THE ELECTRICALLY EVOKED WHOLE-NERVE ACTION POTENTIAL: FITTING APPLICATIONS FOR COCHLEAR IMPLANT USERS

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Abstract

The Electrically Evoked Whole-Nerve Action Potential:
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The goal of this study was to explore the clinical utility of the electrically evoked whole-nerve action potential (EAP), measured with the Neural Response Telemetry (NRT) capabilities of Cochlear Corporation's Nucleus CI24M cochlear implant system. Users of the CI24M cochlear implant system followed at the University of Washington with at least three months of implant experience were subjects (n=12) in this study. EAP growth and refractory recovery functions were successfully quantified on each active electrode of every subject. In addition, two measures of loudness growth were explored at 80 Hz (the frequency of the EAP stimuli) and at 250 Hz (the frequency of clinical implant fitting stimuli). The first loudness measure was a repeated ascending and descending method of adjustment using a continuous signal. The second loudness measure was a magnitude estimation technique. Other information including performance, etiology and duration of hearing loss, and individual electrode impedance was considered. EAP thresholds were found to be highly correlated with threshold loudness responses. The rate of EAP growth with increasing stimulation levels was also found to be correlated with the dynamic range of loudness limits and threshold loudness responses. Inconsistencies were found between the two methods used to measure loudness growth. No relationship was evident between EAP measures and performance. EAP measures can be used to estimate loudness information used in cochlear implant fitting. Suggested cochlear implant fitting protocols based on EAP measures may be more reliable than protocols based only on loudness techniques.

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LIST OF ABBREVIATIONS

ABR. Auditory brainstem response

ACE. Advanced Combination Encoder

C. Maximum comfortable loudness

DPS. Diagnostic Programming System

EAP. Electrically evoked whole-nerve action potential

ECochG. Electrocochleography

IPI. Interpulse interval

NRT. Neural Response Telemetry

RF. Radio frequency

T. Threshold

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DEDICATION

The author wishes to dedicate this work to his wife Lori and daughter Madeline.

CHAPTER 1: INTRODUCTION

A cochlear implant is a neural prosthetic device which is designed to provide acoustic information to adults and children who are profoundly hearing-impaired or deaf. The cochlear implant replaces the Organ of Corti, which exists along the Scala Media of the cochlea. Dysfunction of the Organ of Corti is typically the cause of hearing loss for individuals who are implant candidates. Electrical signals generated by the implant provide a stimulation pattern capable of representing frequency and intensity information to auditory neurons. Neural impulses induced by the electrical stimulation are processed by the auditory brainstem and cortex. The cochlear implant consists of an externally-worn microphone, signal processor, signal transmitter and power source, and a surgically-implanted signal receiver, signal processor and stimulating electrode array. An Audiologist adjusts the cochlear implant so that the amount of electrical stimulation is adequate for perception but not uncomfortable, and so that the pattern of stimulation leads to optimum sound quality and speech perception.

Laboratory-based basic psychophysical and neurophysiological research have provided information as to the perceptual and physical consequences of electrical stimulation of the cochlea. While these studies have led to "electro-acoustics" and better stimulation schemes, they have not led to better device fitting procedures. As a consequence, modern cochlear implant systems have gained flexibility in terms of more advanced stimulation parameters and multiple speech coding strategies. However, clinicians have been given limited guidance concerning appropriate use of these stimulation parameters and speech coding strategies.

Current implant fitting techniques are based on repetitive judgements of loudness, manufacturer-provided setting and random parameter set exploration. Such protocols can be time consuming and difficult, especially for the subject without previous or recent hearing experience or the 18 month old infant without the ability to communicate their perceptions. In addition, these fitting techniques do not take into account the increasing variability of subjects who are being implanted due to relaxing candidacy requirements.

Neural computation theory asserts that simple artificial neural networks are hindered by the detrimental effects of local maxima in performance optimization. Achieving global maxima in performance requires either more sophisticated artificial neural networks or advantageous initial conditions (Hertz et al., 1991). Substituting "clinical fitting protocols" for "artificial neural networks" and "cochlear implant user success" for "performance" in the above statement; Simple *clinical fitting protocols* are hindered by the detrimental effects of local maxima in *cochlear implant user success* optimization. Achieving global maxima in *cochlear implant user success* requires either more sophisticated *clinical fitting protocols* or advantageous initial conditions.

Clinical fitting protocols are often limited by the frequency and duration of visits by the patient imposed by the patient's and clinic's schedules, and the extent of basic science and engineering principles understood by the clinician. These factors are unavoidable. Therefore, ensuring cochlear implant user success (from solely the fitting perspective) is dependent on initial conditions.

This study explores the clinical utility of one neurophysiological measure, the electrically evoked whole-nerve action potential (EAP), in cochlear implant fitting. From the relationship found between EAP and psychophysic loudness measurements, protocols for device fitting can be used which do not rely heavily on loudness judgements from subjects. Information from EAP measurements can give the clinician logical and physiologically-based decision making criteria for device setting. Effective clinical procedures would not be limited to this technique. Rather, the technique would balance the art of cochlear implant fitting with the science of electrical stimulation of the cochlea.

There is no guarantee that each individual cochlear implant user will prefer the processor fittings based on EAP data, or that individual performance will be consistent with the performance of other implant users. The purpose of programming the cochlear implant in a manner more consistent with basic science fundamentals is to provide a logical starting point for each user. The user's cochlear implant should be initially programmed in the theoretically optimal method.

While this study will concentrate on Cochlear Corporation's CI24M Cochlear Implant System, the principles involved are directly applicable to other cochlear implant devices. Current cochlear implant systems are more alike than different. Device design and stimulation parameters of available devices exist along a relatively short continuum.

CURRENT METHODS OF COCHLEAR IMPLANT FITTING

According to Cochlear Corporation's technical reference manual, the goal of programming is to "customize the device so that the cochlear implant provides comfortable and usable stimulation to each patient" (Cochlear Corporation, 1996). To do so, the clinician uses the Diagnostic Programming System (DPS) software to measure threshold (T) and maximum comfortable loudness (C) stimulation levels for each electrode. This information is combined with parameter settings specific to the speech coding strategy, and used in a "map" or "program".

Threshold and maximum comfortable loudness stimulation levels are judgements repeated many times when the cochlear implant is first fit. The measurements are made frequently because stimulation levels typically change as the patient becomes accustomed to the percept elicited by electrical stimulation. Various techniques are used to assess these limits in different clinics. Techniques used include ascending, descending and counted methods. Measurement order is not consistent across electrode or level, and absolute levels are often altered after they are established when electrodes are balanced for loudness. No recommendation of technique is made by implant manufacturers and few researchers have attempted to quantify differences in current measurement techniques (Skinner et al., 1995).

Manipulation of the parameter set specific to the speech coding strategy typically is not done unless the patient complains about the quality of the sound. A wide variety of parameter manipulations can be made, including the choice of speech coding strategy. The choice of speech coding strategy has historically been between the devices manufactured by different companies, making the choice a matter of device marketing rather than appropriateness. Other manipulations include which electrodes are stimulated, the configuration of the current path during stimulation, the frequency range assigned to each electrode or channel, and stimulation amplitude parameters. In pulsatile coding strategies, pulse width and stimulation frequency parameters can also be manipulated. Rationale for manufacturer default settings of these parameters is often considered proprietary information. Clinicians are typically only supplied with information which assures stimulation at low power levels. Power consumption is directly related to marketing issues such as battery life and the availability of more cosmetically-appealing speech processors. In the clinical implant fitting environment, deviations from default parameter settings are based on the subject's preference, typically made in the quiet clinic environment based on minutes of listening experience.

WHOLE-NERVE ACTION POTENTIALS

Compound action potentials

The compound action potential (CAP) is a measure of synchronized VIIIth nerve activity. The CAP is also referred to as the N_1 potential as it has negative polarity, and is the first neural potential recorded. Electrocochleography (ECochG) and auditory brainstem response (ABR) measures commonly quantify the CAP in audiologic diagnostic procedures using acoustic stimulation. In humans, the CAP is normally recorded at approximately 1.6 msec post stimulus presentation for high intensity sounds. This latency represents outer, middle and inner ear transmission and transduction. The averaged neural event is approximately 1 msec in duration. The human CAP is typically measured with surface electrodes. Therefore, hundreds of neural response events must be averaged to reduce electrical noise and compensate for the relatively far-field measurement. Typically, only in animal models are normal hearing recordings made close to the auditory nerve.

EAP studies

The auditory nerve responds to electric, as well as acoustic stimuli. When the CAP is measured in response to electrical stimuli, it is known as the EAP. Theoretically, EAP measurements of the normally functioning human ear could be made with stimulation using an electrode surgically placed on the round window niche and recordings made with surface electrodes. No such studies have been published. Human EAP recordings have been made, however, in hearing-impaired individuals who receive electrical auditory stimulation in close proximity to the neural elements which generate the EAP through the cochlear implant. EAPs generated from cochlear implant stimulation can be recorded from surface potentials (Gantz et al., 1994). EAPs also can be recorded from non-stimulating electrodes with a cochlear implant which uses a percutaneous external / internal device link, such as the Ineraid device (Brown et al., 1996; Brown et al., 1990; Finley et al., 1997), and an experimental device made by Cochlear Corporation (Finley et al., 1997). These devices are rare. Recently, a cochlear implant which has the ability to record EAPs with a transcutaneous external / internal device link has become widely available (Abbas, 1997; Abbas et al., 1999; Brown et al., 1998b). This capability is manifested in the Neural Response Telemetry (NRT) capability of the CI24M device, manufactured by Cochlear Corporation. The CI24M recently completed investigational trials by the Food and Drug Administration (FDA). NRT is available to only approximately 12 sites worldwide.

Only in the animal model has the EAP been recorded in the normally functioning, as well as the hearing-impaired, auditory system (Aran et al., 1987; Brown & Abbas, 1990; Charlet de Sauvage et al., 1983; Nagel, 1974; Prijs, 1980; Stypulkowski & van den Honert, 1984). Use of the animal model allows the flexibility of manipulating a variety of near field recording configurations. Also, direct comparisons can be made in the animal model between the EAPs collected from normal hearing and hearing impaired auditory systems (Stypulkowski & van den Honert, 1984).

Waveform description and origin

When measured directly from the auditory nerve at the junction of the nerve trunk and the cochlear nucleus, an N_1 potential is observed at a latency of approximately 0.5 msec post-stimulus onset in the cat (Nagel, 1974; Stypulkowski & van den Honert, 1984). As the stimulating current is increased, an additional peak, termed N_0, is observed at 0.35 msec. The amplitude of N_0 grows from stimulation levels of 0.40 mA and dominates the EAP above stimulation levels of 1.20 mA. The differing response latencies are thought to be derived from differential stimulation on VIII nerve fibers. N_0 and N_1 derive from axonal and dendritic stimulation, respectively (Stypulkowski & van den Honert, 1984). See Figure 1. Data from the guinea pig show EAPs with latencies similar to the cat N_1 potential (Nagel, 1974; Prijs, 1980).

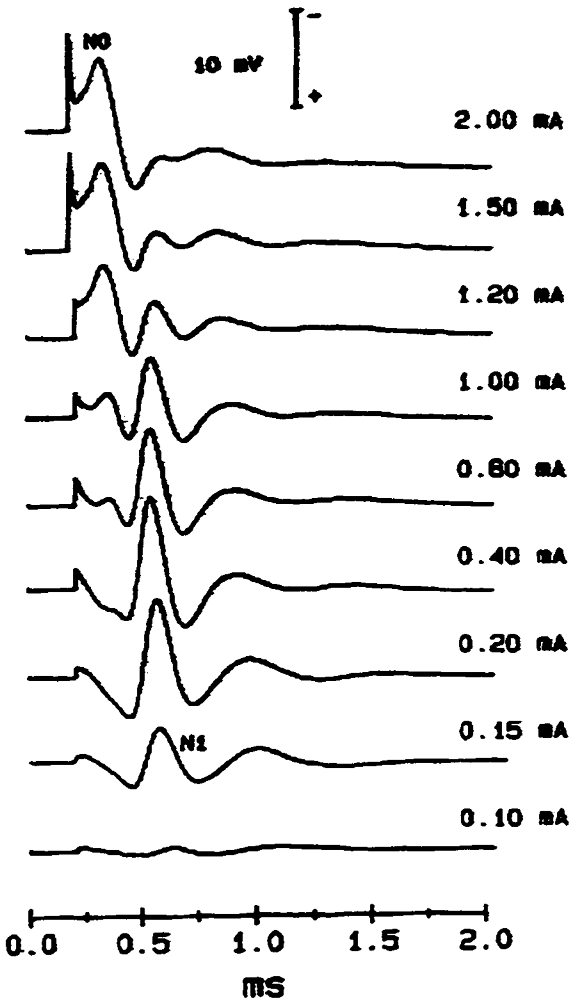

Figure 1. EAPs from nerve trunk in a cat (Stypulkowski & van den Honert, 1984, with permission, modified).

When recorded from within the cochlea of a normal hearing cat, the EAP is also found to be triphasic. See Figure 2. The first negative peak, occurring at ~0.26 msec, is the most prominent peak in the waveform. The second negative peak, at approximately 0.82 msec, is less robust and has a higher threshold (Brown & Abbas, 1990). The latency difference between recordings made from within the cochlea and recordings made at the cochlear nucleus junction may be due to the time action potentials take to propagate from the habenulae perforata to the cochlear nucleus in the cat (Brown & Abbas, 1990).

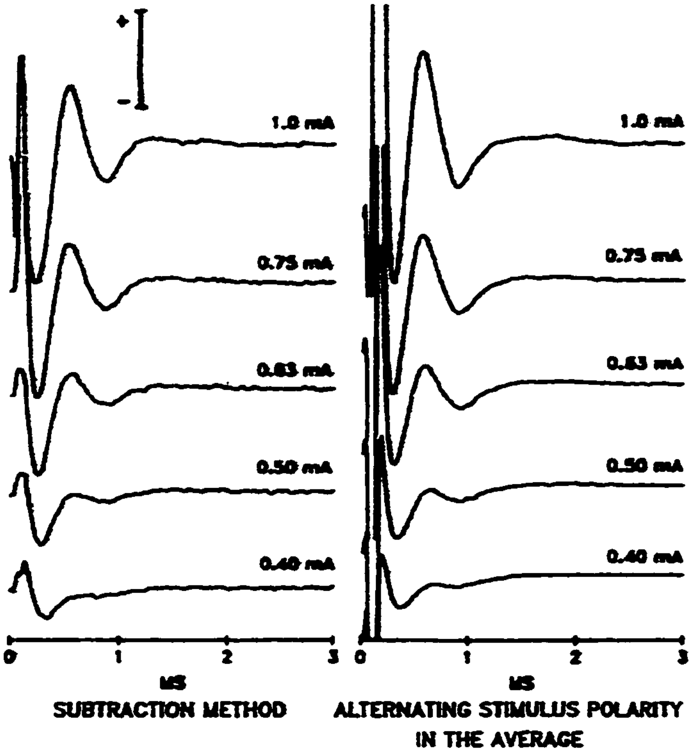

Figure 2. Intracochlear cat EAPs (Brown & Abbas, 1990, with permission, modified).

In the cat treated with the ototoxin neomycin sulfate, which ablates sensory cells within the Organ of Corti but preserves the nerve fiber dendrites, waveform morphology and latencies do not differ from those recorded from the normal cochlea. Cochlear laminectomy, which restricts stimulation to the axonal processes of auditory nerves, resulted in a more monophasic EAP, corresponding to N_0 of normal EAP morphology. These studies suggests that the EAP measure is an appropriate test of VIIIth nerve activity in both normal hearing and sensory-impaired animals. Additionally, it suggests that the EAP measure remains sensitive even if there is damage to VIIIth nerve dendrites (Stypulkowski & van den Honert, 1984).

EAP data obtained from humans is restricted to those with enough hearing loss to warrant cochlear implantation. The status of the cochlea and auditory nerve in most subjects with cochlear implants is unknown. At the least, one can assume cochlear dysfunction, both from the trauma necessitating implantation as well as electrode array insertion. The amount of neural survival and the condition of surviving neurons depends on the duration of deafness and its etiology (Shepherd & Javel, 1997). Nevertheless, waveform morphology and latency is similar across implant recording techniques. Generally, EAPs recorded from human cochlear implant subjects are biphasic. N_1 occurs at approximately 0.3 msec post stimulus onset (Abbas, 1997; Brown et al., 1998a; Brown et al., 1990; Brown et al., 1998b; Finley et al., 1997). The human EAPs are lacking the N_0 peak and triphasic waveform morphology. See Figure 3. These changes may be due to differences in morphology between the animal and human model, and the lower current amplitudes used in human data collection (Brown et al., 1990).

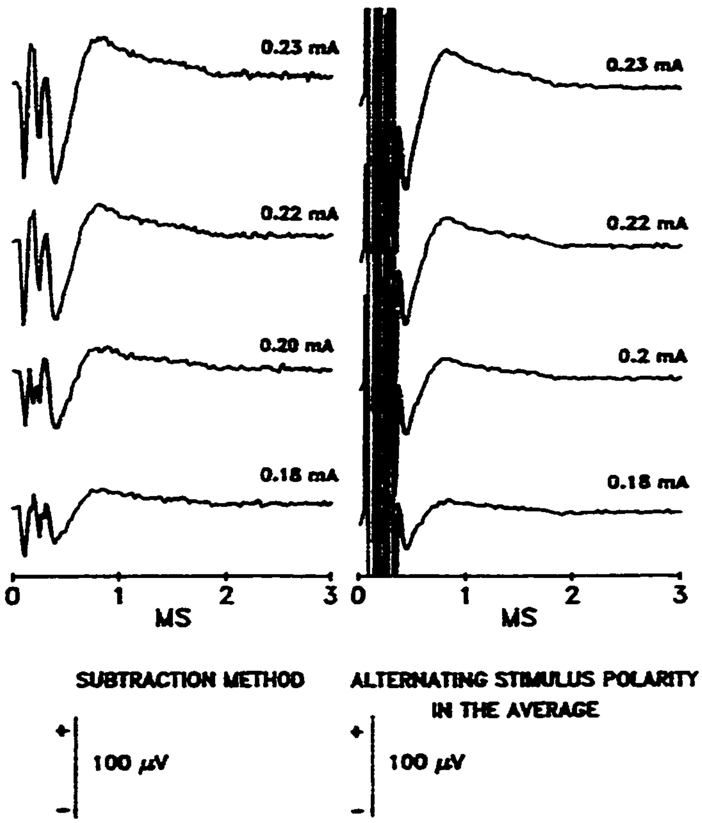

Figure 3. Intracochlear human EAPs (Brown et al., 1990, with permission, modified).

<u>Measurement of intracochlear EAP</u>

Due to the short latency of neural response to electrical stimulation, the stimulus artifact will contaminate the EAP waveform. Two methods have been developed to extract the waveform from the artifact.

One technique to eliminate stimulus artifact developed by Brown and colleagues is termed the subtraction method. The subtraction method was adapted from a procedure used in the recording of the EAP in guinea pigs (Charlet de Sauvage et al., 1983). The details of this artifact cancellation procedure are explained further in Chapter 2. In brief, a measure of the pure stimulus artifact is generated by recording the response to two electrical pulses separated by a brief inter pulse interval (IPI). The first pulse of the pair (the masker) is assumed to cause all neurons to fire. While the neurons stimulated by the high-intensity masker are in a refractory state an additional pulse (the probe) is presented.

and the response recorded. Since no neural response can be recorded while neural elements are in refractory state, this recording will contain only the stimulus artifact. The recording made from the masker and probe condition is subtracted from the response to a probe alone condition without a preceding masker. The probe alone condition will contain both the stimulus artifact and the response. The difference between the two conditions will result in the cancellation of stimulus artifact and pure EAP (Brown & Abbas, 1990; Brown et al., 1990).

