ In their study, the authors suggest an algorithm to identify tip fold-over intraoperatively, with a first step consisting of performing intraoperative telemetry (including SOE testing) followed by basic troubleshooting of hardware and monitoring software; the third step recommended is to obtain an x-ray in modified Stenver's view and repositioning or replacement of the electrode array if these results are suggestive of tip fold-over. Interestingly, their work highlighted that patients with tip fold-over rarely show abnormalities in more than one of these tests.

Our six cases with tip fold-over revealed normal intraoperative telemetry measurements (EI and NRT), which is consistent with the findings by Cosetti and colleagues.⁸ However, those who underwent postoperative SOE and EFI testing revealed abnormal results (Figures 2–4). Given that these tests were completed in the postoperative setting, no attempts to replace the electrode array were attempted. Interestingly, none of the patients reported particularly abnormal audiological complaints. In addition, all cases revealed objective evidence of improved hearing performance compared to their pre-implantation hearing function (table 2). Three patients underwent a protocol for image-guided cochlear implant programming, in which the overlapping electrodes resulting from the tip fold-over were deactivated. Selective deactivation of suboptimally placed electrodes has previously revealed improved hearing outcomes for many CI recipients without tip fold-over^{13,14}. In the setting of tip fold-over, we also observed an improvement in hearing performance in 2 of the three fold-over cases that underwent selective deactivation.

The CI literature clearly emphasizes the important role that the final electrode position plays in hearing outcomes^{1,2,7} with previous work reporting that up to 13% of patients undergoing revision surgery have a problem related to inadequate positioning of the electrode array.¹⁰ Herein we describe that in the setting of electrode tip fold-over, selective deactivation of overlapping electrodes may improve hearing performance giving support for reprogramming prior to consideration of revision surgery. Another interesting finding regarding position was noted in case #1 where tip fold over occurred without migration of the electrode array from scala tympani to scala vestibule and with hearing preservation (figure 1). To the best of our knowledge, this is the first time a tip fold-over with hearing preservation has been reported.

Interestingly, most of the fold-over cases herein reported occurred on the right side with perimodiolar electrodes inserted via a round window approach. Zhou et al investigated the relationship between surgical approach and insertion trauma in 15 fresh frozen temporal bone models.²¹ They observed that electrode insertions through the round window can be tortuous after striking the modiolus; also, the electrode approaches the outer cochlear wall at an angle that is more acute compared to a cochleostomy or extended round window approaches. They observed cochlear trauma only in one specimen that underwent electrode insertion with a round window approach. In the present study the overall number of tip fold-over cases is too low to statistically conclude that use of a pre-curved electrode via a round window approach presents higher risk for tip fold-over. Nonetheless, these factors should be considered when implanting especially considering the ergonomic setup of a right-handed surgeon placing a precurved electrode in a right ear (i.e. tendency to have a trajectory aimed superiorly).

Our findings of incidence of tip fold-over are consistent with prior studies especially another large series⁸ which showed an identical rate of 1.8% indicating that tip fold-over may occur more often than anticipated. This is concerning given that typical intraoperative monitoring (i.e. EI and NRT) more often than not fail to identify fold-over both within our series and others.^{8,11} While EFI and/or SOE testing was more predictive, it is not widely available at the present time. This leaves intraoperative imaging, e.g. fluoroscopy via Stenvers view, as the most widely-available means of identifying tip fold-over. If found intraoperatively, both Cossetti et al.⁸ and Grohlman et al.¹¹ advocate immediate repositioning and/or replacement. The nature of the present study does not allow the authors to state with certainty if the electrode array would have been replaced had the surgeons known about it intraoperatively. However, one of the three surgeons involved in the present study is transitioning his practice to obtain intraoperative fluoroscopy in order to detect possible tip fold-over. Another interesting scenario is the one of a patient with a suboptimal overall health status; if fold-over is suspected intraoperatively, do the benefits of detecting a possible fold-over with subsequent electrode replacement outweigh the risks of increased operative time? Our study again, cannot provide a clear cut answer to this question; however, audiological outcomes herein reported can be used to argue that a different strategy – i.e. postoperative deactivation of overlapping electrodes may be preferable. Finally, if the fold-over is not detected intraoperatively, does detection in the postoperative period justify revision surgery? From our experience, we propose that a reasonable first step should be deactivation of overlapping electrodes.

