

INTRA- AND POST-OPERATIVE MEASURES OF AUDITORY FUNCTION

STUDY PROTOCOL

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Table of Contents

Background and Objectives of the Study.....	2
Cochlear Implantation.....	2
Performance and Candidacy	2
Electrocochleography.....	3
Real-Time ECochG monitoring.....	3
Objectives.....	3
Significance.....	4
Study Design.....	4
Hypotheses.....	5
Participants.....	5
Randomization	6
Protocol timeline	7
Detailed description of measurements and procedure	8
Pure tone and bone-conduction audiometry	8
Electrocochleography.....	9
Intra-operative preparation	9
Post-operative ECochG	9
CT Scan.....	10
Risks.....	10
Statistical Analysis	11
Safeguarding of Protected Health Information (PHI).....	12
Appendix 1: Parameters for CT Scan-based Cochlear Implant Electrode Localization....	17
Area to Scan.....	17
Slice Thickness (Slice Size).....	17
Pixel Size (In-Plane Resolution)	17
Metallic Implant CT Scale (Extended Hounsfield Scale)	17
Scanning Voltage and Current.....	17
Exported File Type	17
References.....	18

Abbreviations

CI	Cochlear implant
FDA	Food and Drug Administration
EAS	Electro-acoustic stimulation
ECochG	Electrococleography
CM	Cochlear microphonic
ANN	Auditory nerve neurophonic
AB	Advanced Bionics
IRB	Internal Review Board
CT	Computed Tomography
CPI	clinical programming interface

Background and Objectives of the Study

Cochlear Implantation

A cochlear implant (CI) is a prosthetic device for the inner ear that bypasses damaged inner ear hair cells and directly stimulates the auditory nerve, thereby providing audible sensations to patients with sensorineural hearing loss (SNHL). The implanted part consists of a hermetically sealed electronics package, a receiver coil which communicates with external components, and a magnet to help align the internal and external receiver coils. Attached to the implant package is the lead assembly that includes an array of electrode contacts that is inserted into the cochlea and interacts with its stimulable elements, the spiral ganglion cells and the cochlear hair cells. Today's CI models have between 12 and 22 intra-cochlear electrode contacts, each of which can be independently stimulated. In the healthy cochlea, different pitches are perceived at distinct locations along the length of the cochlea. This tono-topic organization is utilized when stimulating the cochlea electrically, as individual contacts can preferentially address neural populations associated with discrete regions of the cochlea. For example, when a low-pitched sound is captured by the microphone of the external sound processor, stimulation is routed to more apical electrodes, while for high-pitched sounds more basal electrode contacts are engaged.

Performance and Candidacy

Cochlear implants are currently the standard-of-care for patients with significant SNHL and poor speech understanding. Preservation of the delicate anatomy within the cochlea is well-known to correlate with hearing and speech understanding outcomes. During

electrode insertion, it is common for the surgeon to make subtle adjustments to insertion parameters such as the angle of insertion or speed of insertion; such modifications are part of the standard-of-care of conventional CI surgery. The current state of conventional CI electrode insertion provides the surgeon with *no feedback* as to whether and when the delicate structures of the cochlea are damaged. ***Such a tool by which the surgeon can obtain real-time measurements of the electrophysiological function of the cochlea could help improve the current surgical procedure.***

Electrocotchleography

One means of achieving this level of feedback is using electrocotchleography (ECochG). ECochG is an objective electrophysiological reflection of peripheral acoustic-electric interactions within the cochlea. ECochG devices are FDA cleared Class II devices. An example of a cleared device is the Otometrics device (k143670). The FDA 510(k) clearance letter for this device is provided (See Appendix). During ECochG measurement, a brief acoustic tone burst with a defined frequency and level is delivered to the external ear canal. This results in normal physiologic movements of the outer and the inner cochlear hair cells. These movements produce small electrical potentials that can be sensed by a recording electrode placed near the cochlea (e.g., historically, on the promontory or the round window) [8,9]. Averaging of these recordings in synchrony with the acoustic stimulus allows the small ECochG signal to be reinforced while any physiological or electrical noise is averaged out.