This procedure relies on three assumptions. The first assumption is that neural excitation is linear, so that responses can be subtracted. The second is that the amplifier is not saturated during the recording of the probe pulse. Lastly, the subtraction method assumes that no neurons are excited by the probe pulse following the masker pulse (Brown & Abbas, 1990; Brown et al., 1990; van den Honert et al., 1997). The first assumption has been validated by the observation that the subtraction of the masker response from the masker probe condition results in a flat baseline following the derived EAP response (Finley et al., 1997). The second assumption is validated during individual recording sessions. A saturated amplifier will result in no response or "jagged" response when NRT is in high resolution mode (Abbas et al., 1999). The third assumption can be tested in animals or humans when the subject is anesthetized. An awake patient may not tolerate high masker levels. If the masker level is not high enough to excite all neural tissue, neurons not stimulated by the masker may be easier to stimulate with the following probe than they would be to a probe stimulus alone. Response to the probe pulse of the masker and probe complex, when subtracted from the response to the probe pulse alone, would result in a small amplitude EAP recording. This facilitation is a potential error in EAP recording when using the subtraction technique (Finley et al., 1997).

The second method used to record intracochlear EAP uses more traditional alternating stimulating pulse polarities to eliminate stimulus artifact during response averaging (Brown & Abbas, 1990). This method also assumes linearity of neural responses, which has been shown to be acceptable. The alternating procedure also assumes that negative-leading and positive-leading polarity stimuli are symmetric. Due to switching transients, trigger pulse pickup, or other hardware non-linearities, this assumption is frequently violated (Finley et al., 1997).

Both intracochlear EAP recording procedures have advantages and disadvantages. The subtraction method removes non-invertable components of the stimulus artifact. This advantage compensates for hardware unable to produce identical reversed-polarity pulses. It also allows the recording of EAP responses to alternating polarities. The population of neurons stimulated by positive and negative polarity pulses may have differences in magnitude, latency and waveform morphology which the subtraction method can quantify (Brown & Abbas, 1990; Finley et al., 1997). Disadvantages of the subtraction method include the consequences of violation of the third assumption. If masker levels high enough to stimulate all local neural tissue cannot be obtained, response to the probe pulse may be distorted. In addition, the subtraction method is unable to record responses to pulse durations longer than the IPI (Brown & Abbas, 1990; Finley et al., 1997).

Advantages of the alternating polarity method include the ability to recording stimulus waveforms with any pulse duration or rate. In addition, the alternating pulse polarity method requires fewer recording sweeps. The main disadvantage of the alternating pulse polarity method is that it is only able to be implemented on high-performance hardware (Brown & Abbas, 1990; Finley et al., 1997). EAPs measured using subtraction and alternating polarity methods are shown from the same animal and human subjects in Figure 2 and Figure 3, respectively.

Amplitude growth functions

The EAP is often described by the amplitude of the evoked response as a function of stimulation level. Amplitude growth functions show monotonic increase in amplitude with increasing stimulation level as shown in Figure 4. The growth function may saturate at high stimulation levels (Brown & Abbas, 1990; Charlet de Sauvage et al., 1983; Nagel, 1974; Prijs, 1980; Stypulkowski & van den Honert, 1984). When using the subtraction method for EAP collection, the level of the masker influences the amplitude of the EAP. In order to ensure that no neural response is contained in the probe condition, and thus an artificially small EAP is recorded, the masker stimulation level must be greater than the probe stimulation level (Brown & Abbas, 1990). Depending on stimulus parameters, the stimulation level at which saturation takes place is approximately 1.0 mA (Brown & Abbas, 1990). The amount of current required to saturate EAP growth functions is generally not attained in human studies due to uncomfortably loud stimulus percepts (Brown et al., 1990; Brown et al., 1998b). From EAP growth functions, EAP thresholds, maxima, and slopes are determined. These measures demonstrate great variability. EAP thresholds vary across and within subjects from approximately 0.3 mA to 0.7 mA in both human users of the Ineraid and Cochlear Corporation's CI24M device at 25 µsec/phase (Brown et al., 1998b). EAP thresholds vary from approximately 0.05 mA to 0.17 mA in human users of the Ineraid device at 100 µsec/phase (Brown et al., 1990).

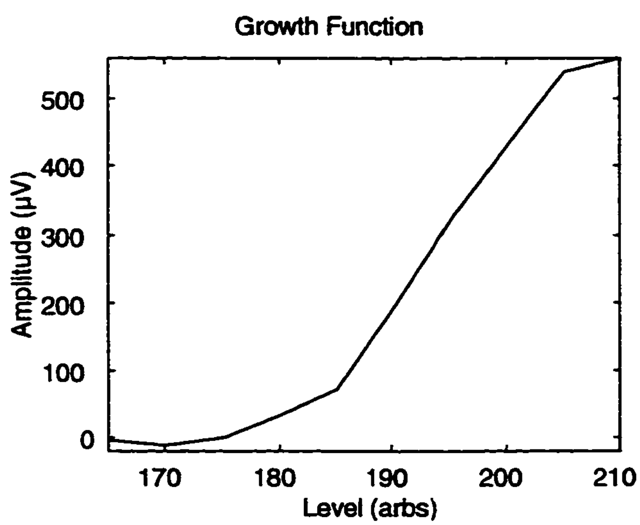

Figure 4. EAP growth function.

<u>Recovery rate functions</u>

In order for the subtraction method to result in a waveform, the IPI must be shorter than the refractory period of the stimulated neurons. If the IPI is longer than the refractory period of the stimulated neurons, the waveform will be reduced or absent, as both conditions will contain stimulation artifact and EAP. As shown in Figure 5, recovery functions are measured by increasing the IPI from durations resulting in high amplitude recordings to durations resulting in low amplitude recordings. This meters the length of the refractory period of stimulated neurons.

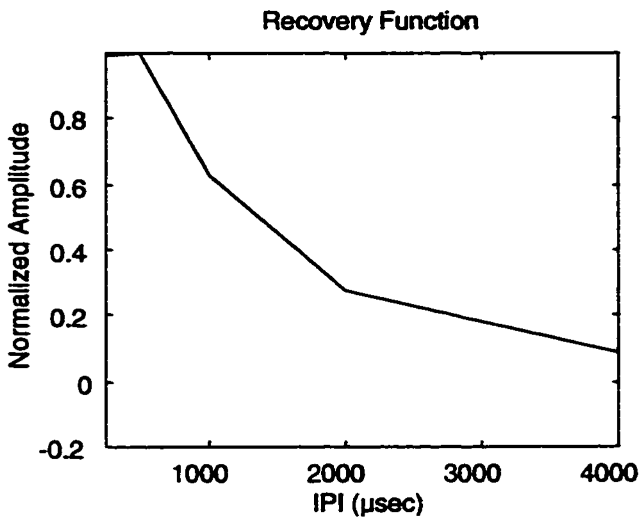

Figure 5. EAP recovery function.

Recovery functions determined using this procedure are independent of probe amplitude, when high masker levels are attained (Brown & Abbas, 1990). For masker amplitudes attainable in awake human subjects using the Ineraid cochlear implant with pulse widths of 100 μsec/phase, recovery functions were also found to be independent of probe amplitude. The slope of the normalized recovery function, when fit with a decaying exponential varied from approximately 0.1 ms^{-1} to 0.3 ms^{-1} in these studies (Brown et al., 1990). With the CI24M cochlear implant using 25 μsec/phase pulses, shorter exponential time constants are reported (Abbas et al., 1999; Brown et al., 1998b). In all experiments, variation in the decay constant exists both within and between subjects. As a function of masker intensity, the rate of recovery increases with increasing masker amplitude (Finley et al., 1997).

Applications

- Comparison to psychophysical responses

Very few studies have examined the relationship between psychophysical performance metrics and EAP waveforms in either animals or humans. In humans, this is mainly due to the small number of people who have percutaneous internal to external device links. Until NRT, EAP recordings could only be made with a percutaneous connector. The purpose of investigating the relationships between psychophysical performance and EAP waveforms is to determine the relative importance of peripheral factors vs other factors such as hearing history and cochlear implant use on implant performance potential.

Hall (1990) postulated that because the slope of the EAP was positively correlated to the number of surviving cochlear ganglia, similar correlations would be found between the slope of the EAP growth function and current amplitude just noticeable differences. This would imply that regions of greater neural survival would result in greater current amplitude resolution. However, poor correlations were found between the slope of EAP growth functions and current amplitude JNDs in the Ineraid studies (Brown et al., 1996). In the same subjects, good correlations supported the hypothesis that psychophysical detection thresholds were related to EAP thresholds at individual electrode sites (Brown et al., 1996). This result is similar to the finding that electrically evoked ABR thresholds (wave III and V) were significantly correlated to perceptual threshold in Digisonic implant users (Truy et al., 1998). Data from the Ineraid subjects also showed good correlation between EAP refractory recovery and psychophysical forward masking functions. This implies that EAP refractory functions are a valuable measure of the temporal response properties of auditory neurons (Brown et al., 1996).

Preliminary data with the CI24M's NRT implementation of EAP recordings replicate the high correlations found between EAP and psychophysical threshold and MCL measurements (Brown et al., 1998b). Due to the recent advent of this technology and the few number of sites performing these studies, more studies are not yet available.

- Measure of neural survival

The EAP measurement may be a means to determine the amount of surviving neural tissue along the length of the cochlear implant electrode array. The EAP amplitude measured from a single intracochlear electrode has been shown to be highly correlated with the total number of surviving spiral ganglion cells in animals (Hall, 1990; Shepherd & Javel, 1997). The use of EAP to measure differential spiral ganglion cell and dendritic survival with a cochlea has not been studied directly. However, the correlations found between the varying EAP measures and psychophysical responses suggest that the EAP is directly measuring the local excitability of the auditory nerve (Brown et al., 1996; Wilson et al., 1995).

- Measure of rate of recovery from refractory period

As long as the assumption that the masking pulse used in the subtraction method is of sufficient amplitude to fire all local neurons is valid, variation of the interpulse interval (IPI) between the masker and the probe allows determination of the rate of recovery from the refractory period. In general, EAP amplitudes are found to decrease as IPI values increase over 500 μsec across implant and stimulus conditions in both humans and cats. Occasionally, at IPI less than 500 μsec, reduced responses are observed (Brown & Abbas, 1990; Brown et al., 1990; Finley et al., 1997). In order to compare recovery functions across electrodes and individuals, the amplitude of the EAP is normalized to the 500 μsec IPI (Brown & Abbas, 1990; Brown et al., 1990; Brown et al., 1998b), or as percent of recovery attained (Finley et al., 1997).

The physiologic basis for differences in the recovery rates may be myelinization of auditory neurons. Studies have shown that the time constant of the EAP recovery rate is slower in mice with myelin deficiencies than it is with control mice (Zhou et al., 1995a; Zhou et al., 1995b).

- Predictor of speech test performance

The EAP measures also have been compared to implant performance. The first correlations were found using the percutaneous connector of the Ineraid implant. In this study, EAP measures from broad intracochlear regions of stimulation were quantified. The slope of the EAP input/output function was found to correlate to performance with the Iowa Sentence Test (r=0.63) and Iowa NU-6 list (r=0.69), and the magnitude of the exponential decay constant of the latency-recovery curves was found to correlate to performance with the Iowa Sentence Test (r=0.74) and Iowa NU-6 list (r=0.85) (Brown et al., 1990). A later study also found EAP to performance correlations when recording the neural responses from localized stimulation, though correlations were weaker (EAP slope r=0.25 to 0.50, EAP recovery time constant r=0.51 to 0.62) (Gantz et al., 1994). In both of these studies, the EAP recordings were made with the Ineraid cochlear implant. Results indicate that individuals whose neurons have a quick recovery time score better on speech tests. The Ineraid cochlear implant uses the Compressed Analog (CA) coding strategy, which is essentially a very high rate coding strategy. In another study, correlations were not found between performance and EAP recovery time. In this study, subjects using the percutaneous Cochlear Corporation device and the Ineraid device were pooled. Continuous Interleaved Sampling (CIS), a fast speech coding strategy, was employed in both implant models in this experiment (Finley et al., 1997).

Correlations for narrow stimulation (Gantz et al., 1994) may have been weaker than for broad stimulation (Brown et al., 1990) in that in the former case, a sub-population of neurons may have been sampled which do not have as good transmission abilities, whereas in the latter case, gross cochlear stimulation likely included the responses of apical neural populations, where neural survival is typically best. Because measuring different populations of neurons results in different strength correlations, it may be possible to optimize performance by choosing subsets of stimulating electrodes based on EAP measures in device fitting (Gantz et al., 1994). Selection of subsets of electrodes has been shown in other studies to increase performance in Cochlear Corporation's N22 device (Zwolan et al., 1997). In this study, electrode selection was based on electrode discrimination measures. Use of localized EAP measurements for electrode selection may be a means to achieve the same improvements.

- Intraoperative monitoring

The decision to pursue cochlear implantation is becoming more complex as individuals with varying degrees of residual hearing are being considered. Preoperatively, there is a need to asses gross neural excitability as well as determine if there are specific regions in the cochlea where the survival of neural tissue is greatest. Optimal use of this information in determining which ear to implant, which type of electrode array and the type of coding strategy can be important.

Data based on subject history have not well correlated with post-implant performance, though correlations were found between onset of hearing loss and speech perception scores using the implant (Gantz et al., 1994). Preoperative promontory stimulation measurements of neural response have not consistently correlated with performance with the device. Some studies report no correlation (Albu & Babighian, 1997; Ito et al., 1994), while others do (Blamey et al., 1992; Kileny et al., 1991). Intraoperative EAP waveform morphology has been found to be stable in comparison to postoperative EAP recordings with the Ineraid device (Gantz et al., 1994). Variability in intraoperative EAP measurements may correlate with performance variability. If such correlations exist, measurement of intraoperative EAP may be useful for estimation of neural survival, predicting performance, and implant fitting

Due to the extent of surgery required for implantation of any intracochlear electrode array, it is unlikely that intraoperative EAP recording will be used for the determination of which ear to implant permanently. Furthermore, insertion and removal of an electrode array before implantation with a permanent array could cause extra cochlear trauma. With a transcutaneous link, recordings could be made intraoperatively. Internal device function, neural excitability, and information valuable to initial device fitting could be assessed during surgery. Protocols to do this are in use (Ash & Shallop, 1997; Firszt &

Rotz, 1997). Some of the measurements could be made while the skin flap is being closed. This would not extend the amount of time required under anesthesia.

DYNAMIC RANGE AND LOUDNESS GROWTH

Normal hearing listeners with acoustic stimulation

In normal hearing listeners, loudness has been found to be a power function of sound amplitude (Stevens, 1955). This power law relationship has been termed "Stevens' Law". A variety of methods can be used to measure loudness growth. The method of magnitude estimation requires that the subject rate the loudness of stimuli numerically. Because the subject will attempt to be self-consistent, the responses elicited by a stimulus will depend of the responses to previous stimuli. However, in loudness perception, this bias is usually negligible (Stevens, 1955). In normal hearing listeners, only one or two judgements per stimulus is adequate (Stevens, 1971). The method of constant stimuli requires the subject to indicate if the loudness of a sound is greater, equal to or less than the loudness of a criterion stimulus. This method is influenced by bias due to the range, order and spacing of the comparison stimuli. (Stevens, 1955). Finally, the method of adjustment requires that the subject alter the amplitude of the criterion level so that the loudness matches the loudness of the stimulus (Stevens, 1955).

Implanted listeners with electric stimulation

Establishing dynamic range

Cochlear implant fitting is constrained by the capabilities of the programming software, the experience of the subject with the cochlear implant, and time limitations imposed by clinic schedules. In the clinic setting, loudness limits (the dynamic range) are ideally established on all used electrodes on the implant array at a single visit. Unlike clinician's universal acceptance of the Hughson-Westlake procedure for the determination of audiometric thresholds (Carhart & Jerger, 1959), consistent methods to determine loudness limits for cochlear implant stimulation have not been established (Skinner et al., 1995). A variety of techniques have been developed to determine the loudness range of perceptible and comfortable stimulation using the Nucleus cochlear implant systems.

Only one study has compared the efficiency and results of different techniques. In this study, procedures using the programming keyboard where single pulse trains were used yielded higher thresholds than knob procedures which used continuous pulse trains. Counted threshold procedures, which required not only detection but correct identification of the number of presentations, resulted in higher thresholds than both keyboard and knob procedures. Maximum comfortable loudness levels were also found to be influenced by stimulation presentation methods. Single pulse train methods resulted in the higher C-levels than repeated pulse train methods. Methods where C-levels were determined on all electrodes in one sweep resulted in higher C-levels than methods where T- and C-level were determined across the electrode array (Skinner et al., 1995).

Establishing loudness growth

The perception of loudness evoked with electrical stimulation in the cochlea is best studied when a single subject has access to both auditory and electrical stimulation of the cochlea. Such subjects are rare. However, in these people, perceived loudness, expressed in dBSPL in the contralateral ear, increases linearly with the amplitude of biphasic pulse trains (Eddington et al., 1978; Dorman et al., 1993). A large number of studies have been performed with cochlear implant subjects who rate the loudness of electrical stimuli without reference to acoustic hearing. Typically, loudness is measured by the use of magnitude estimation techniques where the subject is asked to assign a numerical loudness estimate between 0 and 100 in response to varying-amplitude stimuli at a single electrode site (Busby & Clark, 1997; Shannon, 1981; Shannon, 1983; Shannon, 1985; Zeng & Shannon, 1995).

Loudness has been found to increase as a function of pulse amplitude. The electric dynamic range of implant users is narrower than the acoustic dynamic range of normal hearing listeners. In response to low frequency stimulation (below 300 Hz), growth can be described as a power law function (Shannon, 1983; Shannon, 1985). At higher stimulation frequencies, loudness grows as an exponential function (Zeng & Shannon, 1994). Low frequency biphasic pulses exhibit narrower electric dynamic ranges than high frequency biphasic pulses (Shannon, 1981). Though loudness percepts increase with frequency and intensity of stimulation, loudness does not conform to an equal-charge, equal-loudness relationship (Zeng et al., 1998)

CHAPTER 2: METHODS

SUBJECTS

All adults implanted with Cochlear Corporation's CI24M cochlear implant system at the University of Washington Medical Center with at least three months of implant experience were invited to participate in the NRT study. No attempt was made to base subject selection on performance, length of deafness, or other factors. Patients met the selection criteria of the University of Washington Cochlear Implant Center and of the FDA CI24M investigational trial. Selection criteria included:

- Post-lingual onset of profound hearing loss
- Less than 40% speech perception performance using CID sentences at 70 dBSPL soundfield in the patient's best aided condition.
- Appropriate expectations

Assessing speech perception in cochlear implant users

Subjects had varying amounts of experience with the implant at the time EAP data were collected. In order to allow comparison of performance across subjects, speech perception skills were assessed at two weeks and three months post-initial stimulation. At two weeks post-initial stimulation, performance was assessed using two lists of the CUNY open-set sentence test. At three months post initial stimulation, the CNC open-set word test was used in addition to two lists of CUNY sentences.

All speech perception materials were presented at 70 dBSPL. The speaker was located one meter from the subject, positioned at 0° azimuth at ear-level. Before each session the audiometer was calibrated to each test with a 1,000 Hz calibration tone. Sound pressure level was determined with a sound pressure level meter positioned one meter from the speaker, at 0° azimuth at ear-level elevation. Measurements were made using the C weighting scale.

EXPERIMENT I: EAPS MEASURED USING NRT

EAP recordings were made using the Neural Response Telemetry software which takes advantage of Cochlear Corporation's CI24M implant two-way telemetry system. In normal use of the cochlear implant (see Figure 6 normal text), the external speech processor converts acoustic information using stimulation parameters into radio frequency (RF) pulses. The RF information is transmitted by the external coil across the skin and is received by the internal coil. The internal electronics decode the RF pulses and convert them to electrical pulses which are presented on the electrode array. To measure the EAP response using Neural Response Telemetry (see Figure 6 italic text), stimulation is controlled by a computer running NRT software and the PCI speech processor interface. After stimulation, the internal electronics codes the magnitude of the voltage measured on a specified electrode into a second set of RF pulses. These RF pulses are transmitted by the internal coil to the external coil. The speech processor then converts these signals to voltages which are averaged and analyzed by the NRT software.