Conclusion

In a large academic center with experienced surgeons, tip fold-over occurred at a rate of 1.98% but was not immediately identifiable clinically. CT imaging definitively showed tip fold-over. Deactivating involved electrodes may improve performance, avoiding revision surgery. EFI may be highly predictive of tip fold-over and can be run intraoperatively, potentially obviating the need for intra-op fluoroscopy.

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Figure 1. CT images of each of the six cases with electrode fold-over along with three-dimensional reconstructed images showing the location of the cochlear implant tip fold-over. Scala tympani depicted in red.

Figure 2.

SOE of case #1 reveals more than one local maxima for probe electrodes 8–17, which are the electrodes involved in fold-over as they overlap. Stimulating electrode 15 reveals similar amplitude for the two local maxima, close to the location of the observed fold-over around electrode 18.

Figure 3.

SOE of case #2 reveals a flat or reduced response involving electrodes 17–22. This is suggestive of a lodged tip rather than a fold-over, which is consistent with the CT findings.

Figure 4.

EFI in case #4 reveals more than two local maxima before and after electrodes 2–3. Those electrodes that reveal the local maxima correlate with the overlapping electrodes resulting from the fold-over.

Table 1

Tip fold-over patient and electrode characteristics

Case #	Age	Gender	Side of CI	Indication for CI	Approach	Company	CI system	CI type	Location of fold-over *	Follow up (m)
1	75	Male	Right	Profound SNHL	RW	Cochlear	CI24RE Contour Advance	PM	tip folded at electrode 18	42
2	54	Male	Right	Profound SNHL	RW	Cochlear	CI24RE Contour Advance	PM	lodged tip	30
3	67	Male	Right	Profound SNHL	RW	Adv Bio	HF Midscale	MS	tip folded at electrode 4	30
4	53	Female	Left	Moderate SNHL	ERW	Adv Bio	Advantage 1J	PM	tip folded at electrode 2	36
5	57	Male	Right	Profound SNHL	RW	Cochlear	CI 422 Straight	LW	tip folded at electrode 18	16
6	8	Male	Right	Profound SNHL	ERW	Cochlear	512 Contour Advance	PM	tip folded at electrode 17	77

PM: perimodiolar; MS: mid-scala; LW: lateral wall; RW: round window; ERW: extended round window. (m) = months;

* = Advanced Bionics numbers electrodes starting from apical cochlea while Cochlear starts numbering at the base

Table 2

Tip fold-over audiological testing and outcomes

Case #	Preoperative			Postoperative			Image-guided programming	Post-selective deactivation		
	Aided CNC	AZBio Quiet	AZBio +5	Aided CNC	AZBio Quiet	AZBio +5		Aided CNC	AZBio Quiet	AZBio +5
1	10%	8%	DNT	14%	0%	DNT	Yes	36%	47%	15%
2	<i>no aided hearing</i>			28%	50%	DNT	Yes ^a	12%	14%	DNT
3	28%	42%	DNT	44%	30%	DNT	No			
4	DNT	1%	DNT	42%	73%	DNT	No			
5	0%		0%	48%	70%	DNT	No			
6	NUCHips: 48%			NUCHips: 68%			Yes	* LNT 68%	BbQuiet 91%	Bb+5 90%

^a Pt did not keep post-selective deactivation as no improvement was noted

* Pediatric case; BbQuiet = BabyBio Quiet; Bb+5 = BabyBio =5