With ECochG measurements, the functional integrity of different elements of the peripheral auditory system can be examined. Specifically of interest, ECochG measurements can be resolved into the cochlear microphonic (CM) – generated by the cochlea's outer hair cells – and the auditory nerve neurophonic (ANN) – generated by the auditory nerve. By comparing the energy in the recorded signal at the measurement frequency with the noise floor of the measurement, behavioral hearing thresholds can be estimated with an accuracy of +/- 10 dB [10].

Real-Time ECochG monitoring

Advanced Bionics (AB), a manufacturer of FDA-approved CIs, has introduced a software approach to allow for utilization of ECochG during surgery. The prototype version of the AB-ECochG system has been successfully utilized in several clinical studies [10]. The technological characteristics of the ECochG system utilized here are equivalent to existing FDA-approved systems.

This protocol will utilize the latest system under development from AB that enables data collection with sufficient speed and precision to provide real-time observations to the surgeon during CI electrode insertion.

Objectives

This investigation does not involve a novel CI or a modification of an existing implantable device. The CIs to be used in this study are physically and technologically unchanged and have current FDA approval (Ultra MS: Model# CI-1600-04, FDA PMA Approval Number P960058/S117; Ultra Slim J: Model# CI-1600-05, FDA PMA Approval Number P960058/S121). Utilization of the device in the diagnosis and treatment of disease (i.e., hearing loss) is also unchanged and consistent with existing FDA-approved indications.

ECochG systems themselves are not novel and have been in clinical use for many years. ECochG devices are FDA-cleared Class II devices. An FDA 510(k) clearance letter is provided (See Appendix). Use of ECochG for the purposes described here is consistent with indications covered under this FDA 510(k) clearance.

The objective of this study is to learn about how ECochG-based observations during conventional CI surgery can improve outcomes compared to the standard-of-care technique of blind electrode insertion. Two clinically relevant outcomes will be considered: post-operative electrode location (i.e., correct electrode placement within the scala tympani) and hearing performance (i.e., postoperative audiometric thresholds in clinic).

Significance

Compared with previous relevant work, whereby ECochG was recorded **near** the cochlea **before** and **after** CI electrode insertion, recording ECochG from the vantage point of the CI's apical electrode **within** the cochlea **during** CI electrode insertion has the advantage of closer proximity to the ECochG signal generators (i.e., cochlear hair cells and the acoustic nerve). This approach has been shown to result in larger amplitude recording, and, thereby, more immediate feedback to the surgeon should these potentials change. An added advantage of this method is that it does not involve any change to the CI device itself, to the way the device is used, or to the surgical technique to place the device.

The potential utility of ECochG during CI is illustrated by the following scenario: if the CI electrode touches the delicate structures of the cochlea (i.e., the basilar membrane or the spiral ligament) during insertion, the ECochG potentials become smaller in amplitude. With a real-time measurement system used during electrode insertion, decrease in ECochG potentials could be detected, and the surgeon could more purposely employ their modifications to insertion technique such as changing the insertion angle to avoid trauma or translocation.

Use of intra-cochlear electrodes for ECochG offers an additional capability of observing potentials post-operatively in the clinic. ECochG allows an objective method of monitoring hearing at regular intervals over the early post-operative period and may give insights into hearing outcomes.

Study Design

A prospective, randomized, multi-center controlled study design will be used in this study. The total study duration will be up to two years. This study will be conducted in agreement with the Internal Review Board (IRB). The study will be registered through Clinical Trials.gov (account created; registration pending IRB approval).

Outcome Measures

The post-operative outcome measures of this study will be (1) the CI electrode's scalar position as indicated by post-operative computed tomography (CT) and (2) post-operative hearing performance. Following the clinical convention, the surgeon will pre-operatively select the type of CI electrode (i.e., the MidScala electrode or the SlimJ electrode) that they would like to use during surgery. As detailed below, the patient will then be randomized to "audible ECochG signal off" or "audible ECochG signal on."