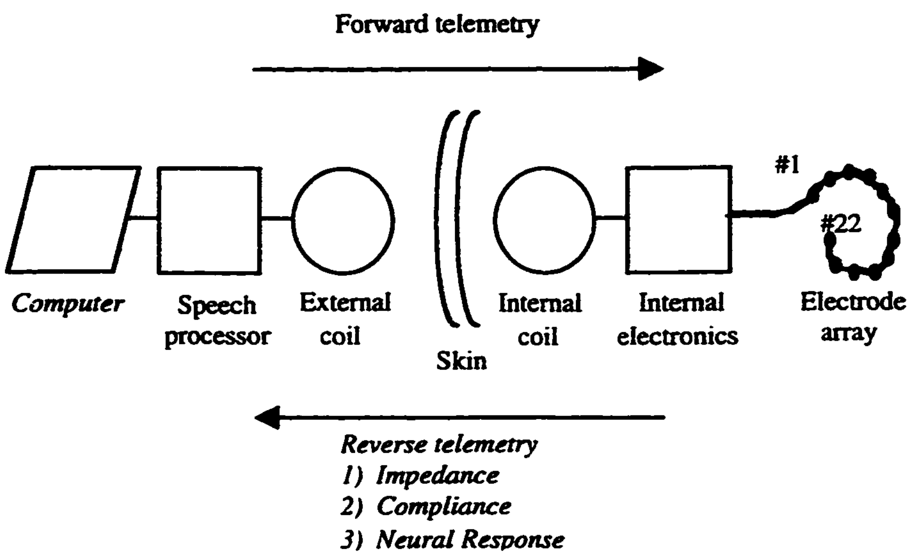

Figure 6. Device schematic.

NRT software description

NRT version 2.01 on a 166 MHz Pentium processor with 32 MB RAM was used to record EAPs. The NRT software was developed by Dillier & Lai (1998). NRT required Cochlear Corporation's IF5 interface card, PCI, SP5 speech processor, and CI24M implant for stimulation and data collection. The same SP5 speech processor was used for all EAP recording.

Stimulus description

A subtraction procedure is used to separate the large electrical artifact produced by the stimulation from the response of the neural tissue. The subtraction procedure was originally designed for use with the Ineraid cochlear implant system with the percutaneous connector (Brown et al., 1990). The subtraction procedure has been further adapted for use with the reverse telemetry capabilities of Cochlear Corporation's CI24M device (Brown et al., 1998b).

As shown in Figure 7, two stimulation conditions are used to record responses. In the first condition, a neural response is recorded to a single biphasic current pulse. This is known as the "probe-alone" condition (Figure 7a). This recording contains both the stimulus artifact as well as the EAP. In the second condition, a pair of biphasic current pulses are used. The first biphasic pulse (the "masker") is separated from the second (the "probe") by a short IPI (Figure 7b). This is known as the "masker-plus-probe" condition. When both pulses are stimulated at suprathreshold levels, only the response to the masker pulse contains the EAP, while both pulses contain the stimulus artifact. Theoretically, the probe pulse in the masker-plus-probe condition does not contain any EAP because the nerve is assumed to be in a refractory state. As shown in Figure 7c and Equation 1, the EAP is recovered by subtracting the masker-plus-probe condition from the probe-alone condition (Brown et al., 1998b).

$$EAP = Probe - (Masker + Probe) \qquad (1)$$

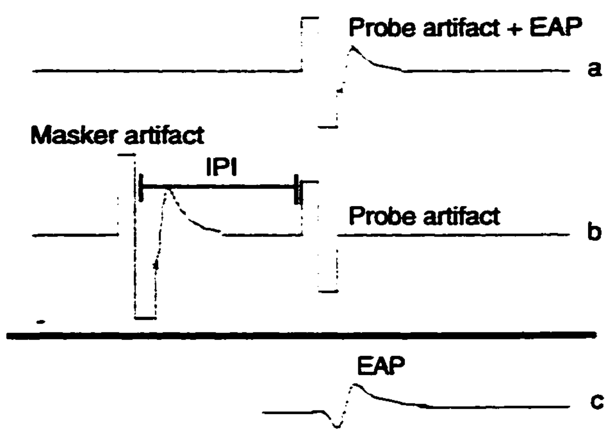

Figure 7. Subtraction method. 7a. Probe-alone condition. 7b. Masker-plus-probe condition. 7c. EAP derived from subtraction.

An additional subtraction can be incorporated into the procedure to eliminate an artifact which can arise in Cochlear Corporation's hardware implementation. The artifact is a decreasing amplitude DC potential, which is caused by a high amplitude masker pulse. The artifact is isolated by the subtraction of the response to a probe artifact from the response of a masker pulse and probe artifact. This potential is subtracted from the "masker-plus-probe" condition. The equation for the EAP response is shown in Equation 2.

$$EAP = Probe - (Masker + Probe - (Masker + Probe\ artifact - Probe\ artifact)) \quad (2)$$

Figure 8 shows an example of the subtraction method with probe artifact correction. In the upper left panel of the figure, "A" represents the response to the probe pulse in the probe-alone condition and "B" represents the response to the probe pulse in the masker plus probe condition. In the lower left panel of the figure, "C" represents the response to the masker plus probe artifact condition and "D" represents the response to the probe artifact alone. In the upper right panel, "A-B" and "C-D" represent the responses to the probe and probe artifact respectively, with the masker effects removed. The lower right panel "A-(B-(C-D))" shows the EAP recorded with the probe artifact removed from the probe waveform.

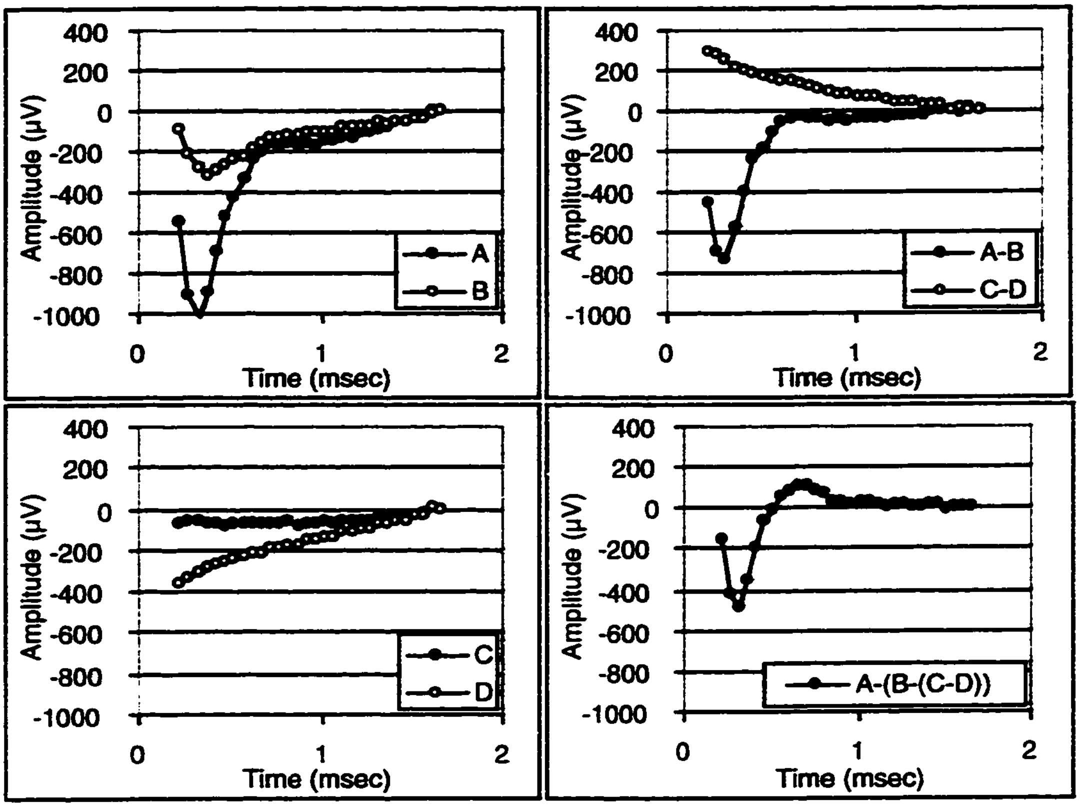

Figure 8. Subtraction method with probe artifact correction. Upper left panel shows responses to probe pulse with (A) and without (B) masker artifact. Lower left panel shows responses to probe artifact with (C) and without (D) masker artifact. Upper right panel shows probe (A-B) and probe artifact (C-D) waveforms corrected for masker artifact. Lower right panel shows EAP response to probe (A-(B-(C-D))).

The sampling rate of the CI24M implant is 10 kHz, which limits resolution to 0.1 msec. In order to increase the resolution of the waveform, a second interleaved sweep is used. The second sweep is delayed 0.05 msec. The aggregate sampling rate is then 20 kHz with a resolution of 0.05 msec. Use of this type of procedure to increase waveform resolution assumes stable stimulus presentation and neural response (Abbas, 1997).

Stimulation level amplitude was metered in "current level" units (CL), as defined by Cochlear Corporation. Current level units range from 1 – 255 arbitrary units, where the range spans 10 – 1,750 µA, increasing in 2% steps per unit. For EAP growth functions dB (re 1µA) units were used.

Parameters

The masker parameter set defines the masker pulse, and the temporal relationship between the masker and probe pulses. Masker association was not used in this study, rather masker stimulation levels remained at the maximum acceptable loudness level for both growth and recovery functions. A single masker pulse was used because measurements were not made to pulse trains in this study. A 25 μsec masker pulse width was used in all cases, because probe pulses of 25 μsec were used and all subjects' implants were programmed with 25 μsec pulse widths. For growth functions, a 500 μsec IPI was used. A IPI value of 500 μsec has been found in previous experiments to result in maximum-amplitude EAP responses (Brown et al., 1998b). For recovery functions, IPI values were varied from 250 to 6000 μsec.

The stimulation parameter set defines the path of stimulation, the shape of the stimulating pulse and the stimulation rate. Stimulating electrode progressed from the apex to the base of the cochlea on all electrodes known not to cause pain or facial stimulation to the patient. The ball electrode located under the temporalis muscle (MP1) was used as the indifferent stimulation electrode. For growth functions, current level decreased from the level of the masker. For recovery functions, current level was set 5 – 10 units below masker level. Stimulation probe pulses of 25 μsec were used because 25 μsec masker pulse width were used in all cases all subjects' implants were programmed with 25 μsec pulse widths. Stimuli were presented at the NRT system's maximum rate of 80 Hz.

The recording parameter set defines the recording electrodes, amplifier gain and delay between stimulation and recording. Active recording electrode was offset two electrodes in the apical direction (approximately 1.5 mm) from the active stimulating electrode. For example, if electrode 1 was stimulating, the EAP was recorded from electrode 3. For this configuration, EAPs can be obtained from a maximum of 20 electrodes. The electrode located on the casing of the internal receiver (MP2) was used as the indifferent recording electrode. A gain setting of 60 dB was used in all cases. Delay setting was adjusted for optimal waveform recording. If the waveform appeared distorted due to saturation or was absent, delay was increased. If N_1 was not visible, delay was decreased. Delay was adjusted so that recording amplifier was not saturated, and early waveform morphology was observed.

Averaging parameters determine computer analysis performed by the NRT software. 100 sweeps were averaged in this study. NRT recordings were made in high resolution mode, explained previously, which invokes an interpolation algorithm to double resolution by interleaving two recording sweeps. An artifact reject value of 90% was used, which excludes input outside 90% of the 0-10 V input range (Dillier & Lai, 1998).

To assess waveform stability, EAPs were recorded during two separate sessions. During the first session, growth functions were measured using 5 current level steps at 7-10 different levels. This established the range between good responses and no responses. In the second session, the 10 levels were replicated, and 10 additional measurements were made near the EAP visual detection threshold with a step size of 1 current level. During the first session, recovery functions were measured with at least five IPI values: 250, 500, 1000, 2000 and 4000 µsec. During the second session, recovery functions were measured for 10 IPI values: 250, 375, 500, 750, 1000, 1500, 2000, 3000, 4000 and 6000 µsec.

Response description

The NRT software is capable of automatically scoring the temporal position of N_1 and P_1, and plotting growth and recovery functions. However, the scoring algorithm used simply selects the lowest point in the waveform as N_1 and the highest point as P_1, without regard to absolute temporal position. Subsequently, the EAP amplitude derived from waveforms not containing a response, or waveforms with low amplitude may be exaggerated. Therefore, response waveforms were scored and analyzed using custom code written in the MATLAB programming environment (Student edition of MATLAB version 5 for the Power Macintosh), as seen in Figure 9. Because the temporal relationship of N_1 and P_1 are assumed not to change for each growth or recovery function, their temporal position was established based on visual inspection of waveforms measured in the growth and recovery functions.

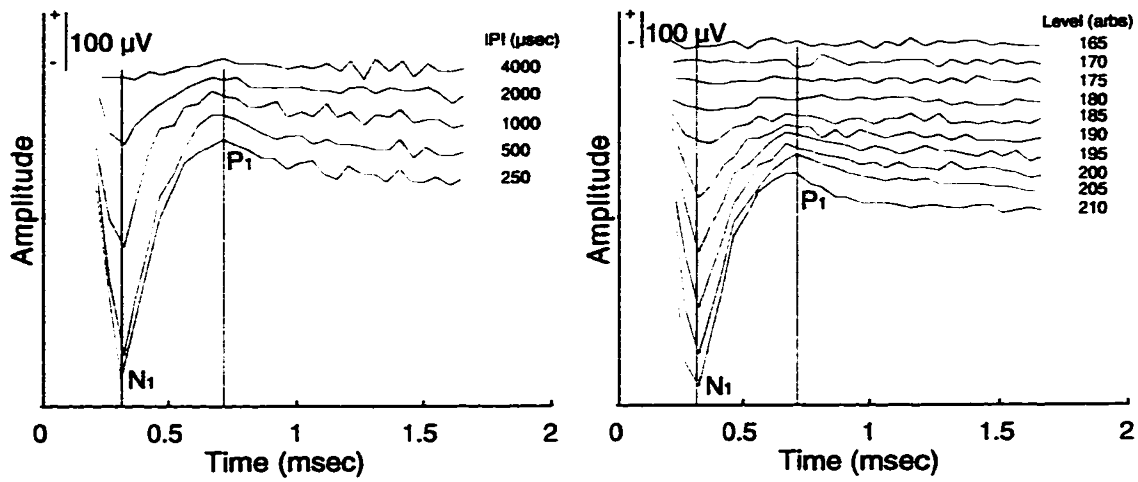

Figure 9. Examples of EAP recovery (left panel) and growth (right panel) waveforms and latency.

The EAP waveforms recorded in high resolution mode consist of two separate sweeps superimposed. Due to effects of recording delay, composite waveforms may have different DC offsets, resulting in a "jagged" waveform morphology (Abbas et al., 1999). Both the NRT software and custom MATLAB code used in this study correct for this shift by subtracting the average difference between sweeps from the higher amplitude sweep.

EAP amplitude was determined by the difference in voltage reading between N_1 and P_1. A linear fit was applied to the growth function data to determine threshold and slope. Upper and lower limits of the linear fit were determined by visual inspection to exclude saturated and sub-threshold responses. An exponential decay function was also fit to recovery functions normalized with respect to 500 μsec IPI to determine the time constant of decay. See Equation 3.

$$\textit{Time constant} = -\ln(\textit{Normalized amplitude}) / \textit{Interpulse interval} \qquad (3)$$

The upper limit of the exponential fit was determined by visual inspection to exclude low amplitude responses to IPI values below 500 μsec. Data resulting from poor fits were eliminated by visual inspection. Examples of growth and recovery functions with their fits are shown in Figure 10.

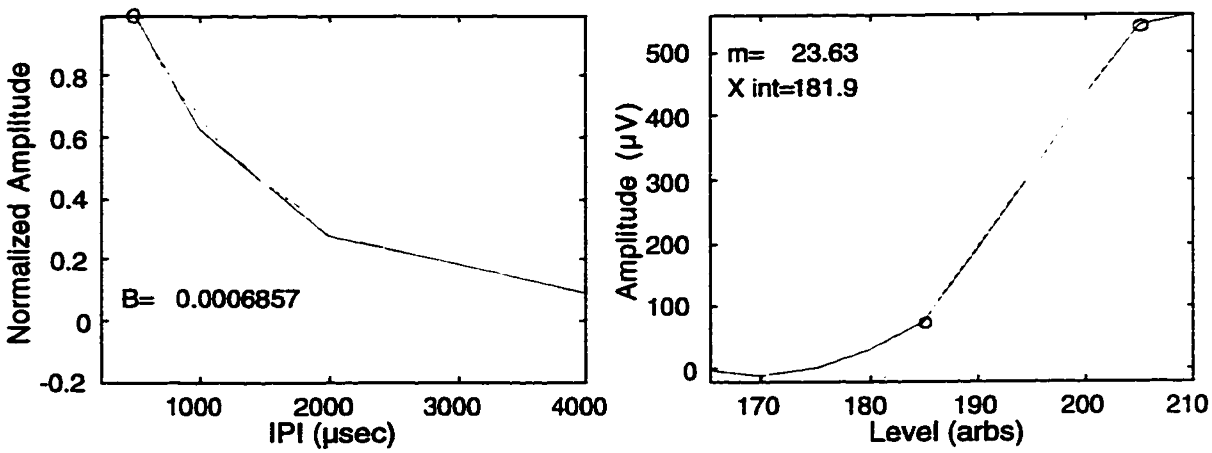

Figure 10. Example EAP recovery function with exponential decaying fit (left panel) and growth function with linear fit (right panel).

For each session, the EAP visual detection threshold, the zero intercept and slope of the linear fit to the growth function, and the decay constant of the exponential fit to the recovery function were derived from the waveforms at each electrode site. In addition, the electrode impedance was recorded at each electrode site in common ground electrode configuration.

EXPERIMENT II: LOUDNESS PSYCHOPHYSICS FOR DEVICE FITTING AND LOUDNESS GROWTH

The software used to deliver stimuli for psychophysical loudness judgements was DPS version 7 release 110.00B8 from Cochlear Corporation. Psychophysical measurements were performed at a pulse rate of 250 Hz, the frequency of stimulation of all implants using the SPEAK coding strategy. Psychophysics were also performed at 80 Hz, the rate of EAP recording. The stimuli were presented with a duty cycle of 100 msec. Pulse widths of positive and negative components of the biphasic pulse were 25 μsec/phase. Stimulating electrode progressed from the apex to the base of the cochlea on all electrodes known not to cause pain or facial stimulation to the patient. The ball electrode located under the temporalis muscle (MP1) was used as the indifferent stimulation electrode.

Repeated loudness judgements with knob

Loudness limits were established at the first session prior to EAPs. The techniques used to determine loudness levels in this experiment were similar to clinical methods used to establish "first hearing" and "maximum comfortable loudness" levels. "T-level" refers to "first hearing", and "C-level" refers to "maximum comfortable loudness". Loudness levels were obtained at least three months post-initial stimulation. Patients had established T- and C-levels at least six times prior to data collection.

Loudness levels were established with a procedure modified from the ascending loudness judgements with knob (ALJK) (Skinner et al., 1995). The procedure was modified so that loudness levels of "first hearing" and "maximum comfortable loudness" were established twice. A knob sensitivity of "medium" was used for all subjects. Based on the clinician's judgement of patient competency, either the patient or the clinician was in control of the knob.

The patient was instructed to report when s/he was "first hearing" stimulation as the current amplitude was increased. "First hearing" was further defined if necessary as the softest level where the patient was sure there was stimulation. Upon pushing the button on the control knob housing, stimulus amplitude was reduced 20% and the patient was instructed to re-establish "first hearing". If the second measurement differed from the first by less than 3 units, the first level established was accepted as T-level. If the second measurement differed from the first by more than 3 units, the patient was re-instructed, the measurement was repeated until the difference was less than 3 units and the last measurement established was accepted as the T-level.

