Introduction

Cochlear implants (CI) are the most successful and popular neural prostheses used in our time. By means of electrical stimulation, this device is capable of restore partial to complete auditory sensation in patients suffering of sensorineural hearing loss. A microphone captures the sound which is converted into electrical pulses by a processor, and sent to an array of electrodes implanted in the cochlea. These pulses activate the auditory nerve and are ultimately perceived as sound by the brain.

After surgical implantation of a CI, a series of programming sessions have to be conducted in order to fit the device. This is a key step for optimal performance and is both challenging and time consuming. Usually, devices are fit based upon subjective behavioral tests and patient feedback to determine a range of stimulation in which the device will operate, often called the dynamic range. These methods, especially for setting the upper limit of stimulation or comfort level (C-level), are not very reliable and present a lot of difficulties with patients that are pre-lingually deaf and with young children that are not able to provide clear, objective judgments regarding their listening level. [1, 2]

Several objective electrophysiological measures have been proposed as an aid for the fitting of CI. [3] The electrically evoked auditory brainstem response (EABR) has been used to evaluate candidacy for cochlear implantation, and recently to assist in the mapping of CI. Whereas, the electrically evoked compound action potential (ECAP) (also called the Neural Response Telemetry (NRT) when using the Nucleus 24 device), has been used to confirm response to electrical stimulation and assisting with setting the programming levels.

Furthermore, the most common measure for the fitting of CI is the electrically evoked stapedius reflex (ESR), measured by monitoring the changes in the eardrum acoustic impedance. The correlation of this measurement with the upper limit of the dynamic range or comfort level (C-level) has been shown through various studies. [1,4,5] Although, the ESR is a good way of establishing the upper limit of stimulation, between 30-40% of cochlear implant patients have not shown any detectable impedance changes due to electrical stimulation. [3,8] The reasons for the absence of the reflex when measuring the impedance can be due to middle ear malformations, motion artifacts, and other reasons that in some cases cannot be determined. It does not mean necessarily that the reflex is absent, just that a better method to obtain it is needed. In addition, children can have a hard time remaining stationary or tolerating the probe that’s used to measure the impedance change. [6, 7]

Using stapedius muscle electromyograms (SEMG) has been proposed as a promising, although invasive, method of recording the ESR more effectively. [8] Other important aspects for the use of this measurement still need to be examined however. In this study, we use an
animal model to investigate the relationship that the less invasive measurements, EABR and ECAP, have with the SEMG to test if independent information can be obtained from them. The effects of high rates of stimulation on the SEMG response are also examined. The results demonstrate the viability of using SEMG as an objective measurement to aid in the process of fitting CI.

Methods

Surgical Procedures

Four healthy Sprague-Dawley rats (300-500g) were anesthetized with a mixture of ketamine/xylazine/acepromazine (50:5:1 mg/kg) with supplemental anesthesia given to maintain areflexia during the entire surgical procedure. The physiological state of the animal was monitored by blood oxygen saturation and heart rate. The animals were placed on a heating blanket maintained at 37 degrees Celsius. All animal procedures followed NIH guidelines and were approved by the Pennsylvania State University Institutional Animal Care and Use Committee's (IACUC).

The top of the skull was cleared and bone screws were placed to anchor a dental acrylic skullcap. One of the screws served as a ground for the EABR electrodes that were sutured to fascia of muscles near the ear canal. A nut was fixed in the acrylic skullcap for a head manipulator to be locked on it and allow the head to be fixed at an appropriate angle for surgical approach to the middle ear.

A post-auricular incision was made, and the tendon of the m.sternomastoideus muscle was identified and followed to the bulla. The tissue surrounding the bulla was removed, and an accessory hole was drilled until the cochlea, round window and stapedius were visualized. Sounds were made to visually confirm the contraction of the stapedius muscle. The stapedius electrodes were placed close to the stapedial cavity with the aid of a manipulator, and pushed to the muscle with forceps. A cochleostomy was made and the cochlear electrodes placed into the first turn of the cochlea. The bulla was repaired with carboxylate cement. The various recording electrodes were connected to a multi-channel programmable amplifier system (AMsystems model #2000).

Electrodes design.

The SEMG electrodes were composed of 50 micrometer diameter insulated tungsten micro wires that were electrolytic sharpened at the tips. Two electrodes were slid together into polyimide tubing and fixed with epoxy to form a bipolar pair approximately 400 micrometers apart. The electrode tips were bent at a right angle to allow easier insertion into the stapedial cavity.
The cochlear implant electrodes were three or four channel hand fabricated ball electrode arrays. They were fabricated from 25 micrometers insulated Pt-Ir wire with ball ends made with a micro-torch. Three or four of these wires were threaded together, with a spacing of ~500 micrometer from ball to ball.