Hypotheses

The hypotheses of this study are that:

- (1) Changes in the ECochG signal observed during CI electrode insertion will correlate with insertion position outcomes as indicated by post-operative CT scan.
- (2) Participants randomized to "ECochG audible response on" will demonstrate a significantly lower rate of scalar dislocation compared to participants randomized to "ECochG audible response off."
- (3) Changes in the ECochG signal during CI electrode insertion will correlate with post-operative audiogram.
- (4) Post-operatively, changes in the ECochG *signal over time in clinic* will correlate with changes observed *over time* in post-operative audiograms.

Participants

In total, 192 participants will be included in this study. This sample size was determined by a power analysis, detailed below in Statistical Analysis.

Inclusion criteria are:

- Pure-tone audiometry thresholds ≤80 dB HL at 500 Hz
- One year of age and older
- Normal candidacy requirements for cochlear implantation met
- No cochlear abnormality that might prevent full insertion of the CI electrode array
- No additional handicap that would prevent study procedures from being followed

Exclusion criteria are:

- Chronic otitis media
- Malformed cochlea
- Auditory neuropathy spectrum disorder (ANSD)
- Presence of ear tubes
- Prior middle ear surgeries or trauma including disruption of ossicles

At any point in the study, the participants are free to end their involvement without any effect on their clinical care. Because this study does not involve any changes to the CI, its use, or the surgical technique, if a participant were to elect to end involvement in the study, it does not impact their treatment in any way. CI candidates meeting inclusion criteria will be given the opportunity to participate at the time of their regular pre-operative clinic visit or on the day of surgery itself.

Randomization

Interested CI candidates meeting study inclusion criteria will be randomized to one of two treatment arms. Randomization has been accomplished using a “randomized block design” to ensure that equal numbers of participants are included in each “treatment condition.” For each participating institution, an impartially designed randomization schedule has been drawn up with the assistance of a biostatistician. The arm to which participants are randomized will be unknown to the investigators at the time of enrollment and to the participants themselves. By necessity, surgeons themselves will be “unblinded” on the day of surgery. Figure 1 depicts the study’s randomization arms and post-operative outcome measures.

Arm 1: Audible ECochG Response Off

This condition is identical to the current standard-of-care for conventional CI surgery used worldwide. The surgeon will perform his or her electrode insertion without ECochG monitoring. Minute manipulations of the electrode are a normal part of conventional electrode insertion; manipulations such as redirecting the insertion vector or slowing down insertion speed will be made, as deemed necessary by the surgeon. A full electrode insertion will be performed, as appropriate. The ECochG responses will be recorded, but the surgeon will be blinded to this information during surgery.

Arm 2: Audible ECochG Response On

This condition will have the audible ECochG response on and available to the surgeon. In this condition, the surgeon perform a conventional electrode insertion while listening to the running ECochG signal for drop in amplitude (suggesting impending trauma). If no drop is detected, insertion will proceed to the full electrode length according to the standard-of-care. If an ECochG amplitude drop is observed, the surgeon will place this observation in its clinical context and evaluate insertion parameters, (i.e., insertion vector, insertion speed, etc.), customary practice with conventional CI surgery, but here

supplemented by the ECochG response. In the case of an ECochG amplitude drop that does not recover, the standard-of-care practice of achieving a full electrode insertion will be followed.

Protocol timeline

1) Pre-Operative (typically 1-30 days before surgery)

- a) Standard counselling regarding CI study; collect consent form for adults or assent form for pediatric participants; collect data release forms.
- b) The surgeon makes his or her CI electrode selection between two options: (1) the HiFocus SlimJ (lateral wall array) or (2) the HiFocus MidScala. Electrode selection is a normal component of conventional CI surgery. All CIs models to be utilized in this study are FDA-approved and will be used within their approved indications (Ultra MS: Model# CI-1600-04, FDA PMA Approval Number P960058/S117; Ultra Slim J: Model# CI-1600-05, FDA PMA Approval Number P960058/S121).
- c) Pure tone audiometry (standard-of-care pre-operative CI candidacy evaluation). In pediatric patients, for whom completion of pure tone audiometry may be difficult or unreliable, auditory brainstem response (ABR) testing can be used to supplement or estimate behavioural thresholds.
- d) Pre-operative CT scan (standard-of-care) for surgical planning.