As current levels were increased beyond T-level, the patient was instructed to report when stimulation reached "maximum comfortable loudness". The patient was then instructed to increase stimulation slightly to an uncomfortable level, and then back down to "maximum comfortable loudness". If the second measurement differed from the first by more than 3 units, the patient was re-instructed, stimulation was decreased, and both the ascending and descending measures of C-level were repeated. The last measurement was accepted as C-level upon pushing the button on the control knob housing.

Loudness levels were established on all electrodes, except for those deactivated due to impedance, non-compliance, facial stimulation, or painful percept. If facial stimulation or painful percepts were encountered during current level increase, stimulation was stopped immediately and higher subjective loudness levels on that electrode were not evaluated.

The psychophysical dynamic range was calculated with Equation 4.

$$Dynamic\ range = C - T \tag{4}$$

The T- and C-level and dynamic range were determined for stimulation rates of 250 Hz and 80 Hz at each electrode site.

Magnitude estimation

At the second session, a magnitude estimation technique was used to assess loudness growth between T- and C-levels established during the first session. Seven evenly spaced loudness levels were presented twice per electrode in random order. Stimulation levels included the subject's T- and C-levels. Subjects were instructed to rate the loudness of the presented stimuli with a number between 1 and 100, where one corresponded to their perception of "first hearing" and 100 corresponded to their perception of "maximum comfortable loudness". Magnitude estimation was completed for stimulation rates of 250 Hz and 80 Hz. For magnitude estimation loudness growth functions, dB (re 1μA) units were used.

CHAPTER 3: RESULTS

SUBJECTS

Descriptions

Twelve patients with three or more months of experience with the Nucleus CI24M cochlear implant (as of August, 1998) participated in this study. All patients were followed at the University of Washington Medical Center. As seen in Table 1, subjects represented a wide range of age (mean=52 years), age of onset of deafness (mean=25 years), and duration of pre-implant profound hearing loss (mean=17 years). Hearing loss etiology and progression characteristics were heterogeneous. All subjects were post-lingually deafened, as per requirements of the FDA clinical trial regulating CI24M candidacy.

Table 1: Subject descriptions.

Subject	**Age (years)**	**Age of onset of hearing loss (years)**	**Duration of pre-implant profound hearing loss (years)**	**Etiology**	**Onset**
1	48	5	26	Familial	Progressive
2	44	42	0.42	Ototoxin	Sudden
3	82	63	17	Ototoxin	Sudden
4	60	25	13	Familial	Progressive
5	48	0	34	Usher's	Progressive
6	47	26	20	Unknown	Progressive
7	59	59	0.17	Unknown	Sudden
8	66	25	10	Otosclerosis	Progressive
10	37	7	30	Unknown	Progressive
12	50	16	10	Unknown	Progressive
13	23	4	19	Meningitis	Sudden
15	62	35	27	Unknown	Progressive
mean (std dev)	*52 (15)*	*25 (21)*	*17 (11)*		

Performance

Candidacy for implantation with CI24M device during FDA trials required 40% or worse discrimination on CUNY sentence tests presented in quiet in the subject's best aided condition. Mean pre-implant performance was 4% (range 0% - 19%). Two weeks post stimulation mean performance was 39% (range 0% - 96%). Three month post stimulation mean performance was 56% (range 5% - 98%). See Table 2. Subjectively, all subjects deem themselves successful cochlear implant users and believe that they are better off with the implant than they were without it.

Table 2: Speech perception performance for CUNY sentences and CNC words for individual subjects.

Subject	**CUNY pre-implant**	**CUNY at 2 weeks**	**CUNY at 3 months**	**CNC words at 3 months**	**CNC phonemes at 3 months**
1	19%	14%	48%	22%	50%
2	0%	96%	95%	52%	69%
3	0%	6%	38%	8%	20%
4	0%	78%	82%	14%	45%
5	8%	27%	57%	6%	35%
6	0%	8%	20%	4%	19%
7	1%	92%	98%	82%	91%
8	0%	60%	94%	34%	59%
10	12%	2%	34%	10%	35%
12	12%	8%	11%	2%	15%
13	0%	0%	5%	8%	24%
15	0%	72%	87%	32%	55%
median	*0%*	*21%*	*53%*	*12%*	*40%*

EXPERIMENT I. EAPS MEASURED USING NRT

Sessions were on average separated by 16 days. There were no statistically significant effects of session on EAP growth ($p=.483$), recovery ($p=.415$), or threshold ($p=.074$)

using two-tailed bivariate correlations. Also, no session effects were discernable using visual inspection of EAP waveform, growth and recovery functions.

For 11 of the 12 subjects, average masker levels exceeded 250 Hz C-levels. For 8 of the 12 subjects, average masker levels exceeded 80 Hz C-levels. C-levels measured for 80 Hz and 250 Hz pulse rates and stimulus masker levels used to measure EAPs are shown in Table 3.

Table 3: NRT masker level compared to 80 Hz and 250 Hz pulse rate C-levels for individual subjects.

Subject	Days between sessions	80 Hz C-level	250 Hz C-level	Masker level
1	5	180	177	219
2	13	217	205	212
3	N/A	203	197	229
4	7	231	224	219
5	8	182	178	208
6	63	187	187	215
7	12	248	226	228
8	35	219	214	240
10	16	205	194	211
12	9	216	205	220
13	7	218	213	223
15	9	227	223	227
mean (std dev)	*17 (17)*	*211 (21)*	*204 (17)*	*221 (9)*

Waveform morphology

In general, EAP waveforms were characterized by a negative (N_1) followed by a positive peak (P_1). Figure 11 shows selected EAP waveforms from four subjects. Each waveform represents a high-amplitude EAP response from the subject. The upper left panel of the figure shows a typical EAP waveform, measured from subject 12, electrode 13. The upper right panel waveform has a positive peak occurring between N_1 and P_1, measured from subject two, electrode 14. Similar waveform morphologies were also found in subjects seven and 12. The additional peaks were observed from recording on the electrodes placed in the apical region of the cochlea from these subjects. The lower left panel shows a relatively low amplitude EAP response, measured from subject 8, electrode 13. The lower right panel exhibits an EAP waveform where N_1 is poorly defined due to amplifier saturation at shorter delay values, measured from subject 13, electrode 4.

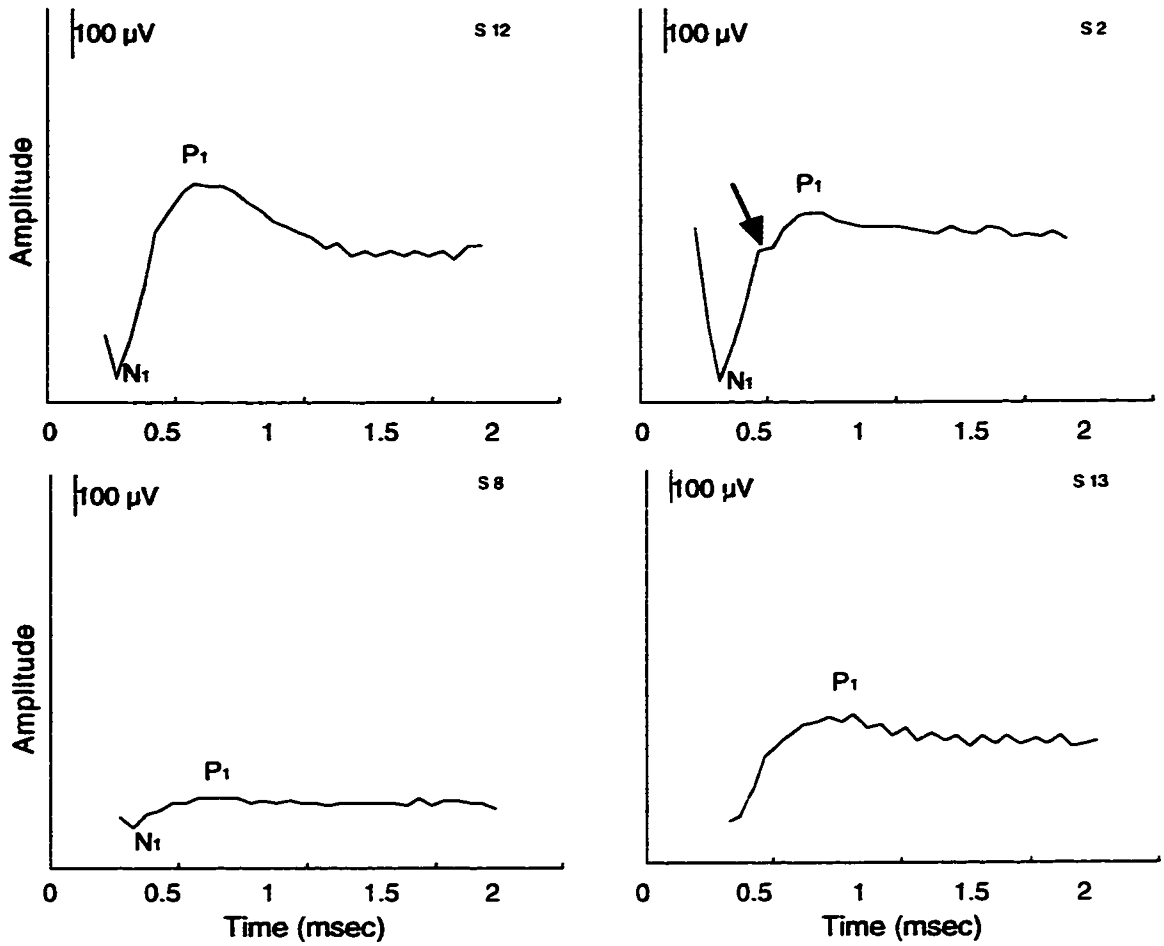

Figure 11. Example EAP waveforms. Upper left panel depicts a clear high-amplitude EAP. Upper right panel depicts an EAP waveform with an additional peak between N_1 and P_1. Lower left panel depicts a low-amplitude EAP waveform. Lower right panel depicts a waveform with a poorly defined N_1 due to amplifier saturation at shorter recording delay values. Vertical bar in each panel indicates 100 µV amplitude.

The temporal resolution of the recording system is 0.05 msec. The latency of N_1 did not change by more than 0.05 msec between recording sessions or within a session between recordings of growth and recovery functions. In two cases (subject 10 and 4) the average P_1 latency differed between sessions by more than 0.05 msec. In one case (subject 4) the average P_1 latency differed between growth and recovery family of curves by more than 0.05 msec.

EAP growth functions

When measuring the latencies of N_1 and P_1 for the family of curves which comprised the growth functions, N_1 and P_1 occurred at 0.30 and 0.68, msec respectively (standard deviations 0.04 and 0.11, msec respectively). The maximum amplitude of the growth function is not a relevant measure because in many cases, higher amplitude responses could be elicited by higher stimulation levels if they had been tested.

Across subjects, growth functions exhibited a subthreshold region, a region of linear growth, and often a reduction of response at the highest probe stimulation levels. The reduction of response amplitude occurred when the probe amplitude was near the masker amplitude.

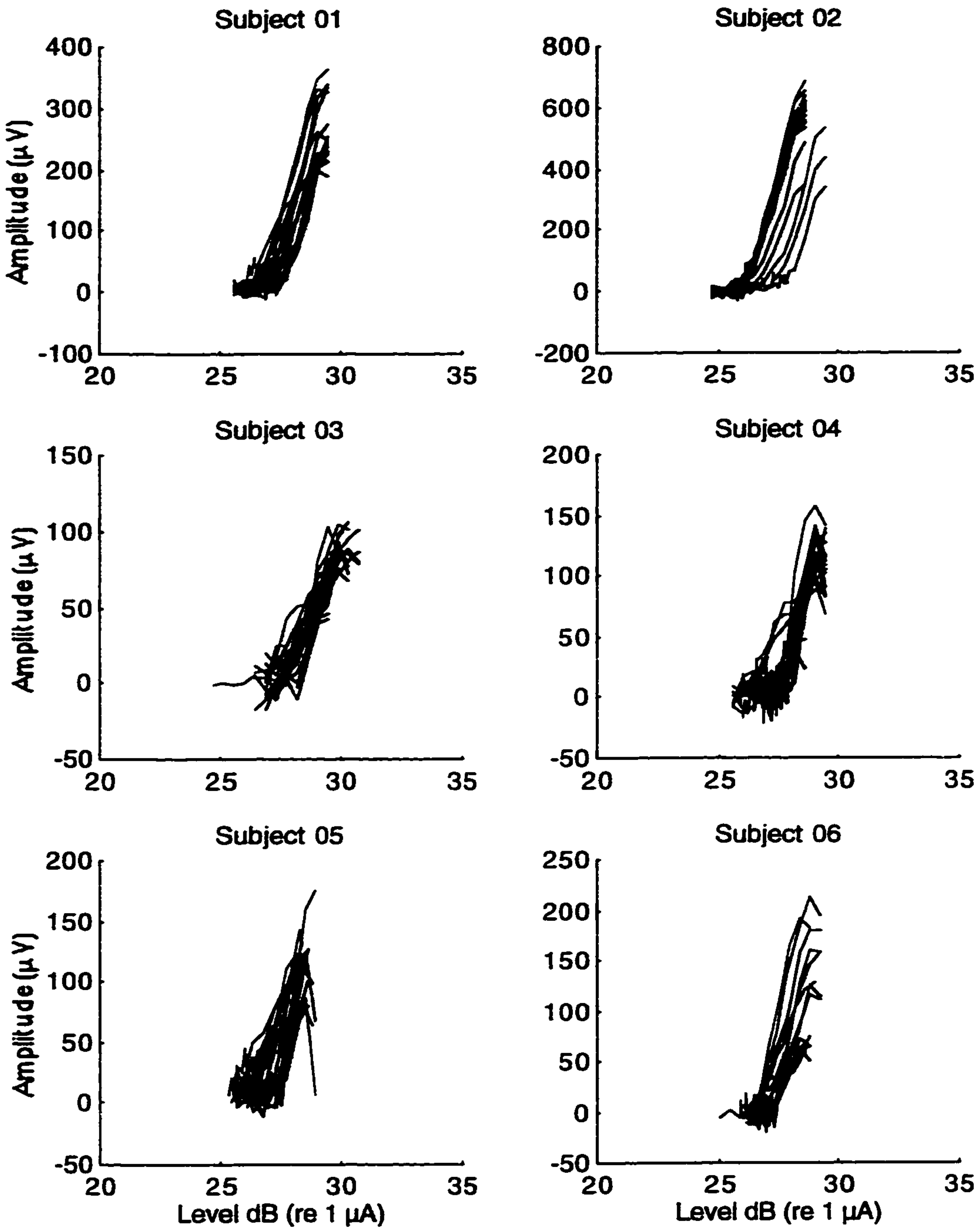

Figure 12. EAP growth functions from each stimulating electrode. Panels represent subjects 1-6.

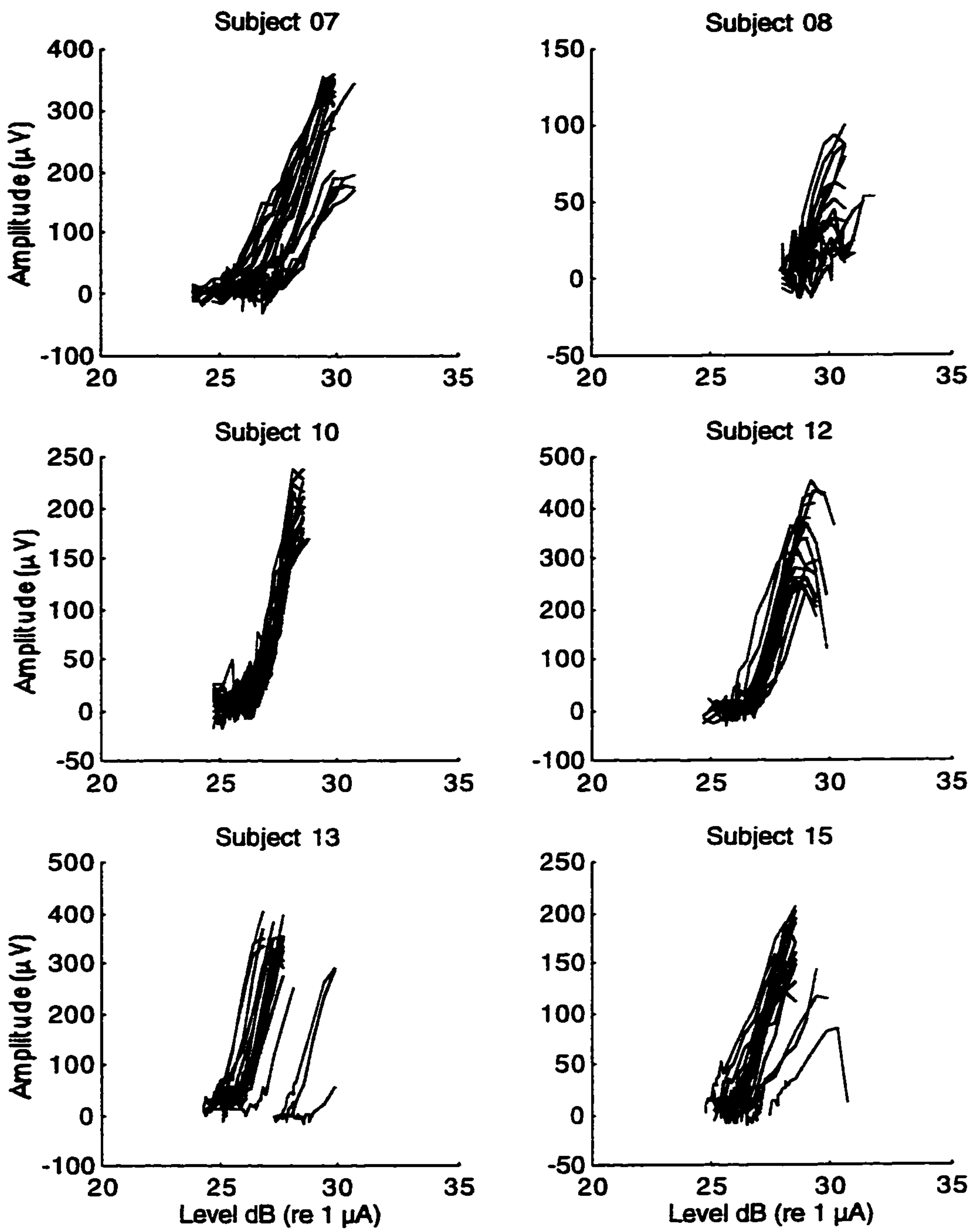

Figure 13. Same as Figure 12 except for subjects 7-15.

EAP recovery functions

EAP recovery functions are characterized by exponentially decreasing amplitude with increasing IPI values. Frequently, at short IPIs (~250 μsec), the EAP amplitude is smaller than the response for 500 μsec IPIs. For this reason, such data points were removed from the exponential fit.

EAP recovery functions were recorded on each active electrode. Due to poor exponential fits to the recovery functions, some decay constants were eliminated from the analysis. Criteria for exclusion were based on visual inspection of the quality of the fit. Table 4 lists the recovery functions eliminated. Figure 14 shows examples of recovery functions eliminated from analysis.

Table 4. Recovery functions removed from analysis.