**Stimulation and Electrophysiology Recordings**

The cochlea was stimulated using biphasic pulse trains delivered through a Nucleus CI24M cochlear implant system (Cochlear Corporation). Stimulation was delivered either between two intra-cochlear electrodes (bipolar) or an intra-cochlear and an extra-cochlear reference (monopolar). Current levels varied up to a maximum of 1750mA. Pulse widths were 25-50 microseconds. The stimuli for EABR and ECAP responses were single biphasic current pulses presented at 10 Hz. Stimuli for obtaining growth functions of the SEMG were delivered in 250 milliseconds bursts separated by an inter-stimulus interval (ISI) of 2 seconds.

EABR and ECAP were filtered (0.3 Hz-20 kHz), amplified (20k gain) and sampled at 50 kHz. All results presented were obtained from stimulation delivered to the middle channel.

The stapedial EMG was recorded differentially from the bipolar SEMG electrodes. The SEMG was filtered (300 Hz-20 kHz), amplified (20k gain) and sampled at 50 kHz. The stimuli consisted of 10-20 presentations delivered in 250 milliseconds bursts with an ISI of 2 seconds. Pulse widths were 25-50 microseconds with frequencies of 250 Hz, 500 Hz and 1 kHz.

**Data Analysis**

ECAP response was obtained calculating the magnitude of the first wave from the EABR electrodes. Intracochlearly, the ECAP wave was the only one measured by the electrodes.

Growth functions were obtained by plotting the average magnitude of each response against the current level. When normalizing, each corresponding value was divided by the maximum magnitude in the series.

Artifact was eliminated in the SEMG recordings by a threshold algorithm that blanked out any magnitudes above it, the values were adjusted to take into account the “dead time”, leaving just the stapedius muscle response.

**Results**

Representative samples of the ECAP and EABR recordings from the cochlear and stapedius electrodes, and the EABR electrodes respectively, during single pulses stimulation are shown in Figure 3. Each plot represents the average response to 600 stimulus presentations (300 in one polarity and 300 in the opposite polarity to reduce artifact) superimposed at different current levels ranging from 170 to 1581μA. Threshold was observed around 170 and 255 μA, when a visible response was noted.
Figure 3. ECAP recorded from the cochlear electrodes (column 1), the stapedius electrodes (column 2), and the EABR electrodes (column 3).

The ECAP response obtained from three different places is shown in Figure 4. Using the stapedius electrodes to get the ECAP response has never been reported before, and represents an alternative function of these electrodes. The responses from the different methods varied in magnitude, but after normalizing each, as shown in Figure 5 (dividing by the greatest response), it is noticeable the similarity in morphology of these three techniques.

Figure 4. ECAP response growth from the cochlear, EABR and stapedius electrodes.
Figure 5. Normalized ECAP response growths from the cochlear, EABR and stapedius electrodes.

The SEMG response characteristics at different stimulus rates are shown in Figure 6. An evident increase in threshold is observed as rate increases. On Figure 7, response growths obtained from a previous animal at different rates of stimulation support our observations for the current study [8].

Figure 6. SEMG responses at 250 Hz, 500 Hz and 1 kHz.
The ECAP thresholds were lower than the ESR threshold as would be expected (313 uA for the ECAP, 703 uA for the ESR, Figures 8 & 9). The amplitude between the ECAP growth function with that of the SEMG growth functions were also not consistent, suggesting that both signals could provide independent information about the level of stimulation. A similar trend was observed between the EABR growth function (threshold: 210 uA) and the SEMG growth functions (threshold: 390 uA) (Figure 10).

Figure 7. SEMG responses at 250 Hz, 500 Hz, 750 Hz and 1 kHz.

Figure 8. Comparisons between the ECAP growth functions and the SEMG growth functions. Threshold for the ECAP was around 313 uA and for the SEMG around 703 uA.
Discussion and Conclusions

We have successfully explored the features of the stapedius muscle activation using electromyograms during high rates of stimulation with a cochlear implant and compared the response with other objective measurements. The threshold of the SEMG was observed to increase as the rate augmented. A new function of the stapedius electrodes to capture the ECAP response, when single pulses stimuli is used, was also encountered. The SEMG technique is a feasible alternative for characterizing the electrical stapedius reflex for cochlear implant fitting. In the future, further research to study the effects that deafness has on the response and to develop a chronic model will be done. New ways of dealing with artifact are yet to be explored. The SEMG signal could be someday incorporated into the cochlea implant system to provide an automatic gain control of the stimulating current.
References