2) Day of surgery

- a) Ensure that no cerumen or surgical preparation fluid is in the external ear canal. Place the ear piece in the external ear canal and fold the pinna forward, as in the conventional procedure.
- b) Enter the pre-op audiogram into the software.
- c) Normal CI surgical approach. A conventional round window or extended round window entry into the cochlea is prepared.
- d) Measure ECochG in response to a 500 Hz tone burst stimulus, at 110 dB SPL, during insertion of the CI electrode and after insertion of the CI electrode. Figure 2 schematically depicts the intraoperative set-up. Figure 3 shows the non-invasive surface electrode and earphone array used in ECochG. Figure 4 shows the enclosure box and monitoring screen.
 - i) For participants randomized to Arm 1 of the study, the surgeon will perform CI electrode insertion without ECochG feedback.
 - ii) For participants randomized to Arm 2 of the study, the surgeon will make insertion modifications as appropriate in response to ECochG feedback.

3) Initial CI Activation Visit (3-5 weeks after surgery)

- a) Audio Assessment
 - i) Unaided pure tone audiometry in the implanted and the unimplanted ear
 - ii) Bone-conduction thresholds when possible, depending on the patient's residual hearing status

- iii) For pediatric patients, unaided audiometric data may be collected as tolerated, across different visits, to accommodate the unique challenges of hearing assessment of young children.
- b) **Measure ECochG responses in clinic** (to coincide with audiology, +/- 1 week)
 - i) 125-2000 Hz (frequency scan)
 - ii) At an acoustic intensity level at or below their comfortable level through an insert earphone
 - iii) Directly through the CI
- c) Post-Op CT scan to identify CI electrode scalar location
 - i) Obtain scan within one month following surgery
 - ii) Patient identifiers removed from CT scan data and sent to collaborators in DICOM format for analysis (See Appendix 1).

4) Approximately 3 Month Visit

- a) Audio Assessment
 - i) Pure tone unaided audiology in the implanted and the unimplanted ear
 - ii) Bone-conduction thresholds when possible, depending on the patient's residual hearing status
- b) Measure ECochG responses in clinic (to coincide with audiology, +/- 1 week)
 - i) 125-2000 Hz (frequency scan)
 - ii) At an acoustic intensity level at or below their comfortable level through an insert earphone
 - iii) Directly through the CI

5) Approximately 12 Month Visit

- a) Audio Assessment
 - i) Pure tone unaided audiology in the implanted and the unimplanted ear
 - ii) Bone-conduction thresholds as appropriate
- b) Measure ECochG responses in clinic (to coincide with audiology, +/- 1 week)
 - i) 125-2000 Hz frequency scan
 - ii) At an acoustic intensity level at or below their comfortable level through an insert earphone
 - iii) Directly through the CI

Detailed description of measurements and procedure

Pure tone and bone-conduction audiology

Pure tone audiology will be performed following the conventional, routine protocol currently in place for determining CI candidacy. Where possible, pure tone thresholds will be established in the implanted ear for 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, and 8000 Hz. Testing will be conducted using insert earphones, and where indicated, the contralateral ear will be masked. Both the implanted and the non-implanted ear will be measured. If clinically appropriate, bone-conduction testing will be performed as well following conventional practices. For young children in our cohort, for whom

hearing testing can be uniquely challenging, thresholds obtained across more than one visit will be permitted and thresholds may be estimated base on auditory brainstem response (ABR) testing.

