ADVANCED BIONICS
POWERFUL CONNECTIONS

CLINICAL RESEARCH

The AIM System

The AIM™ system is a new surgical and audiological system for recording electrophysiological responses intraoperatively and in a clinical setting using Advanced Bionics cochlear implants. The AIM system takes advantage of the unique recording capabilities of Advanced Bionics implants and provides valuable information in an easy-to-use interface.

The AIM system offers:

- Real-Time Insertion Monitoring: recording the electrocochleography responses from a patient's own cochlea during electrode insertion
- Objective Audiometry: convenient monitoring of a patient's objective measurement thresholds over time
- Objective Measure Suite: designed for intra-operative and post-operative clinical use; includes impedances, neural response imaging, and electrical stapedius reflex thresholds

INTRODUCTION

The cochlear implant (CI) is arguably the most successful neural prothesis ever developed, yet there is still much to understand about how the implant interacts with a patient's individual cochlear anatomy. The AIM system is a new surgical and audiological platform that takes advantage of the unique recording capabilities of Advanced Bionics (AB) cochlear implants to monitor how a patient's cochlea responds to sound in real-time.

The AIM system runs on a rugged, drop-proof tablet that can be easily stored and transported between the operating room and the clinic. The tablet (figure 1) includes an internal battery and audiometer grade transducers for the generation of acoustic test stimuli. The screen of this tablet can be used with bare hands, through gloves, or while placed inside a sterile bag.

Figure 1. AIM Tablet

The software user interface is designed to accommodate touch controls and allows for custom workflows in which a tailored selection of available tests can be combined and completed with a few taps on the screen. Data can be exported and a full PDF report can be generated automatically, showing an overview of the test results. The ease of data sharing means greater opportunity for clinic efficiency, collaboration, and research.

ELECTROCOCHLEOGRAPHY (ECOCHG)

In the context of cochlear implant electrode insertion, the cochlea has been described as a black box. The exact geometry of this bony anatomical structure may not be known at the time of surgery and the interaction between the electrode and structures of the cochlear anatomy can be a mystery specific to every ear. However, these structures respond to sound, and the AIM system

provides insight, in real-time, about how the responses from these structures are affected by the electrode array during insertion. One method of illuminating the impact of electrode insertion in the cochlea is through the measurement of stimulus-evoked auditory potentials measured from intra-cochlear electrodes. This technique of intra-cochlear measurement dates back to research applications that spawned decades of learning (Weaver and Bray, 1930; Fomm et al., 1935; Kohlloffel, 1970).

Since then, the cochlear implant has emerged and developed into a standard intervention for the treatment of severe-to-profound hearing loss. Advanced Bionics most recent cochlear implants (HiRes 90K and later) are built on a technology platform that allows for measurement of these same auditory potentials, enabling the first clinical application for the real-time measurement of an electrocochleogram (ECochG) during electrode insertion (Dalbert et al., 2015; Harris et al., 2017; O'Connell et al., 2017). Using the bi-directional telemetry of the HiRes Ultra Implant system, information is sent back from the implant to the external components through the same inductive coupling that allows the sound signal to be transmitted from the external components to the implant. This allows the clinician to verify the integrity of the implanted electronics before, during, and any time after surgery.

WHY ECOCHG?

Electrocochleography is a diagnostic measurement technique with a 70 year history (Eggermont, 2017) that can be used to assess the health and function of the cochlea. Historically, it has been used to diagnose Meniere's disease and Auditory Neuropathy Spectrum Disorder, for intraoperative monitoring, and for objective estimation of hearing ability.

The ECochG is an evoked potential that combines several measurable impulses from the cochlea and auditory nerves, in response to an acoustic stimulus. One conventional method for recording ECochG is the trans-tympanic approach. Trans-tympanic ECochG involves passing a needle electrode through the tympanic membrane to rest on the cochlear promontory, or placing a ball electrode on the round window intraoperatively.

The AIM system uses the cochlear implant array to measure ECochG, eliminating the need for needle electrodes and additional equipment. It records these measurements and plots the response amplitudes through the implant during electrode insertion (see figure 2). Advantages of ECochG recorded via the implant array compared to the trans-tympanic method include 1) a larger signal from recording closer to the potential generators, and 2) a much simpler setup. Measurement of the ECochG is completed by first placing an ear-tip in the patient's ear-canal for presentation of the acoustic stimulus, while recordings are collected from the cochlear implant electrodes. During insertion of the implant, the apical-most electrode is used for measurement of the cochlear microphonic amplitude; higher number (more basal) electrodes may be used with other measures.

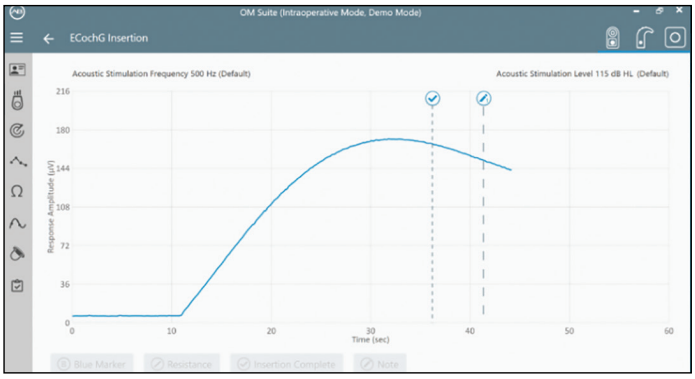

Figure 2. ECochG response growth is shown in real-time as the electrode array is advanced during insertion. Notes can be added at any time during the measurement.

