Precurved Cochlear Implants and Tip Foldover: A Cadaveric Imaging Study

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Abstract

Objective. This study aims to define a reliable protocol for radiographic identification of placement and tip foldover of newly designed precurved and straight electrodes.

Study Design. Prospective imaging study.

Setting. Academic institution.

Methods. Three models of cochlear implants (Cochlear, MED-EL, and Advanced Bionics) were inserted into fresh cadaveric specimens (n = 2) in 3 configurations (normal positioning in the scala tympani, intracochlear tip foldover, and placement into the vestibular system) for a total of 9 implant scenarios. Specimens were imaged with plain radiography in Stenvers projection, as well as by high-resolution computed tomography.

Results. Electrode placement and presence or absence of electrode tip foldover were easily identified in all 9 scenarios on plain radiography based on the described technique. Each was confirmed with high-resolution computed tomography. Plain film temporal bone images of new electrode designs with proper and improper placement are provided for reference.

Conclusion. A defined protocol for intraoperative plain film radiography allowed for reliable imaging of 3 newly designed cochlear implant electrodes and immediate identification of extracochlear placement and tip foldover. Findings may be used for intraoperative confirmation of electrode array placement.

Keywords
cochlear implantation, tip foldover, perimodiolar electrode, intraoperative radiography

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Cochlear implantation is a well-established procedure to restore hearing in patients with severe to profound sensorineural hearing loss.1-3 Cochlear device manufacturers recently designed new electrodes with precurved conformations that allow for perimodiolar placement within the scala tympani and for higher potential for selective activation of spiral ganglion neurons.4,6 These electrodes have also been developed with soft flexible tips to achieve optimal positioning with minimal cochlear trauma.7 The popularity of these electrode arrays has increased, as recent data show improved audiologic outcomes when compared with previous lateral wall designs.4

While providing perimodiolar positioning when placed correctly, precurved devices also present the potential for electrode array tip foldover, which occurs when the most distal electrodes fold back onto the more proximal electrode array.8,9 Tip foldover diminishes audiologic performance due to distal electrode interference and loss of apical cochlear coverage; however, given that new devices are reloadable, this complication is correctable, if identified intraoperatively.8,10

Following electrode insertion, some surgeons may obtain intraoperative radiography to evaluate for major complications, such as extracochlear misplacement.1-3 Plain film radiography is a rapid, inexpensive, and minimally invasive method to evaluate labyrinthine anatomy and cochlear implant (CI) electrode position. When plain film radiography is performed in the operating room correctly, a single film following each insertion allows for immediate electrode position identification and correction, when necessary. While reinsertion of a misplaced electrode may necessitate additional imaging and radiation exposure, this risk is
minimized if a single exposure produces an optimal image. However, since the advent of high-resolution computed tomography (HRCT) scans, routine plain film imaging of the temporal bone is infrequently performed, and as a consequence, intraoperative imaging may be subject to poor projection and underexposure, making interpretation challenging, if not impossible.

Given recently reported difficulties with electrode tip fold-over,8,9 a review of proper plain film imaging techniques of the temporal bone is warranted. When plain film radiography is performed correctly, the resulting images provide the opportunity to identify electrode tip foldover or misplacement into the vestibular system, while the patient is still in the operating room. A review of the current literature indicates that postimplantation imaging protocols vary widely among institutions, which may affect imaging accuracy and interpretability and require multiple films after a single insertion.11 Variability in intraoperative imaging technique explains why there is concern that the cost and risk of repeat radiation exposure as well as extended intraoperative time from multiple films outweigh the information gained from imaging.1-3,11 Given new electrode designs and the reported risk of tip foldover, routine imaging may now be warranted.

To date, few groups have investigated plain film imaging of precurved electrodes in proper and improper configurations. In this study, we aim to (1) investigate radiographic findings of precurved electrodes after proper and improper placement and (2) provide a standardized plain film imaging protocol for assurance of proper electrode placement.