In line with the Minimum Reporting Standards for Adult Cochlear Implantation recommendations [11], in patients with functionally relevant pre-operative low frequency pure tone averages (125, 250, 500 Hz) < 80 dB HL, post-operative residual hearing will be reported. Each frequency will be reported individually (125, 250, 500, 1000, 1500, 2000, 4000, and 8000 Hz) rather than as a pure tone average.

Electrocotileography

In the operating room, a 500 Hz tone burst will be presented to the participant at a 110 dB SPL through an insert earphone in the external auditory canal. This acoustic stimulus will provoke movements of remaining inner and outer cochlear hair cells and evoke a response from the auditory nerve. Tone burst stimuli at 500 Hz have been shown to produce the largest amplitude ECochG response, therefore, will be used as the default stimulus here. The resulting cochlear potentials will be recorded using the recording electrode from the apical aspect of the CI electrode. By averaging the recorded signal synchronized with stimulus delivery, the responses can be reinforced while unsynchronized noise will average out. For a more detailed description of ECochG measurements, please see [10]. This utilization is consistent with indications covered under this FDA 510(k) clearance.

Intra-operative preparation

The insert earphone will be placed in the external ear canal after cerumen removal. The ear canal will be surgically prepared, followed by suctioning of prep fluid. Following the conventional technique, the measurement ear will be folded forward and taped. The surgery will proceed following the standard-of-care practice consisting of a cortical mastoidectomy, a facial recess (posterior tympanotomy), and preparation of intracochlear access via the round window or an extended round window approach. Before the CI electrode will be inserted, the headpiece will be connected to the implant, and the ECochG software will be triggered to begin the ECochG recordings. Figure 2 depicts a schematic of the measurement system setup. Figure 3 shows an example of the noninvasive surface electrode and earphone array. Figure 4 shows the monitor and unit through which the ECochG is observed and recorded.

To facilitate correlation of changes in ECochG potentials during CI electrode insertion and surgical events that ultimately relate to trauma within the cochlea, the surgeon will verbally indicate the progress of electrode insertion (e.g., “at the round window,” “at the first marker on the electrode,” “at the last marker on the electrode”), which will be recorded in the software by an assistant and synched with the ECochG signals.

Post-operative ECochG

For post-operative ECochG measurements in the clinic, the setup depicted in Figure 3 will be utilized. For this testing, the external component of the CI will be temporarily removed (equivalent to simply taking off a hearing aid) and replaced with an external head coil component (physically identical to the CI's external head coil) that allows for ECochG measurement. After connecting the head piece, a frequency scan from 125-2000 Hz will be presented to the participant at an acoustic intensity level at or below their comfortable listening level through an insert earphone in the external auditory canal. After measurements are collected, the participant's own external component will be put back in place. This measurement takes up to 5 minutes and does not require active participation of the participant.

CT Scan

A single post-operative CT scan will be conducted to identify the electrode's scalar location. A post-operative CT scan is often performed as a part of the regular clinical routine in patients for whom more information about the CI electrode location is needed. The post-operative CT will be collected per parameters outlined in Appendix 1.

Risks

The chief risks associated with this study are those inherent to CI surgery itself. The use of intraoperative ECochG has been well-demonstrated to pose no added patient risks, but may, as discussed above, provide an important benefit. Participation in this study will involve the following specific considerations:

1. *Increased surgical time:* The ECochG measurement procedure adds up to 5-15 minutes to the procedure. During this added procedure time, the Anesthesia team will closely monitor the patient. If there are any concerns at any time, the study activity will be ceased.
2. *Post-operative CT scan:* Associated radiation exposure.

The implant, sound processor, and the clinical programming interface (CPI) hardware are all FDA-approved, and their use in the study is not associated with any additional risk to the patient. ECochG devices are FDA-cleared Class II devices. For an example of an FDA 510(k) clearance letter for the Otometrics device (k143670), please see Appendix. The ECochG recording software is not FDA/*Conformité Européenne* (CE) certified, but it has been thoroughly tested per AB's internal quality system. The recording software is not part of the CI operation and does not introduce any new or changed risk to the patient. It has been verified that the experimental software does not affect the performance of the FDA-approved software or hardware. Further, the entire protocol detailed above has been utilized and reported upon across several institutions validating the feasibility, ease, and safety of this modification to the convention "no feedback" approach to CI electrode insertion. This study's principal investigator (PI) also has experience using the current system.