Subject	Session	Electrode number
3	1	1, 2, 3, 4, 5, 6, 7, 8, 16, 18
4	1	1, 11, 16
	2	1, 3, 5, 6, 7, 12, 14, 16
5	2	19
6	1	8, 15
	2	6, 19
7	1	2, 13, 14, 20
	2	17, 19
8	1	3, 4, 6, 7, 11
	2	1, 2, 3, 5, 7, 11, 12
12	1	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13
	2	1, 2, 3, 9, 11, 14
13	2	3, 4, 9, 12
15	1	1, 2, 3, 5, 11, 13
	2	1, 6, 7, 8, 9, 10, 11, 15

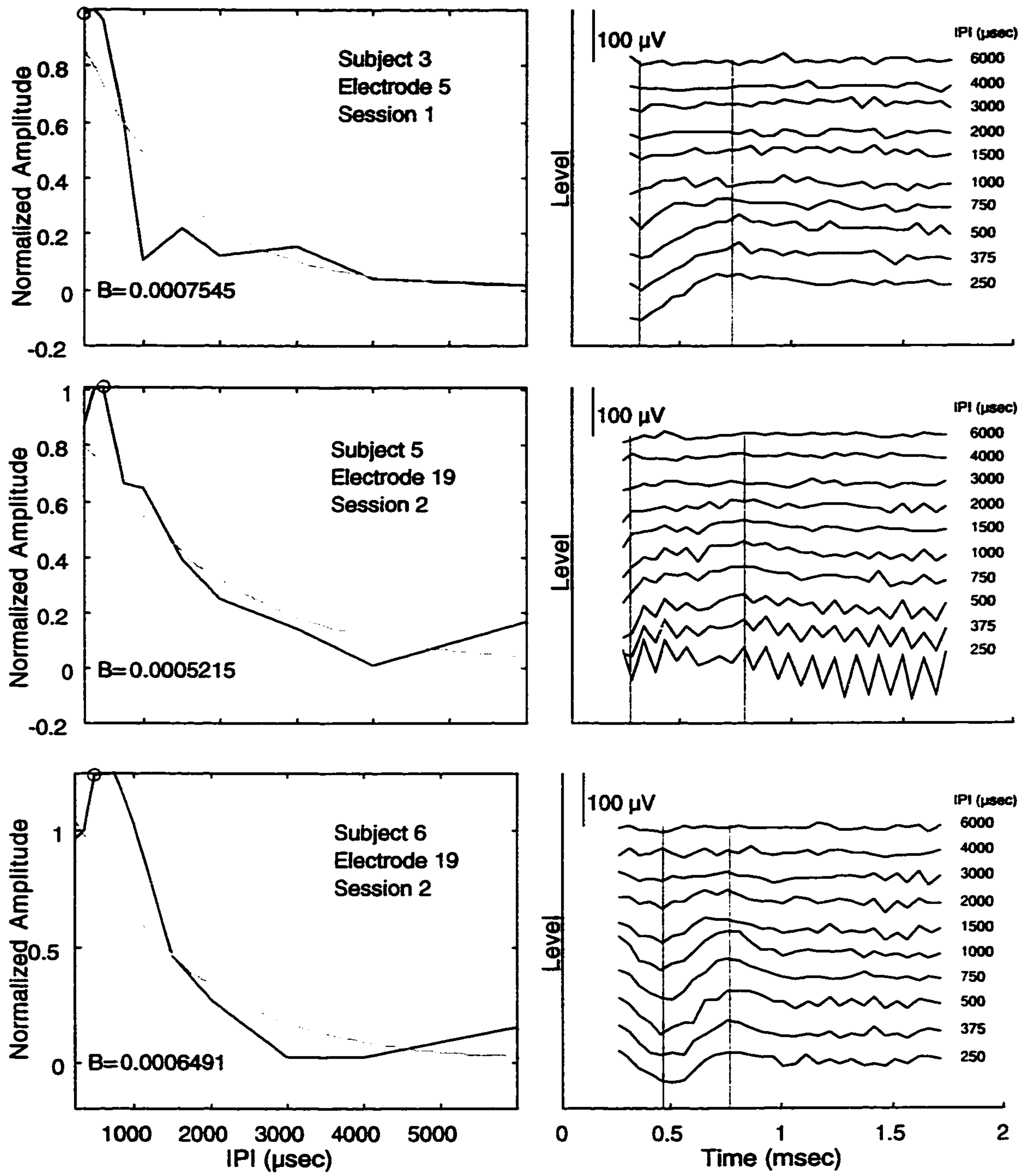

Figure 14. Examples of recovery functions removed from analysis.

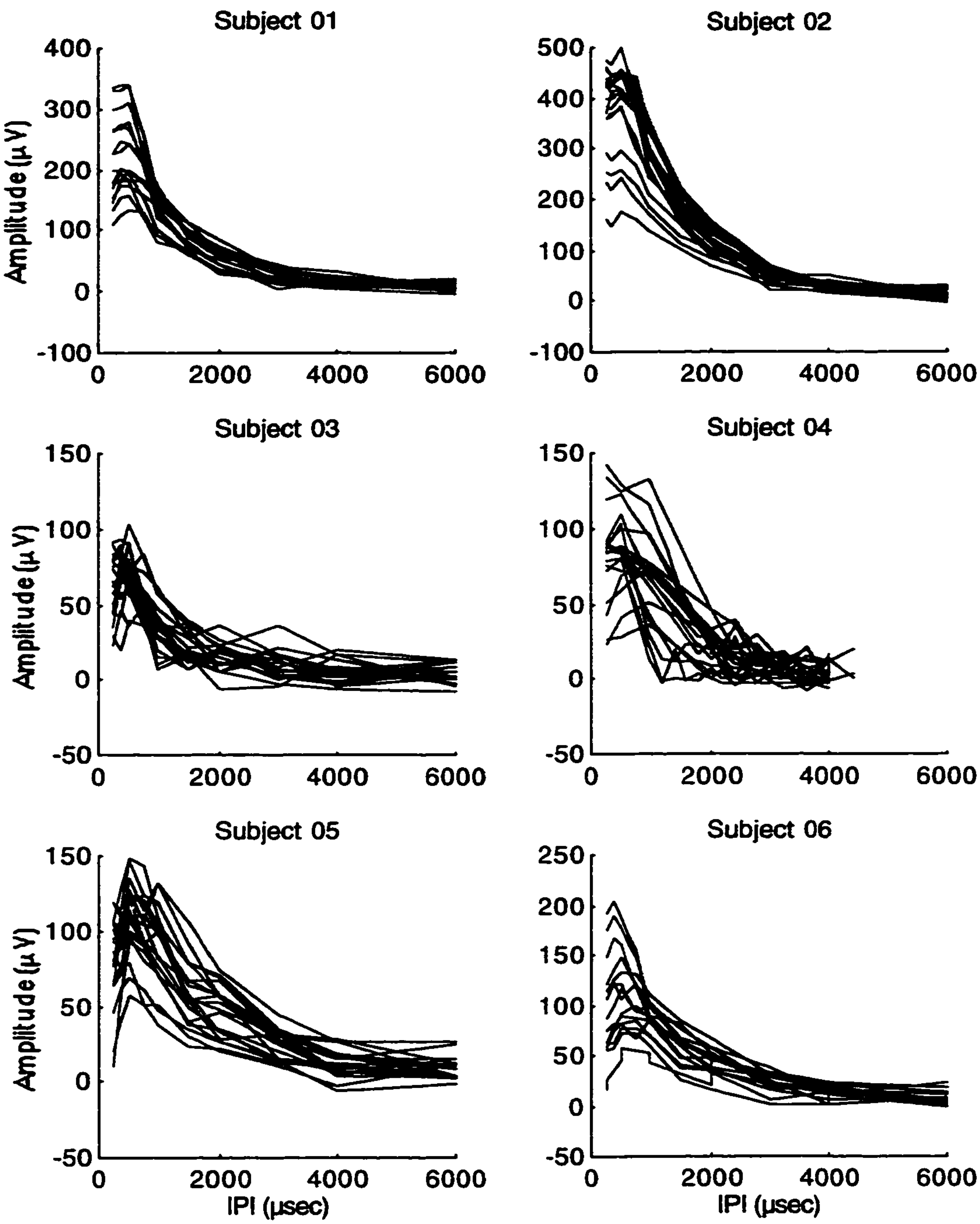

Figure 15. EAP recovery functions from each stimulating electrode. Panels represent subjects 1-6.

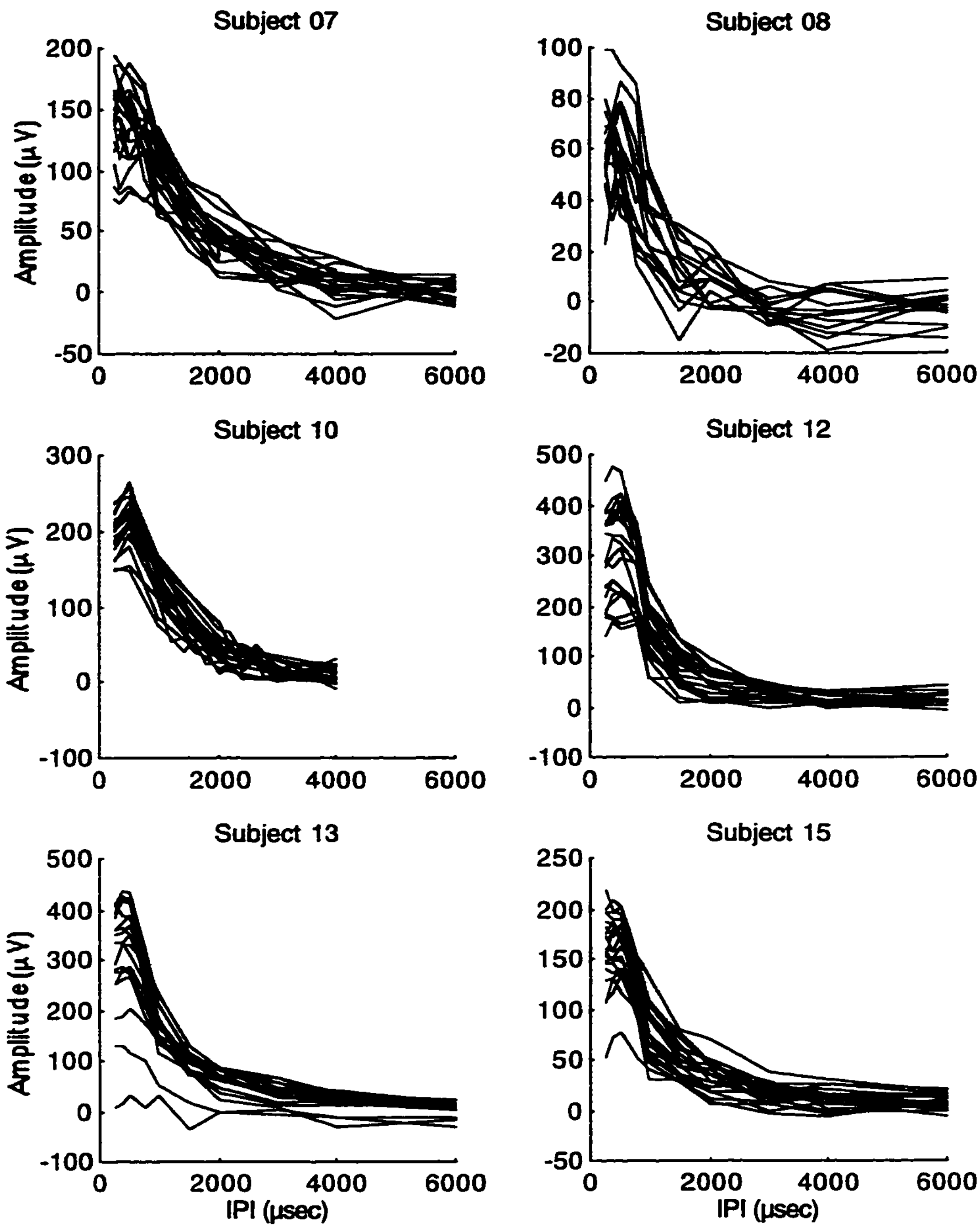

Figure 16. Same as Figure 15 except for subjects 7-15.

Adverse reactions

Immediately following EAP recording sessions, three subjects (1, 5, and 6) reported fullness and buzzing sensations. In each case, these perceptions lessened dramatically within approximately 10 minutes and had completely abated by the next morning. The three subjects who noted these sensations had the lowest average C-levels. Their C-levels were more than one standard deviation below average.

Two subjects (3 and 8) noted dizziness the morning following an EAP session. Both subjects experienced more dizziness than other subjects after surgery and during use of the implant. Subject 3 chose not to participate in a second session because of the dizziness sensation.

EAP threshold

<u>Relationships across subjects</u>

When data were analyzed across subjects, significant correlations were found between T-levels and EAP thresholds measured at both 80 Hz and 250 Hz using two-tailed bivariate correlations. Because correlations were slightly better for the visual threshold detection technique (Table 5) than for the linear fit-based technique (Table 6), and the visual threshold detection technique does not rely on the linear growth assumption, the visual detection EAP thresholds were used throughout the analysis.

Table 5. Visual threshold correlation coefficients.

Session	**80 Hz**		**250 Hz**	
	T-level r (p)	**C-level** r (p)	**T-level** r (p)	**C-level** r (p)
1	.7642 (<.001)	.0027 (.968)	.5915 (<.001)	.0665 (.325)
2	.7729 (<.001)	.0313 (.658)	.5967 (<.001)	.0905 (.199)

Table 6. Linear fit threshold correlation coefficients.

Session	80 Hz		250 Hz	
	T-level r (p)	C-level r (p)	T-level r (p)	C-level r (p)
1	.7141 (<.001)	.0098 (.885)	.5263 (<.001)	.0659 (.329)
2	.7690 (<.001)	.0377 (.595)	.5727 (<.001)	.0876 (.214)

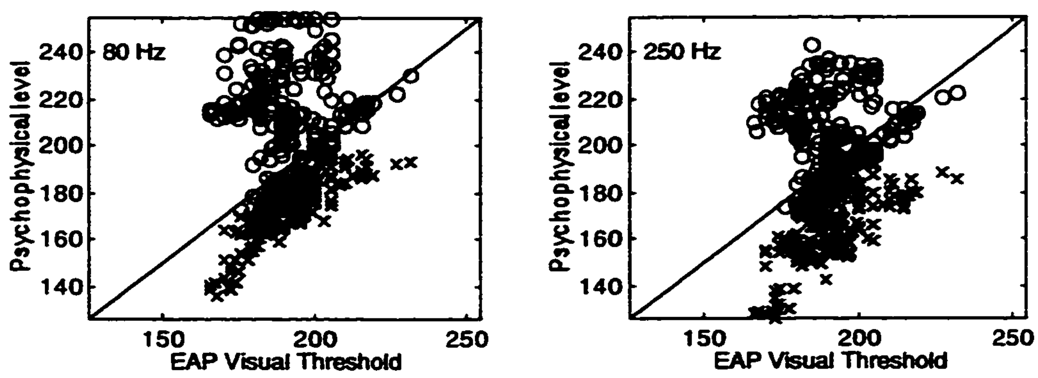

Figure 17. T- and C-level psychophysics as a function of EAP visual threshold. The left and right panels depict 80 and 250 Hz psychophysics respectively. "X" represents T-levels. "O" represents C-levels.

Relationships across electrodes

Subjects who experienced sudden hearing loss had EAP thresholds between their T- and C-levels. Subjects whose deafness was progressive had EAP thresholds near their T-levels, C-levels or between their T- and C-levels.

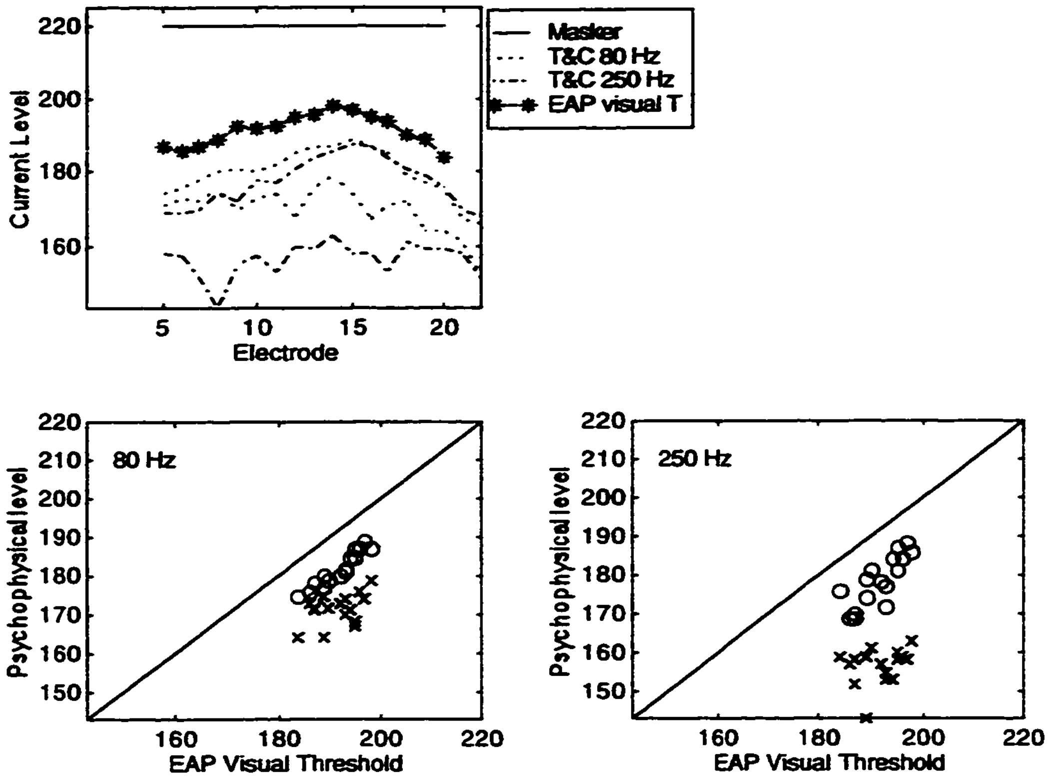

Figure 18. Subject 1. In the upper left figure, EAP threshold is plotted with T- and C-levels at 80 Hz and 250 Hz. Correlation plots are displayed in the lower row of figures. The lower left and right figures depict 80 and 250 Hz psychophysics respectively. "X" represents T-levels. "O" represents C-levels.

Table 7. Correlations between EAP visual threshold and psychophysical levels for subject 1.

Session	80 Hz		250 Hz	
	T-level r (p)	**C-level** r (p)	**T-level** r (p)	**C-level** r (p)
1	.3168 (.232)	.9345 (<.001)	.1449 (.592)	.7455 (.001)
2	.4318 (.095)	.9475 (<.001)	.2545 (.342)	.7947 (<.001)

EAP thresholds were above both the T- and C-levels for subject 1. EAP thresholds were highly correlated with C-levels. The correlation between EAP threshold and C-levels improved in the second session. The masker level was constant for each electrode. The flat masker level profile was not reflected in the EAP threshold profile.

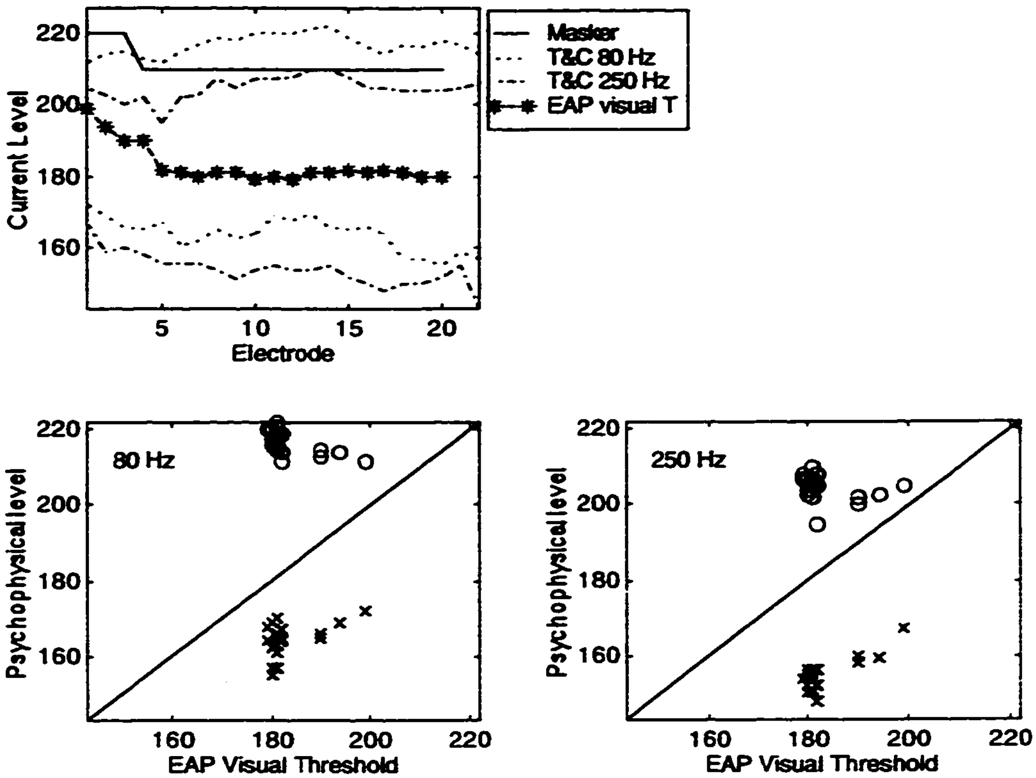

Figure 19. Same as Figure 18 except for subject 2.