Methods
Specimens
This study was considered nonhuman research by the Human Studies Committee of the Massachusetts Eye and Ear Infirmary. Two fresh adult cadaver heads (1 female and 1 male) were obtained. In each specimen, a left postauricular incision and anteriorly based soft tissue flap were made, followed by a standard canal wall up mastoidectomy with posterior tympanotomy. The round window was exposed and an extended round window opening made into the scala tympani.

Cochlear Implant Insertion
Three models of electrodes, without the associated receiver/stimulator device, were received from manufacturers and tested: Cochlear Nucleus Profile Slim Modiolar 532 (COCH; Cochlear Corporation, Centennial, Colorado), Advanced Bionics HiFocus Mid-Scala (AB; Advanced Bionics Corporation, Sylmar, California), and MED-EL Flex24 (ME; MED-EL Corporation, Durham, North Carolina). Each electrode model was inserted with a surgical microscope into the cadaveric specimens in 3 configurations: scala tympani, vestibular system, and scala tympani with tip foldover. Each electrode and the round window niche were lubricated with saline prior to insertion. This resulted in a total of 9 electrode scenarios, with a new electrode used for each configuration. All insertions were terminated when the electrode ceased to advance or recoiled with additional insertion force.

Plain Film Imaging Technique
Specimens were imaged with a defined positioning protocol to obtain a reliable plain film Stenvers projection. In the axial plane, the head is rotated 45° contralateral to the side of interest (Figure 1A). The 45° angle can be confirmed intraoperatively by ensuring that a line defined by the mastoid process on the implanted side and the lateral bony wall of the orbit is parallel to the film. In the sagittal plane, the chin is tilted caudal until the Frankfort horizontal line (from the superior external auditory meatus to the infraorbital rim) is approximately 12° from being perpendicular to the film (Figure 1B). The center of the x-ray beam is targeted ~12 mm anterior to the tragus and directed...
perpendicular to the film. Exposure settings of 75 peak kVp and 16 mAs were used with a film plate (18 × 24 cm) centered directly between the occiput of the skull and the bed mattress, not in the operating room table x-ray cassette.

Stenvers view x-rays were analyzed for location of labyrinthine structures, including the vestibule, semicircular canals, and cochlea, as previously described by others. Figure 2 illustrates the respective orientations of these structures. The round window is located by the intersection of a line drawn from the superior tip of the superior semicircular canal to the middle of the vestibule and a line formed by an intracochlear electrode array. The insertion depth (ID) is then determined by measuring the angle between a line defined by the most distal electrode and the center of the modiolus, approximated by the center of the electrode coil, and a 0° reference line defined by the round window and the center of the modiolus.

Computed Tomography Imaging Technique
HRCT images were obtained with a Discovery CT750HD Scanner (GE Medical Systems) with the cadaveric head placed supine within the gantry. Sequences were performed in the axial plane with a slice thickness of 0.625 mm and with settings of 120 kVp and a 1.460-second exposure time.

DICOM computed tomography image series of all 9 combinations of CI models and placements were imported into a Synapse image viewer (Version 4.2; FUJIFILM Medical Systems USA, Inc., Stamford, Connecticut). With the Multi-Planar Reformatting software package (Version 4.2; FUJIFILM Medical Systems USA, Inc., Stamford, Connecticut), an oblique view of each image was projected in the Stenvers plane, which is perpendicular to the superior semicircular canal. Final images were obtained with multiplanar volumetric reconstruction of 6 sections over a slab thickness of 4 mm.

Results
Electrode Insertion
Cochlear implant electrodes were successfully placed into the scala tympani first without and then with tip foldover. Two precurved electrodes were placed into the vestibule, and 1 electrode (ME) was placed into the superior semicircular canal. Misplacement into the vestibular system was relatively difficult to achieve for all 3 electrode models and required an inferior-to-superior approach with significant resistance noted on insertion.

Each electrode was inserted into the scala tympani with tip foldover. This occurred more readily with the precurved devices, COCH and AB. The COCH and AB electrodes were initially inserted in straight conformations when loaded on a sheath and stylet, respectively. When the sheath or stylet was prematurely retracted ~2 mm, the tip of each electrode began to curl, which resulted in tip foldover upon insertion. In contrast, the ME is a straight electrode and did not naturally fold on itself. When the tip of this electrode was angled against the modiolus, insertion caused the tip to bend, which ultimately led to tip foldover.