Data Acquisition and Storage

Post-operative audiometric measurements and post-operative CT scan results will be recorded in the participant's study binder. Results of intra-operative and post-operative ECochG will be saved by the ECochG software program but will also be printed and kept in the participant's binder. All files will be archived. The main study results will be transferred to Excel-files for analysis. Further analyses will be done with Excel, Matlab or statistical software packages. A member of the Biostatistics Department will assist in statistical analysis. All results will be made anonymous prior to being shown to any third party. It will not be possible for any individual study participant to be recognized from his or her study data.

In addition, we will compare ECochG-based predictions associated with CI electrode scalar position and hearing outcomes to predictions made based on conventional demographic and audiometric data. To facilitate multivariate analysis, we will extract biographical (e.g., age, etiology of hearing loss, duration of deafness) and surgical (e.g., device and electrode type) factors from the electronic medical record.

Statistical Analysis

Randomization

Block randomization is statistical strategy to prevent unequal numbers of participants from being randomized to one arm vs the other (here, audible signal "on" versus audible signal "off"). For example, using a random number generator set to individually assign 100 participants to one of two groups, there is no assurance that an equal numbers of study participants would end up in the "audible signal on" group, resulting in an unbalanced overall sample, despite randomization of each participant.

Using a block approach, the total sample is divided into smaller blocks and randomization is performed within each block with the rule that the number of allocations is balanced within that block. In our study, although each institution will likely only contribute about 40 participants, we have designed a randomization schedule to allow for 100 participants to be run for each program. This sample of 100 was divided into 50 blocks of two participants; the two participants are randomized ensuring that one goes into the "signal off" group and one goes to the "signal on" group.

Power Analysis

To ensure that our study is appropriately powered to detect a significant difference in the primary outcomes measures, we performed a power analysis with the assistance of a biostatistician. Post-operative CT-based indication of scalar position is treated as a dichotomous variable (i.e., either in the scala tympani or in the scala vestibuli); post-operative hearing outcomes are treated as a continuous variable.

Scalar Dislocation: Preliminary data indicates that the current state of CI electrode dislocation from the scala tympani to the scala vestibuli is approximately 35% (or, a “successful” scala tympani position is achieved at a rate of 65%). For participants randomized to “ECochG audible signal on,” our expectation, driven by preliminary data, is to decrease the rate of scalar dislocation to approximately 15% (or, a “successful” scala tympani position rate of 85%). Setting the alpha error rate at 2.5%, a total sample size of 192 participants, or 96 participants in each of the two randomization groups, was determined using a Fischer exact test. If we permit a 5% error rate, the total sample size drops to 162 patients (81 randomized to audible signal “on”; 81 randomized to signal “off”). While these numbers of participants are higher than would be possible to achieve at our site alone in an average two-year period, through a coordinated effort to pool multi-center data, it will be easily achievable.

Secondary Planned Analysis

Electrode Type: As detailed above, once a participant is enrolled in the study, the surgeon will select which of two CI electrodes are most appropriate. A secondary analysis comparing scalar position and hearing preservation outcomes will be performed (i.e., four total between-group analyses) between the two electrode groups.

Pediatric Participants: This study will include both adult and pediatric participants. A secondary analysis comparing scalar position and hearing outcomes between adult and pediatric participants will be performed (again, four total between-group analyses).

Regression Analysis: To model the influence of “ECochG on” on the primary outcome measures in the context of participant age group and electrode choice, two regression analyses will be performed – one for the outcome measure of scalar position and one for hearing outcomes.

Hospital Effect Analysis: To determine if there is a meaningful difference in outcome measures across the different participating hospital settings, a secondary analysis will be performed as well.