Table 8. Correlations between EAP visual threshold and psychophysical levels for subject 2.

Session	80 Hz		250 Hz	
	T-level r (p)	**C-level** r (p)	**T-level** r (p)	**C-level** r (p)
1	.5503 (.012)	-.4643 (.039)	.6556 (.002)	-.1404 (.555)
2	.4750 (.034)	-.6361 (.003)	.8021 (<.001)	-.2736 (.243)

EAP thresholds were between the T- and C-levels for subject 2. EAP thresholds were correlated with T-levels at 250 Hz. The correlation to 250 Hz T-level improved for the second session. The masker level profile is flat with the exception of a decrease in level between electrodes 3 and 4. This profile is similar to the EAP threshold profile, exhibiting a decrease in level in the basal 5 electrodes, and flat on more apical electrodes.

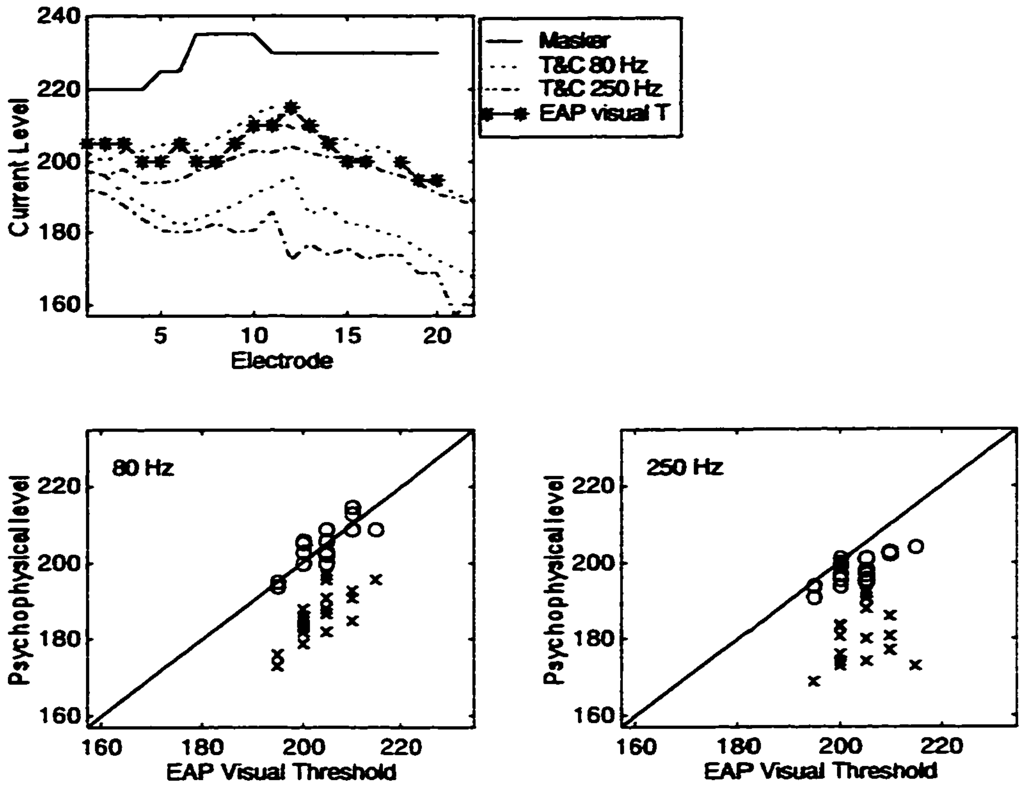

Figure 20. Same as Figure 18 except for subject 3.

Table 9. Correlations between EAP visual threshold and psychophysical levels for subject 3.

Session	**80 Hz**		**250 Hz**	
	T-level r (p)	**C-level** r (p)	**T-level** r (p)	**C-level** r (p)
1	.7497 (<.001)	.7666 (<.001)	.3062 (.202)	-.2870 (.234)

EAP thresholds, when established visually, were approximately the same as 80 Hz C-levels and above the C-levels at 250 Hz for subject 3. Linear fit-based thresholds were between 80 Hz T- and C-levels. Subject 3 was not seen for second session which typically established lower threshold measures due to smaller step sizes in growth function. EAP thresholds were significantly correlated with T- and C-levels at 80 Hz, but not at 250 Hz. The masker level profile was not similar to the EAP threshold profile.

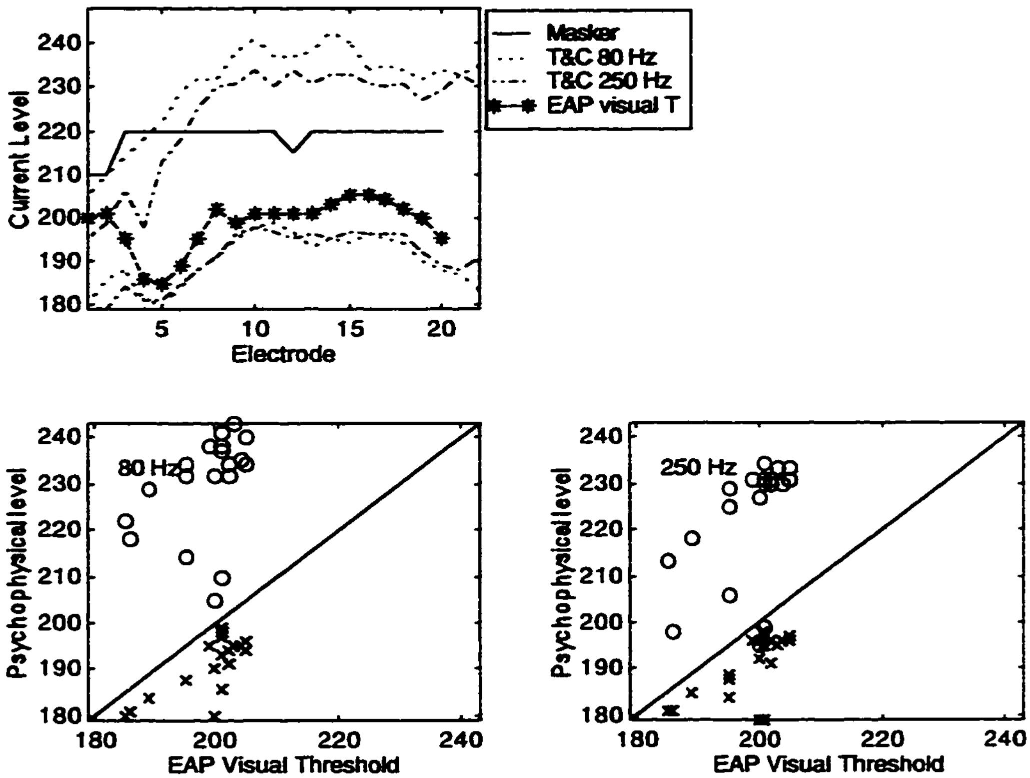

Figure 21. Same as Figure 18 except for subject 4.

Table 10. Correlations between EAP visual threshold and psychophysical levels for subject 4.

Session	80 Hz		250 Hz	
	T-level r (p)	**C-level** r (p)	**T-level** r (p)	**C-level** r (p)
1	.7404 (<.001)	.5834 (.007)	.7340 (<.001)	.6941 (.001)
2	.7476 (<.001)	.4177 (.067)	.6688 (.001)	.5281 (.017)

EAP thresholds were near the T-levels at 80 and 250 Hz for subject 4. EAP thresholds were highly correlated with T-levels. Correlation with T-levels remained approximately the same between sessions. EAP thresholds were also correlated with C-levels in session 1. This C-level correlation was lost in the second session. The masker level profile was not similar to the EAP threshold profile.

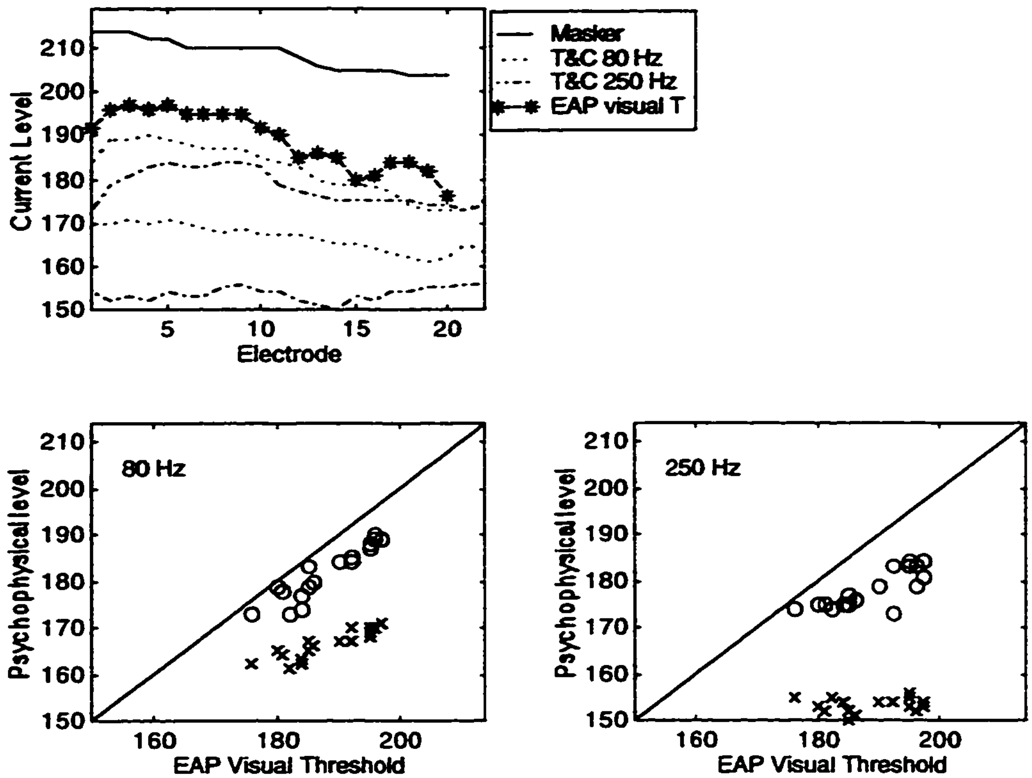

Figure 22. Same as Figure 18 except for subject 5.

Table 11. Correlations between EAP visual threshold and psychophysical levels for subject 5.

Session	80 Hz		250 Hz	
	T-level r (p)	**C-level** r (p)	**T-level** r (p)	**C-level** r (p)
1	.8907 (<.001)	.9244 (<.001)	.8501 (<.001)	.0863 (.717)
2	.9054 (<.001)	.9367 (<.001)	.0536 (.823)	.8262 (<.001)

EAP thresholds were above C-levels for subject 5. At 80 Hz, EAP thresholds were highly correlated to both T- and C-levels. At 250 Hz, EAP thresholds were highly correlated to T-levels in session 1 and C-levels in session 2. The masker level profile was not similar to the EAP threshold profile.

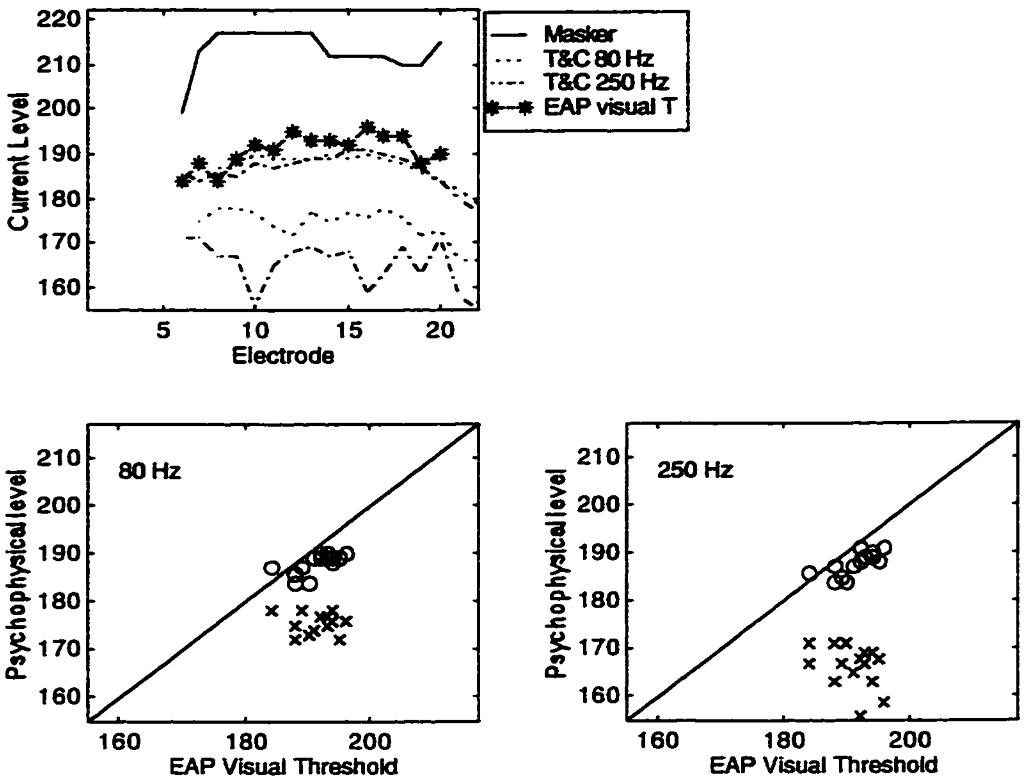

Figure 23. Same as Figure 18 except for subject 6.

Table 12. Correlations between EAP visual threshold and psychophysical levels for subject 6.

Session	80 Hz		250 Hz	
	T-level r (p)	**C-level** r (p)	**T-level** r (p)	**C-level** r (p)
1	.0661 (.822)	.6804 (.007)	-.2252 (.420)	.7741 (.001)
2	-.0644 (.827)	.6559 (.011)	-.3593 (.188)	.7041 (.003)

EAP thresholds were approximately equal to 80 Hz C-levels and above 250 Hz C-levels for subject 6. EAP thresholds were correlated with C-levels. Correlation decreased slightly at 80 Hz and increased at 250 Hz in the second session. The masker level profile was not similar to the EAP threshold profile.

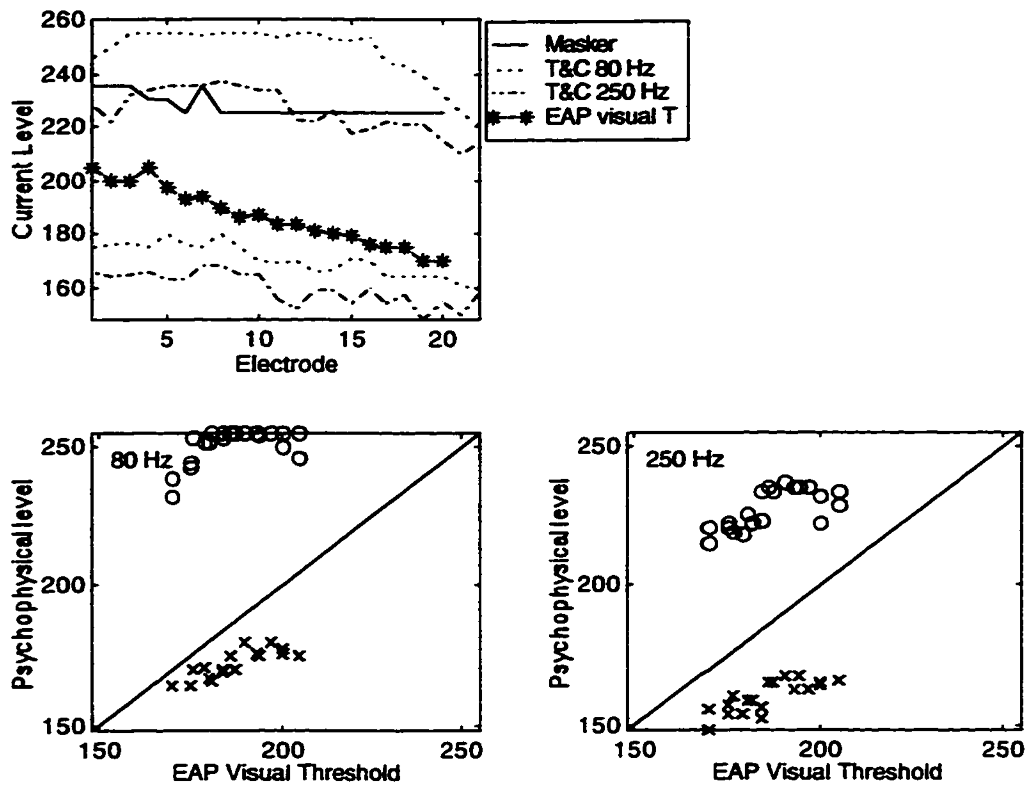

Figure 24. Same as Figure 18 except for subject 7.

Table 13. Correlations between EAP visual threshold and psychophysical levels for subject 7.

Session	80 Hz		250 Hz	
	T-level r (p)	C-level r (p)	T-level r (p)	C-level r (p)
1	.8608 (<.001)	.6676 (.001)	.8402 (<.001)	.7478 (<.001)
2	.8330 (<.001)	.5395 (.014)	.7813 (<.001)	.6600 (.002)

EAP thresholds were between T- and C-levels for subject 7. High correlations were found between EAP thresholds and C and T-levels both at 80 Hz and 250 Hz. Correlations decreased in the second session, more notably to C-levels. The masker level profile was not similar to the EAP threshold profile.

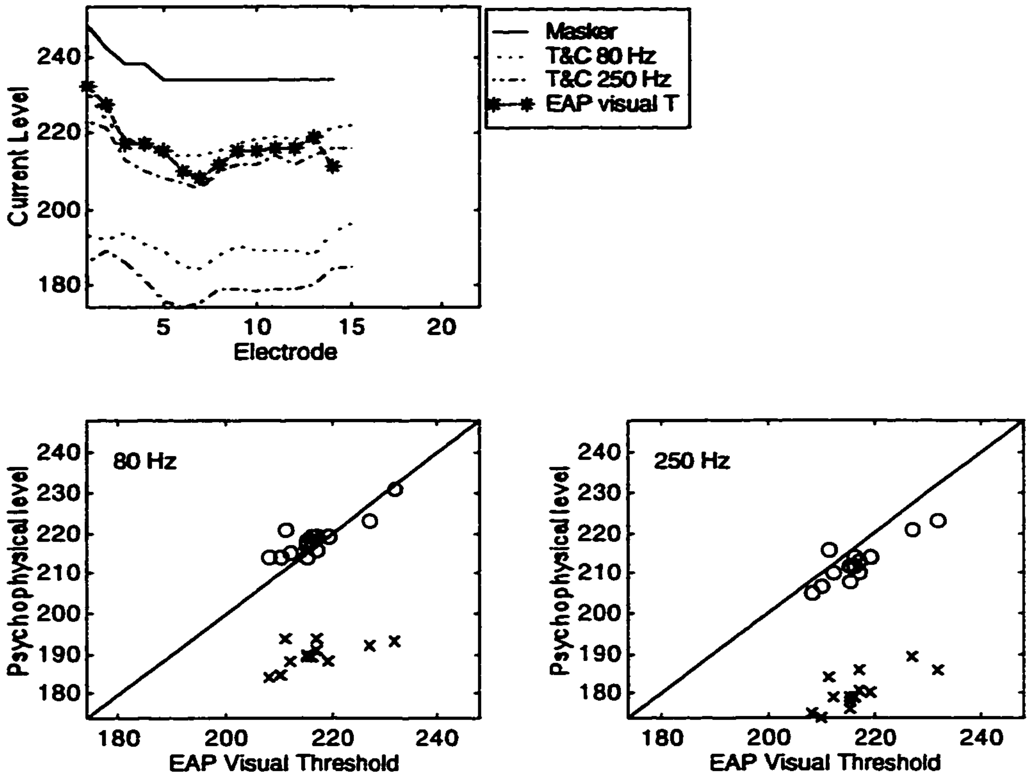

Figure 25. Same as Figure 18 except for subject 8.