Radiography Interpretation
Following electrode insertion and imaging, radiographs were evaluated to identify labyrinthine structures (Figure 2) and electrode placement. Initially, we identify the petrous ridge as a horizontal opaque curve traversing the radiograph superior to labyrinthine structures. The superior semicircular canal appears as a lucent line perpendicular to and extending inferiorly from the petrous ridge. The vestibule is an oval lucent structure inferior to the superior semicircular canal and is located lateral to the internal auditory canal. The expected area of the cochlea is anteroinferior to the cochlear nucleus 532

Imaging of Cochlear Nucleus 532
The COCH electrode was successfully inserted into the scala tympani, which was identified on plain radiography as a coiled hyperdensity with 450° ID anteroinferior to the
vestibule (Figure 3A). Insertion of the COCH electrode into the vestibular system was easily identified on radiography as a 1.5-turn coil within an oval lucent structure representing the vestibule (Figure 3B). Tip foldover of the COCH electrode within the scala tympani was identified as a folding of the distal electrode array, which limited insertion to within the basal turn of the cochlea (Figure 3C). All 3 electrode placements were confirmed with HRCT (Figure 3D-3F, respectively).

Imaging of AB HiFocus Mid-Scala

The AB electrode was successfully inserted into the scala tympani, which was identified on plain radiography as a coiled hyperdensity with 540° ID anteroinferior to the vestibule (Figure 4A). Insertion of the AB electrode into the vestibular system was identified on radiography as a 1.5-turn coil within the vestibule (Figure 4B). Tip foldover of the AB electrode within the scala tympani was identified as a folding of the 3 most distal electrodes onto the proximal electrode array leading to <360° ID (Figure 4C). All 3 electrode placements were confirmed with HRCT (Figure 4D-4F, respectively).

Imaging of MED-EL Flex24

The ME electrode was successfully inserted into the scala tympani, which was identified on plain radiography as a coiled hyperdensity with 360° ID antero-inferior to the vestibule (Figure 5A). Of note, the ME electrode results in lateral wall placement, which was detected on radiography (Figure 5A) with an electrode coil diameter greater than that produced by the COCH (Figure 3A) and AB (Figure 4A) perimodiolar electrodes. Insertion of the ME electrode into the vestibular system was identified on radiography as a linear hyperdensity within the superior semicircular canal, extending vertically from the vestibule (Figure 5B). Tip foldover of the ME electrode within the scala tympani was identified as a folding of the 2 most distal electrodes onto the proximal electrode array, limiting insertion to within the basal turn of the cochlea (Figure 5C). All 3 electrode placements were confirmed with HRCT (Figure 5D-5F, respectively).

Discussion

We find that the described radiographic protocol, based on plain film exposure settings of 75 kVp and 16 mAs, consistently provided a high-quality Stenvers projection with an accurate representation of vestibular and cochlear structures. With this study, we present a well-defined protocol for patient positioning, film placement, radiograph settings, and film interpretation to characterize radiographic findings of proper and improper placement of newly released precurved electrodes and 1 straight electrode. Identification of labyrinthine structures on plain radiography was an important initial step of film interpretation, as coiling of the electrode may appear similar within both the cochlea and the vestibule. Without proper analysis, a misplaced electrode may be misidentified as being intracochlear based on degree of coiling alone. Proper patient and x-ray beam positioning also allowed for identification of tip foldover when distal electrodes were viewed as overlapping more proximal electrodes. Accurate positioning is essential to prevent form distortion, which causes circular objects to appear elliptical.
when the object is outside the plane of interest and which may produce an image that inappropriately suggests tip foldover.\textsuperscript{15}

Upon electrode insertion, it was noted that misplacement into the vestibule occurred more easily with an inferior-to-superior approach but required noticeably greater force than
insertion into cochlear structures. While objective insertion force was not measured in this study, future studies could evaluate the differential force necessary to obtain a cochlear versus vestibular insertion. Tip foldover also readily occurred when the sheath and stylet were prematurely retracted approximately 2 mm from the COCH and AB electrodes, respectively. The appropriate technique for insertion of precurved devices should avoid premature electrode tip folding from sheath or stylet retraction. When performed properly, tip foldover can be avoided.