Safeguarding of Protected Health Information (PHI)

Upon study enrollment, participants will be assigned an alphanumeric code that will be used to track their data. A code key will be maintained by the investigators on a secure server and accessed using password-protected computers located in a locked office in a secure research space. Participant identity cannot be discovered from ECochG data. Likewise, CT images and audiometric data will not reveal participant identity and will be made fully anonymous prior to sharing with any third party. Participant study binders, labeled using their alphanumeric code only, will be stored in a locked cabinet, in a locked office, in a secure research area accessible only to the investigators.

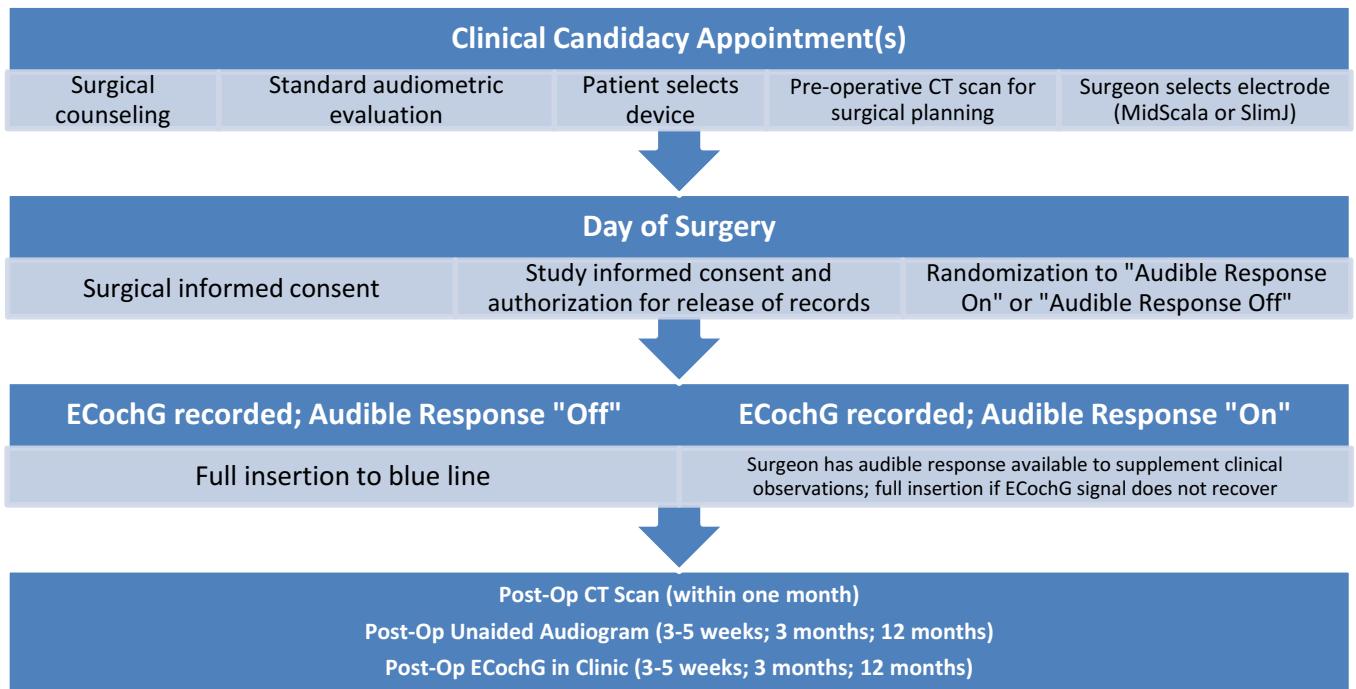


FIGURE 1. Study protocol overview

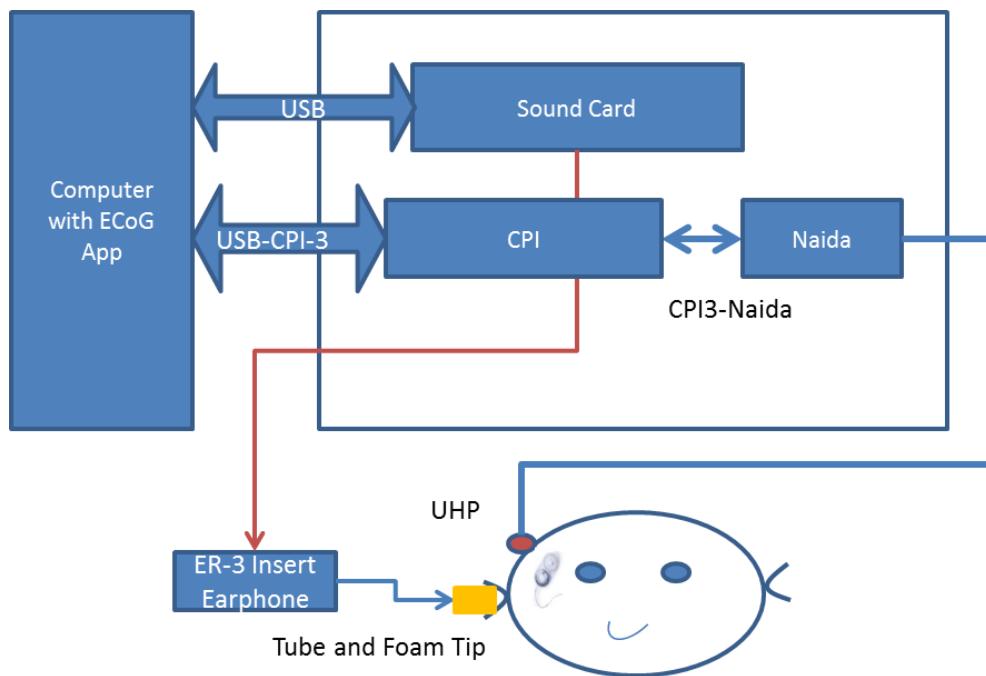


FIGURE 2. Schematic depicting measurement setup for intra-operative or post-operative ECochG recording via the implant. CPI = clinical programming interface; USB = universal serial bus; UHP = universal head piece.



FIGURE 3. Photograph showing an example of the ECochG surface (nonpenetrating) electrode and earphone array. (Pauliana Lamounier (October 4th 2017). Electrophysiology in Ménière's Disease, Up to Date on Meniere's Disease. Faye Bahmad, IntechOpen, DOI: 10.5772/intechopen.69668. Available from: <https://www.intechopen.com/books/up-to-date-on-meniere-s-disease/electrophysiology-in-m-ni-re-s-disease>)