ECochG response amplitudes measured through the implant reflect the health and function of the cochlea, and an increase or decrease in amplitude during electrode insertion may be indicative of physiological changes within the cochlea. The AIM system provides real-time feedback, in 130ms intervals, during insertion. These measures can be used to quickly estimate an objective audiogram in the operating room following electrode insertion and post-operatively in the clinic.

OBJECTIVE AUDIOMETRY

In addition to the surgical applications, AIM is capable of recording intra-operative and post-operative measurements to provide objective ECochG threshold estimation. Ongoing research is investigating the relationship between ECochG measurements and behavioral audiometric thresholds, for clinical interpretation that may be useful in both the fitting and follow-up of CI recipients. To date, the published results appear promising, suggesting a clinically meaningful correlation (Koka et al., 2016; O'Connell et al., 2017; Harris et al., 2017; Riggs et al., 2019).

Conventional behavioral audiometry is typically conducted in a soundproof booth, and relies greatly on patient cooperation. The test requires that patients not only understand the task at hand, but also that they concentrate and respond consistently over a period of time. In the case of young children or recipients with complex needs, the tests may require conditioned play or visual

response audiometry that often add additional clinic time.

The AIM system offers the audiologist a valuable clinical tool to enhance the CI fitting experience. In less than one minute, clinicians can quickly and objectively assess post-operative unaided acoustic hearing between 125 and 4000 Hz in the implanted ear (see figure 4). The measurement is automatic and does not require subjective feedback. AIM offers a quick and convenient method for tracking acoustic hearing over time, and may be especially useful for making measurements with children or other patients who are difficult to test. ECochG estimated threshold measurements can be obtained outside the booth, meaning the clinician is not limited by the availability of a soundproof booth, saving valuable time during appointments.

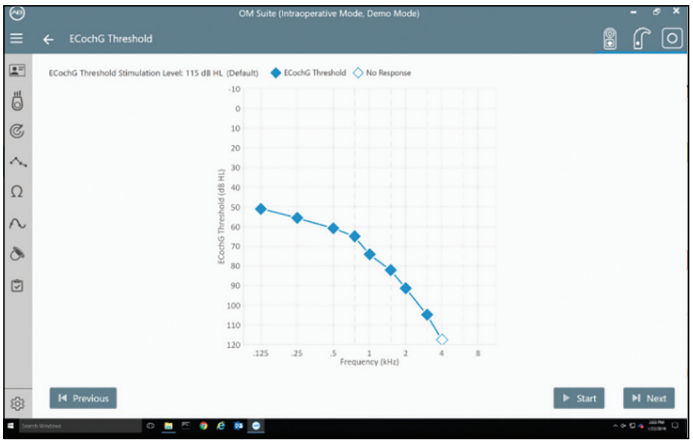

Figure 3. ECochG threshold estimation screen. The ECochG threshold are recorded from each of audiometric test frequencies from 125-4000 Hz. It takes approximately 45 seconds to 1 minute to complete and can be completed in the operating room immediately after insertion, and any time after in clinic follow-up.

AN OBJECTIVE MEASURES SUITE

AIM is a suite of measures that includes reporting of the previously discussed ECochG amplitude during surgery, estimation of objective audiometry as well as a number of objective measures that have become standard of practice in CI fitting and management (table 1).

MEASURE	CLINICAL BENEFIT
Impedances	• Impedance measurements are color coded to indicate valid, short, or open impedances in green, purple, and gold, respectively. • The OM Suite allows impedance measurements using the case ground or the ring ground (or both).
Neural Response Imaging (NRI)	• NRI measures the responsiveness of the auditory nerve to electrical stimulation, and is a valuable tool for CI programming. • NRI can provide a method of verification of program settings and is particularly helpful with young children and difficult to program individuals. • The OM Suite offers a fast, objective, and automatic measure of NRI.
Electrically-evoked Stapedius Reflex Threshold (ESRT)	• ESRT testing is a useful objective measure to assist clinicians with fitting CI recipients, who are unable to provide reliable subjective feedback about loudness levels. • Although ESRTs are sometimes more difficult to obtain than NRI, they generally show a stronger correlation with behaviorally set M levels. • The AIM system makes measuring ESRTs an easier procedure.

Table 1. Objective Measures

CONCLUSION

The AIM system is the first comprehensive suite of real-time objective measures. From measurement of intra-cochlear ECochG during electrode insertion to electrical stapedial reflex thresholds, NRI, impedances, and objective threshold estimation, the features of this system fluidly span clinical needs that arise in the operating room and in the audiology clinic. During surgery, real-time measurement of the ECochG during electrode insertion and objective audiometry provide immediate feedback regarding cochlear health, providing a unique window into each individual's hearing ability. In the clinic, simple and quick measurement of objective audiometry, impedances, and NRI present an opportunity for clinical efficiency that may not be realized otherwise. The AIM system is the only FDA and TÜV approved option that bundles these utilities into a configurable workflow that is easily completed and delivered as a digital report that can be included in patient files.

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028-Q060-02 Rev A