CI complication rates are relatively low, and many surgeons assess electrodes intraoperatively with telemetry and imaging. However, some authors have recently suggested that postimplantation imaging is unnecessary, as the rate of extracochlear misplacement is only 0.37% and intraoperative imaging did not alter clinical management in studies. This viewpoint may be challenged with the development of precurved electrodes that require evaluation for a potential new problem of tip foldover. Zuniga et al and other researchers have shown that this complication decreases CI function and may occur 10 times more frequently than other major complications, such as extracochlear misplacement. Thus, there is a need to identify and prevent tip foldover, given that it can be readily identified in the operating room prior to waking the patient from anesthesia.

Many groups have assessed nonimaging modalities to identify tip foldover, such as electrical impedance, subjective patient complaints, and surgeons’ clinical assessments. All of these methods have been shown to be unreliable for this purpose. Neural response telemetry has many applications and can be used intraoperatively to identify electrode failure, scalar translocation, and specific cases of misplacement. However, neural response telemetry may not be a reliable indicator of tip foldover or misplacement in the vestibule, as cochlear and vestibular placements produce similar action potentials. Others suggest that spread of excitation testing can identify tip foldover if ≥2 electrode positions show >1 local maxima on testing. Unfortunately, spread of excitation is not universally available for all CI models and in all hospitals, and use of this software requires a spread of excitation–trained audiologist, who may not be able to determine proper electrode placement.

There are several limitations to this study. First, cadaveric specimens allowed for optimal positioning during imaging, whereas positioning of live patients can be challenging if there are limitations to neck mobility. Modification of the film angle may be necessary in such circumstances. Our goal was to create the ideal situation as a potential model for comparison for clinicians, but future studies could review how slight alterations in x-ray angle change the appearance of implant electrodes. Electrodes were also inserted and imaged solely on the left ear, which provides a more comfortable insertion for most surgeons. However, the presented protocol for patient positioning and film interpretation should be independent of these variables. The validity of these results is limited to patients with normal temporal bone anatomy. For cochlear malformations or cochlear ossification, proper electrode positioning may have a different configuration than those represented within this study. Finally, repeated electrode insertion was implemented to achieve the 9 presented configurations, which may slightly alter temporal bone anatomy. To limit this complication, we performed all electrode insertions first into the scala tympani without tip foldover, second into the scala tympani with tip foldover, and third into the vestibular system. HRCT did confirm that repeat intracochlear insertions remained within the scala tympani, thereby minimizing anatomic differences among films; however, it was difficult to exclude subtle damage to the basilar membrane from repeat insertions.

Despite limitations of a cadaveric study, this study provides a potential guidance of intraoperative evaluation of CI electrode placement. The aforementioned protocol for imaging technique and interpretation demonstrates a rapid and reliable method to analyze precurved electrode placement and presence or absence of tip foldover. Intraoperative identification of these complications allows for immediate proper reinsertion of the electrodes, which should result in optimal CI performance and hearing outcomes. With proper patient positioning, radiographic specifications, and film interpretation, the placement of 3 new electrode models was easily identified.

Conclusion
A well-defined radiographic protocol allowed for reliable imaging of 3 newly designed CIs and identification of extracochlear misplacement and tip foldover. This protocol may be used to standardize intraoperative confirmation of CI electrode placement.

Author Contributions
Danielle R. Trakimas, design of work; acquisition, analysis, and interpretation of data; drafting and revision of work; Elliott D. Kozin, design of work; analysis of data; drafting and revision of work; Iman Ghanad, design, drafting, and revision of work; Sam R. Barber, design, drafting, and revision of work; Hugh Curtin, design of work; analysis of data; drafting and revision of work; Aaron K. Remenschneider, design of work; acquisition, analysis, and interpretation of data; drafting and revision of work.

Disclosures
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