Table 14. Correlations between EAP visual threshold and psychophysical levels for subject 8.

Session	80 Hz		250 Hz	
	T-level r (p)	C-level r (p)	T-level r (p)	C-level r (p)
1	.6651 (.013)	.6838 (.010)	.8481 (<.001)	.8195 (.001)
2	.5586 (.038)	.8548 (<.001)	.7288 (.003)	.8615 (<.001)

EAP thresholds were approximately equal to C-levels for subject 8. EAP thresholds were correlated with C-levels at 80 Hz and T- and C-levels at 250 Hz. Correlation to C-levels increased, while correlation to 250 Hz T-levels decreased in the second session. The masker level profile decreases from electrode 1 – 5, then flattens on more apical electrodes. This profile is similar to the EAP threshold profile.

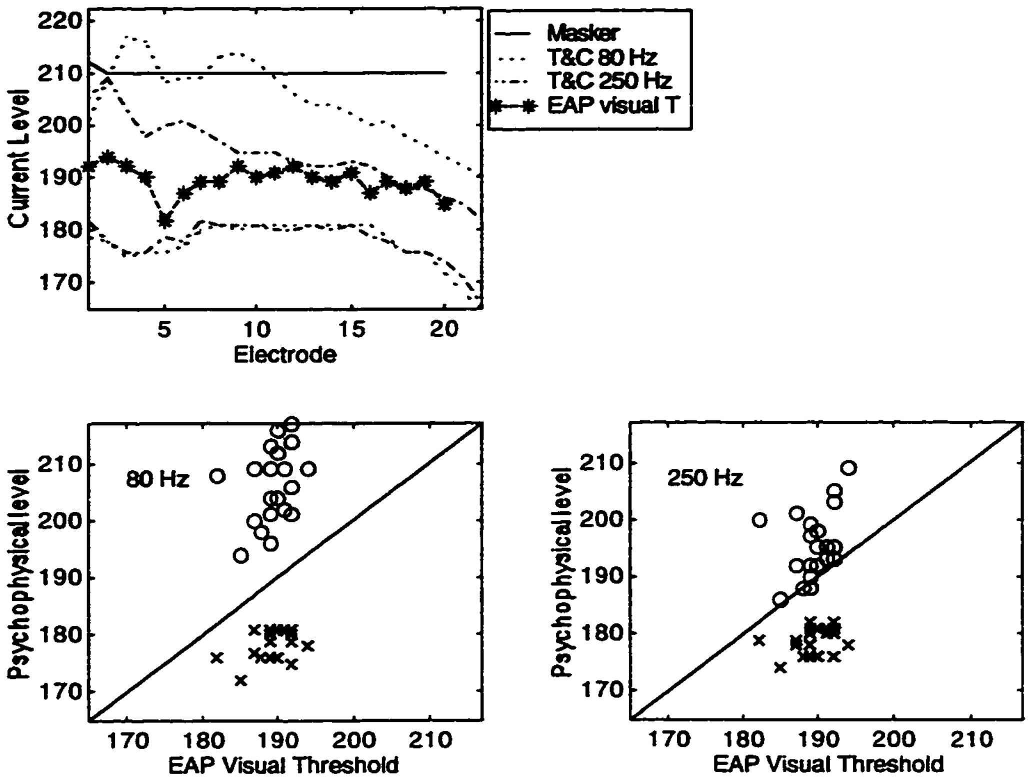

Figure 26. Same as Figure 18 except for subject 10.

Table 15. Correlations between EAP visual threshold and psychophysical levels for subject 10.

Session	80 Hz		250 Hz	
	T-level r (p)	**C-level** r (p)	**T-level** r (p)	**C-level** r (p)
1	.3351 (.149)	-.0110 (.963)	.3663 (.112)	.4671 (.038)
2	.4021 (.079)	.3380 (.145)	.2973 (.203)	.3574 (.122)

EAP thresholds were between T- and C-levels in the basal electrodes and approximately equal to 250 Hz C-levels in the apical electrodes for subject 10. Poor correlations were found between T- and C-levels at 80 Hz and 250 Hz in both sessions. The masker level profile was not similar to the EAP threshold profile.

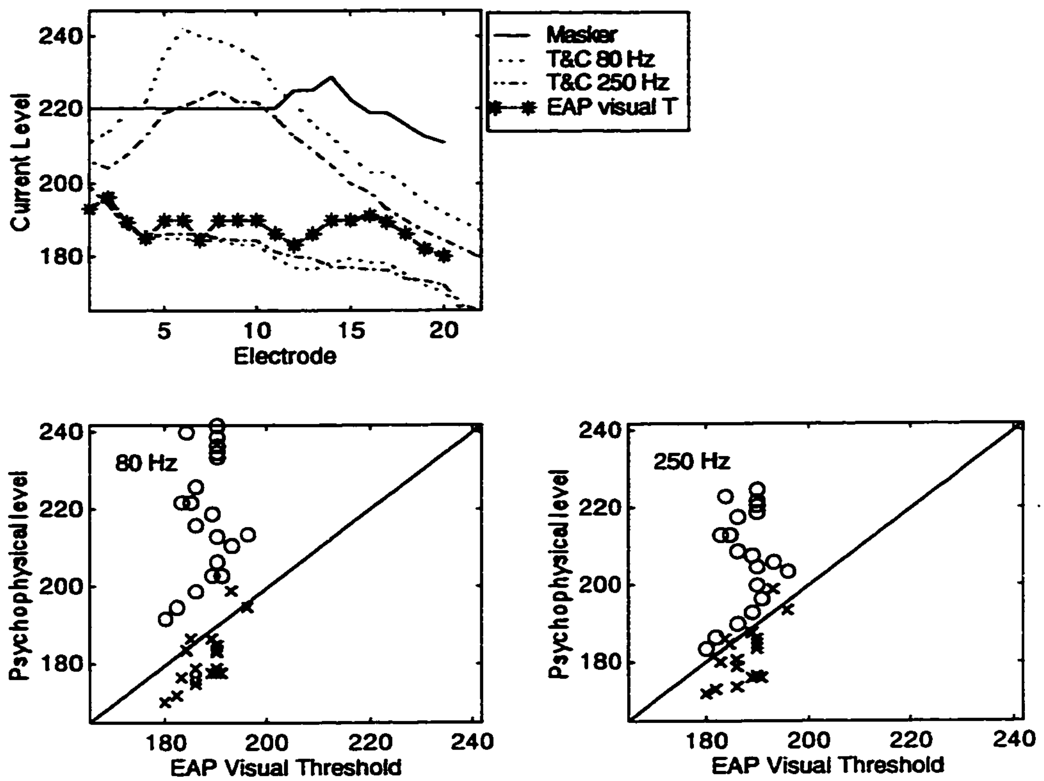

Figure 27. Same as Figure 18 except for subject 12.

Table 16. Correlations between EAP visual threshold and psychophysical levels for subject 12.

Session	80 Hz		250 Hz	
	T-level r (p)	C-level r (p)	T-level	C-level r (p)
1	.4742 (.035)	-.2024 (.392)	.3393 (.143)	-.1223 (.607)
2	.7110 (<.001)	.2459 (.296)	.6105 (.004)	.2709 (.248)

EAP thresholds were approximately equal to T-levels for subject 12. EAP thresholds were highly correlated with T-levels both at 80 Hz and at 250 Hz in the second session only. The masker level profile was not similar to the EAP threshold profile.

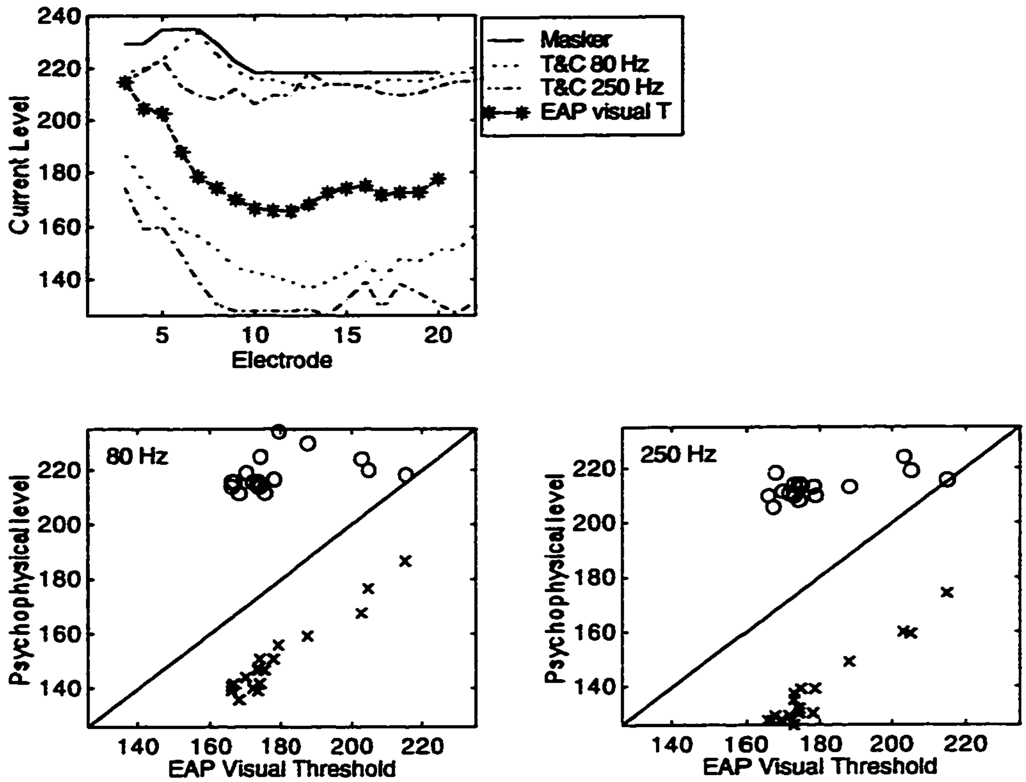

Figure 28. Same as Figure 18 except for subject 13.

Table 17. Correlations between EAP visual threshold and psychophysical levels for subject 13.

Session	80 Hz		250 Hz	
	T-level r (p)	C-level r (p)	T-level	C-level r (p)
1	.9502 (<.001)	.4064 (.094)	.9710 (<.001)	.6865 (.002)
2	.9683 (<.001)	.3626 (.139)	.9670 (<.001)	.6682 (.002)

EAP thresholds were between T- and C-levels for subject 13. High correlations were found between EAP thresholds and T-levels at both 80 Hz and 250 Hz, and between EAP threshold and C-level at 250 Hz. Correlation remained approximately the same in the second session. The masker level profile was not similar to the EAP threshold profile.

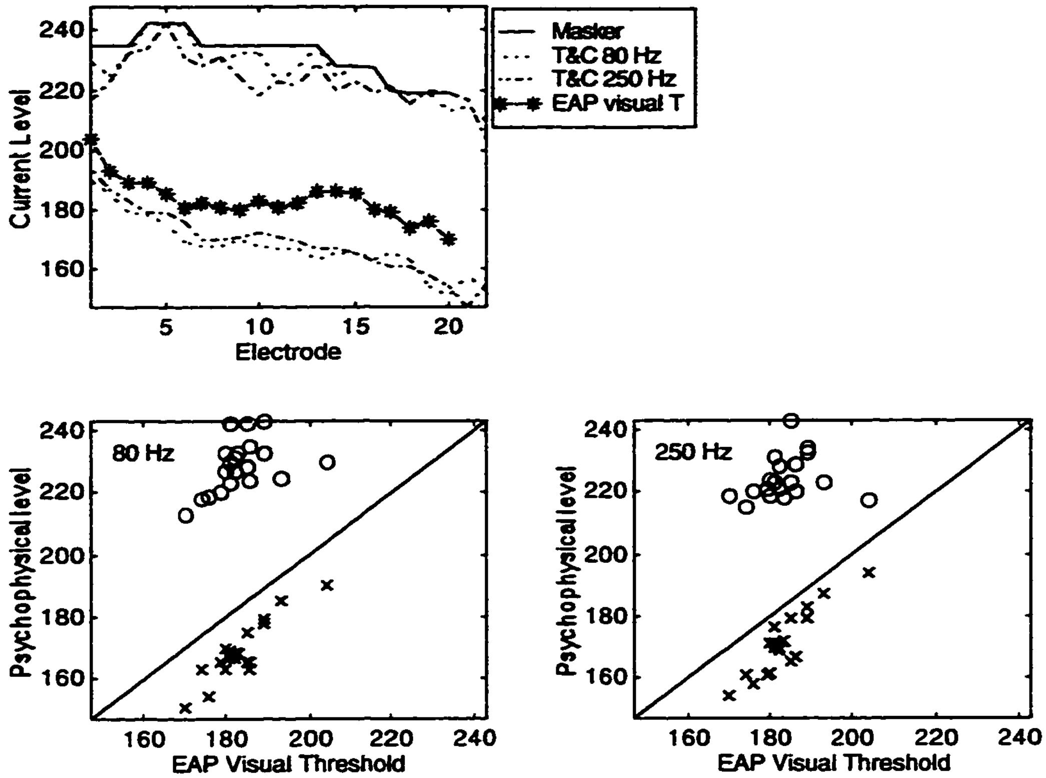

Figure 29. Same as Figure 18 except for subject 15.

Table 18. Correlations between EAP visual threshold and psychophysical levels for subject 15.

Session	80 Hz		250 Hz	
	T-level r (p)	C-level r (p)	T-level r (p)	C-level r (p)
1	.8691 (<.001)	.3904 (.089)	.8728 (<.001)	.1615 (.496)
2	.8879 (<.001)	.4551 (.044)	.8846 (<.001)	.1727 (.466)

EAP thresholds were slightly above T-levels for subject 15. High correlations were found between EAP thresholds and T-levels at both 80 Hz and 250 Hz. Correlations improved slightly in the second session. The masker level profile was not similar to the EAP threshold profile.

In all subjects except 10, EAP thresholds were significantly correlated (p<.001) with either the T or C-levels. More correlations between EAP thresholds and psychophysical levels occurred to T-levels than to C-levels, and correlations of higher significance were found to T-levels than they were to C-levels.

Table 19. Summary of visual threshold correlation coefficients (*<.01 **<.001).

Subject	Session	80 Hz		250 Hz	
		T-level	C-level	T-level	C-level
1	1		**		**
	2		**		**
2	1			*	
	2		*	**	
3	1	**	**		
4	1	**	*	**	**
	2	**		**	
5	1	**	**	**	
	2	**	**		**
6	1		*		**
	2				*
7	1	**	**	**	**
	2	**		**	*
8	1		*	**	**
	2		**	*	**
10	1				
	2				
12	1				
	2	**		*	
13	1	**		**	*
	2	**		**	*
15	1	**		**	
	2	**		**	
combined	1	** (6) * (0) (6)	** (4) * (3) (5)	** (6) * (2) (4)	** (5) * (1) (6)
	2	** (5) * (0) (6)	** (3) * (1) (7)	** (5) * (2) (4)	** (3) * (3) (5)

Using two-tailed bivariate methods, the EAP threshold was found to be significantly correlated to the masker level ($r=0.43$ $p<0.01$). The variance of the EAP threshold and masker level is smaller than the variance of the T- and C-levels. This may imply that the EAP threshold is determined by the masker level instead of the T- and C-levels.

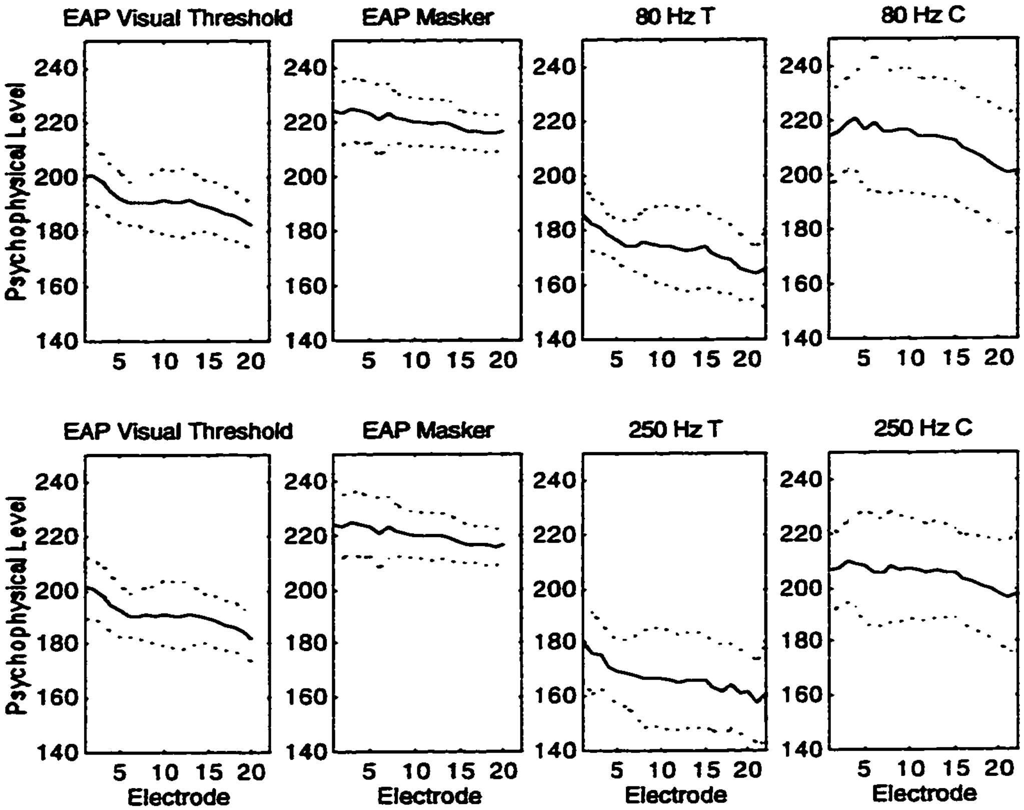

Figure 30. EAP and psychophysical levels plotted by electrode. Upper row of figures displays psychophysics at 80 Hz. Lower row of figures displays psychophysics at 250 Hz. First column displays EAP visual threshold. Second column displays EAP masker level. Third column displays T-level. Fourth column displays C-level. Within each panel, the solid line represents mean level. Dotted lines represent +/- 1 standard deviation.

EAP growth function slope

The mean slope of the growth function was 104.07 μA/dB (re 1 μA) with a standard deviation of 57.90 μA/dB (re 1 μA). Using two-tailed bivariate methods, there was a significant correlation between the slope of the EAP growth function and the dynamic range (C-T). Correlations for 80 Hz ($r=0.32$ $p<0.01$) were not significantly different than correlations for 250 Hz ($r=0.34$ $p<0.01$). Also, significant correlation was found between the slope of the EAP growth function and T-levels. Correlations for 80 Hz T-levels ($r=-0.44$ $p<0.01$) were slightly stronger than correlations for 250 Hz T-levels ($r=-0.41$ $p<0.01$).

There was a weak correlation between the mean slope of the EAP growth function and sudden onset of hearing loss ($r=0.51$ $p<0.05$). The mean slope of the EP growth function was not significantly correlated to the duration of profound hearing loss before implantation. The slope of the EAP growth function was not strongly correlated to electrode number ($r=0.10$ $p<0.05$). It was expected that if the apical, low-frequency region of the cochlea had greater neural survival, the slope of the EAP growth function would be higher in this region. Removal of subjects whose hearing loss was sudden only slightly improved correlation.

