Intra- and Post- Operative Measures of Auditory Function Using Cochlear Implants

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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.***

Electrocochleography

One means of achieving this level of feedback is using electrocochleography (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).

Hypotheses

The hypotheses of this study are that:

(1) Changes in the ECochG signal during CI electrode insertion will correlate with post-operative audiogram.

(2) Modification of insertion speed and trajectory of electrode can recover ECochG response and improve postoperative hearing preservation in implanted ear

(3) Post-operatively, changes in the ECochG *signal over time in clinic* will correlate with changes observed *over time* in post-operative audiograms.