FIGURE 4. The system contains an enclosure box, which contains clinician programming interface (CPI), programming cables, NaidaCI Q70 or Q90 processors, sound card, as well as commercial insert headphone (ER-3).

Appendix 1: Parameters for CT Scan-based Cochlear Implant Electrode Localization

Area to Scan

Set to scan the inner ear / cochlea. Make sure to scan the whole inner and the temporal bone are in the scan area.

Slice Thickness (Slice Size)

Slice thickness (slice size) should be set to be equal to or less than 0.5 mm.

Pixel Size (In-Plane Resolution)

In-plane resolution should be smaller than 0.4×0.4 mm (2.5 pixels per mm). The smaller the pixel size (i.e., the larger the in-plane resolution) the better the localization.

Metallic Implant CT Scale (Extended Hounsfield Scale)

The area that is being scanned contains a metallic implant. There should be a selectable setting for scanning a metallic implant that will extend the CT scale (Hounsfield Scale) so that the metallic implant is brighter than the surrounding bone. Select this setting.

Scanning Voltage and Current

Standard voltage and current for the appropriate scan type and age of the patient should be used. No special settings are needed.

Exported File Type

Digital Imaging and Communications in Medicine (DICOM) files are needed to perform the analysis. This should be the typical file type that is exported by the software. The data can be saved/burned onto a compact disc (CD), and then retrieved from the CD for later use.

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