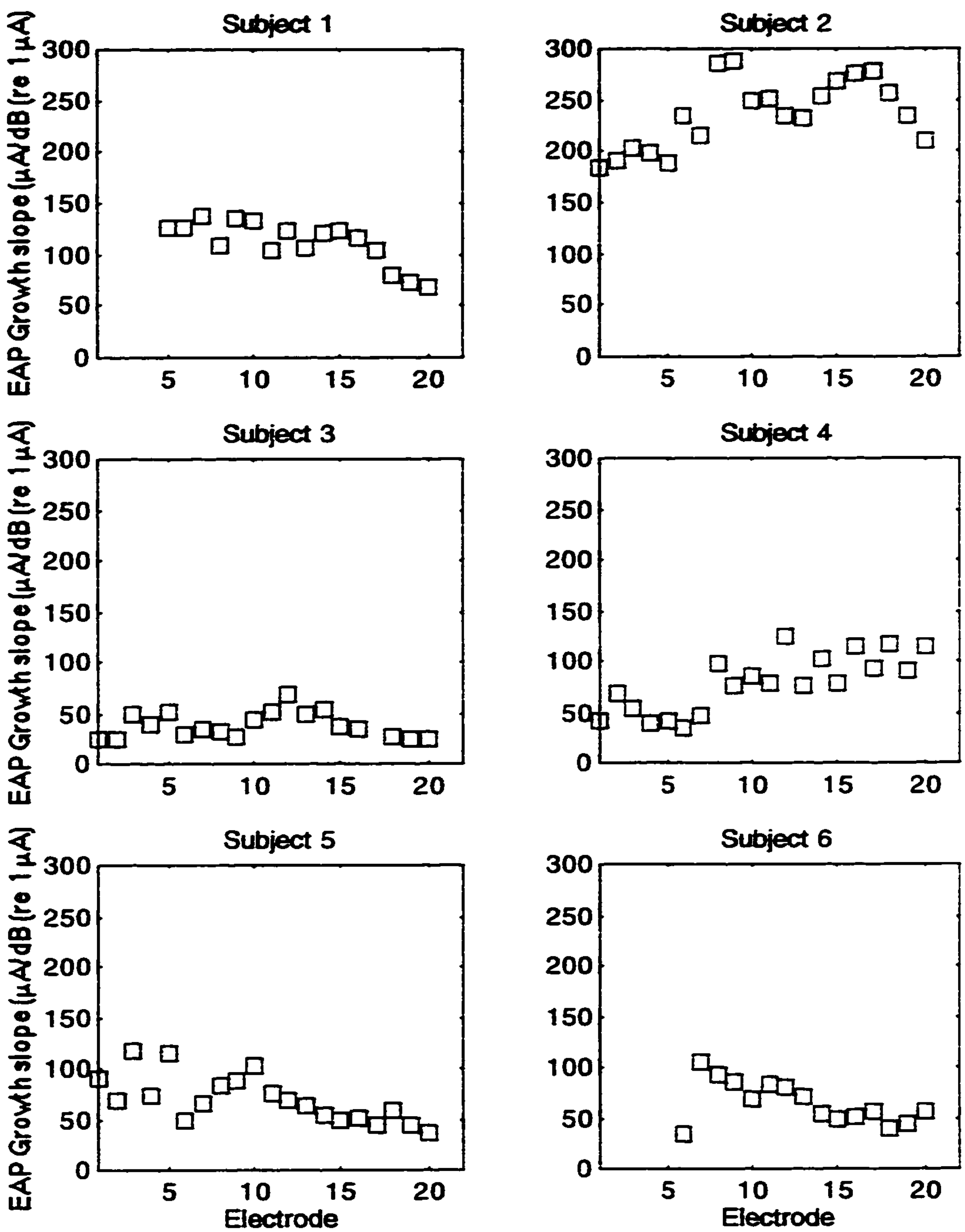

Figure 31. EAP growth function slopes. Panels represent subjects 1-6.

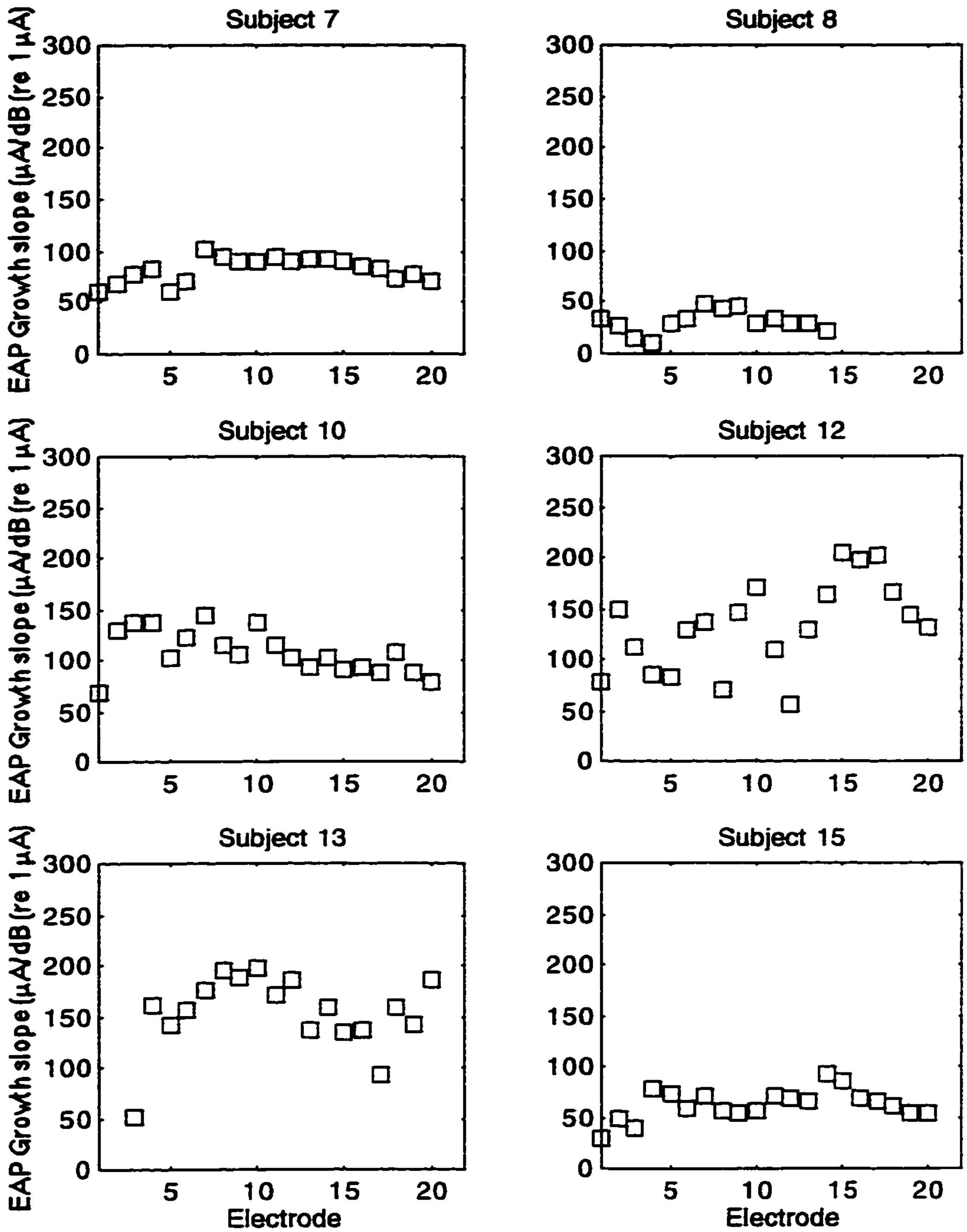

Figure 32. Same as Figure 31 except for subjects 7-15.

EAP recovery function slope

Before removal of the poorly fitting decay constants, the average decay constant was 7.58e-4 μsec^{-1} with standard deviation of 1.60e-4μsec^{-1}. After removal, the average decay constant remained essentially unchanged, at 7.69e-4 μsec^{-1} with standard deviation of 1.59e-4μsec^{-1}.

Using two-tailed bivariate methods, the slope of the EAP recovery function was found to be significantly correlated with the psychophysical T- and C-levels. Without the exclusion of the waveforms in Table 4, correlation to T- and C-levels were 0.28 and 0.21, respectively, at 250 Hz, and 0.23 and 0.22, respectively, at 80 Hz ($p<0.01$ in all cases). With the exclusion of the waveforms in Table 4, correlation to T- and C-levels were 0.42 and 0.24, respectively, at 250 Hz, and 0.34 and 0.23, respectively, at 80 Hz ($p<0.01$ in all cases).

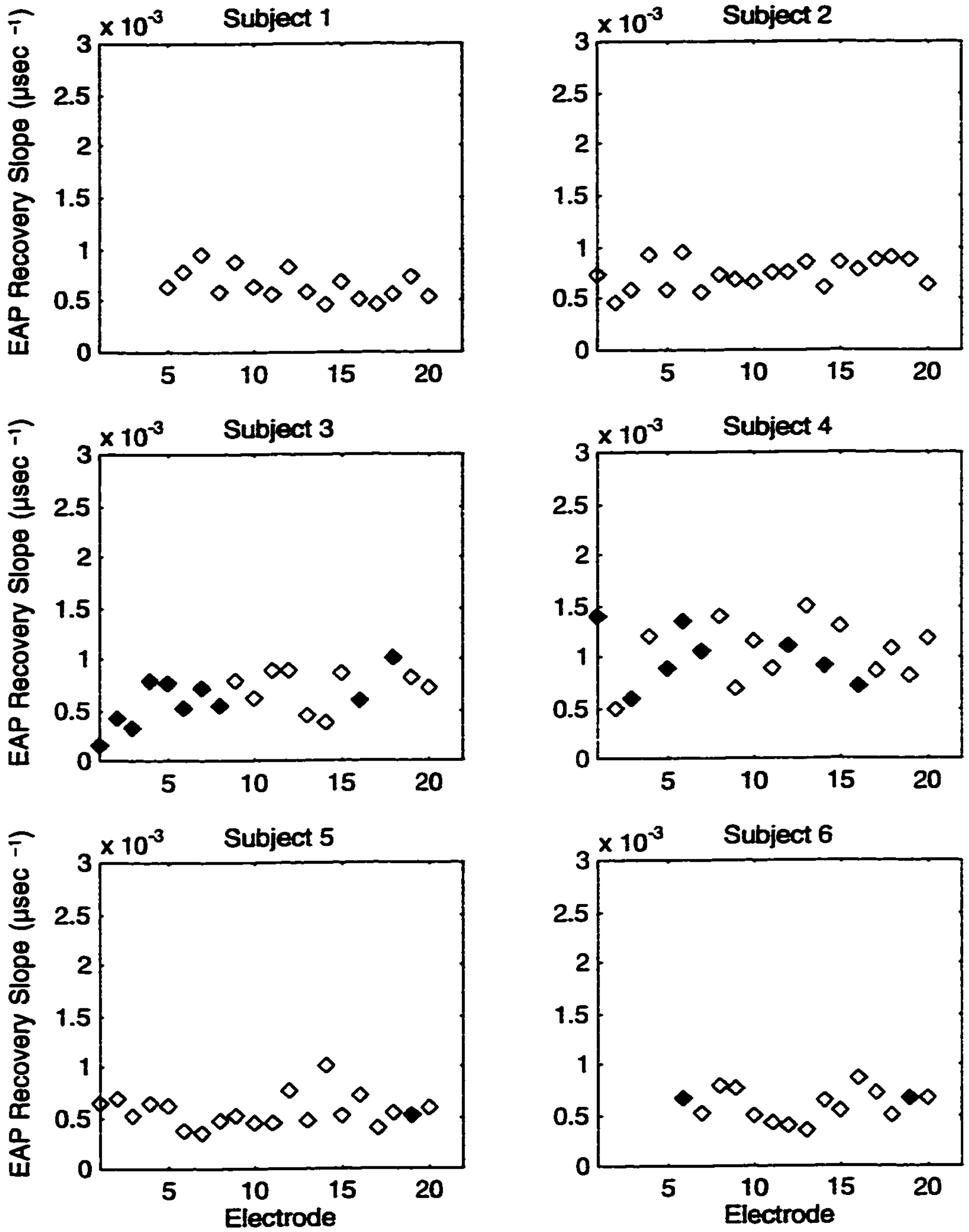

Figure 33. EAP recovery function slopes. Panels represent subjects 1-6. Filled diamonds represent poor exponential fit to recovery function.

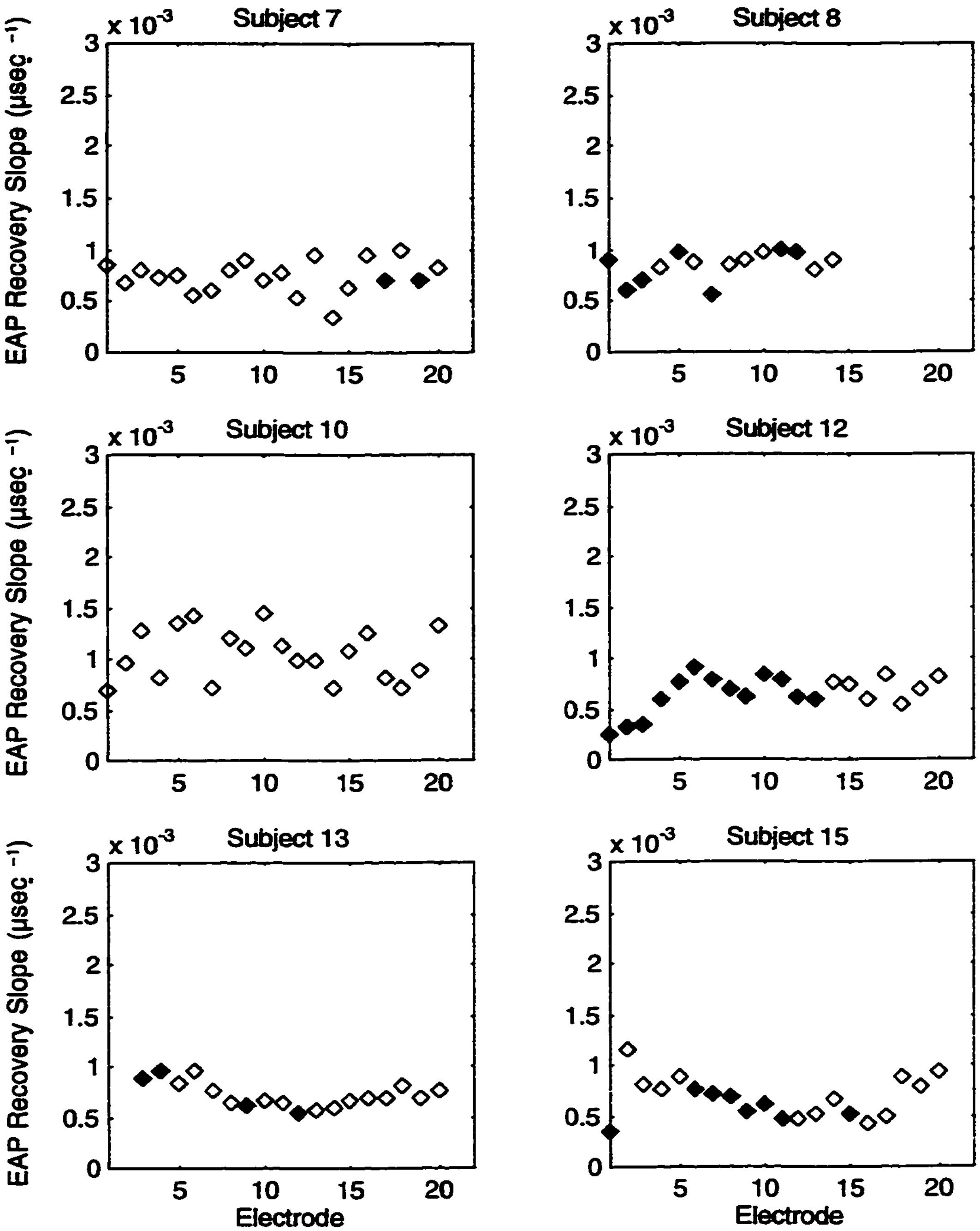

Figure 34. Same as Figure 33 except for subjects 7-15.

Electrode

EAP thresholds decreased with electrode number in 9 of the 12 subjects. That is, in the high-frequency basal region of the cochlea, EAP thresholds were higher than in the low-frequency apical region of the cochlea.

Table 20. Correlation coefficients between EAP threshold and electrode number.

Subject	Session	r	p
1	1	.2140	.426
	2	.2096	.436
2	1	-.4903	.028
	2	-.6787	.001
3	1	-.2870	.234
4	1	.6893	.001
	2	.4887	.029
5	1	-.8701	<.001
	2	-.9024	<.001
6	1	.4393	.101
	2	.5380	.039
7	1	-.9457	<.001
	2	-.9835	<.001
8	1	-.3482	.244
	2	-.5158	.059
10	1	-.3700	.108
	2	-.3148	.176
12	1	-.2113	.371
	2	-.5351	.015
13	1	-.6624	.003
	2	-.6467	.004
15	1	-.7796	<.001
	2	-.7738	<.001
combined	1	-.3359	<.001
	2	-.3921	<.001

Performance and patient characteristics

No significant correlations were found between EAP characteristics and subject performance data. Elimination of poor exponential fits from EAP recovery functions did not improve the relationship. The duration of profound hearing loss before implantation was significantly correlated ($r=-.60$ $p<.01$) to performance at two weeks post-initial stimulation, but not significantly correlated ($r=-.40$ $p>.05$) to performance at three months post-initial stimulation.

Sudden hearing loss was significantly correlated with the psychophysical dynamic range at both 80 and 250 Hz ($r=.63$ and $r=.70$, respectively, $p<.01$). That is, individuals with sudden hearing loss had larger dynamic range than individuals whose hearing loss was progressive. Sudden hearing loss was also significantly correlated with the slope of the EAP growth function ($r=.51$ $p<.05$). Individuals whose onset of hearing loss was sudden had steeper EAP growth function slopes than those whose hearing loss was progressive. Significant correlations were also found between a sudden onset of hearing loss and psychophysical T-levels at 250 and 80 Hz ($r=-.54$ $p<.01$ and $r=-.49$ $p<.05$ respectively). Subjects with sudden hearing loss had lower T-levels than subjects with progressive hearing losses.

EXPERIMENT II. LOUDNESS PSYCHOPHYSICS FOR DEVICE FITTING AND LOUDNESS GROWTH

Repeated loudness judgements with knob

Threshold and maximum comfortable loudness levels were measured at 80 and 250 Hz. As seen in Figure 18-Figure 29, on average, 80 Hz T- and C-levels were significantly ($p<0.01$) higher than 250 Hz T- and C-levels. However, analysis of each subject revealed that in half of the subjects, either the T or C-levels were not different at 80 and 250 Hz. In subjects 4, 10, 12 and 15, T-levels did not differ, and in subjects 1 and 6, C-levels did not differ significantly.

Three subjects (5, 12 and 15) were uncomfortable with use of the stimulus control knob, so T- and C-levels were established with the clinician in control of the knob. No significant differences ($p>0.5$) were found between the controller of the knob and psychophysical levels.

Magnitude estimation

In session 2, subjects quantified 7 loudness levels presented twice randomly between and including their T- and C-levels established during session 1. Subjects were given a range of 1 to 100 to quantify loudness, where 1 was instructed to be what they perceived as their T-level, and 100 as their C-level. In few subjects did loudness estimations approach the value of 100. Rather, the average loudness estimate at C-level was 51, which is far from the expected value of 100. The average loudness estimate at T-level was 4, which is close to the expected value of 1.

Table 21. Loudness ranges from magnitude estimation.

Subject	T-level 80 Hz	C-level 80 Hz	T-level 250 Hz	C-level 250 Hz
1	17	56	6	67
2	5	90	2	70
3	4	53	7	43
4	5	40	5	47
5	3	23	1	40
6	5	65	4	72
7	2	50	2	49
8	8	21	3	30
10	3	30	3	48
12	5	31	4	39
13	3	60	4	72
15	2	53	3	74
average	*5*	*48*	*4*	*54*

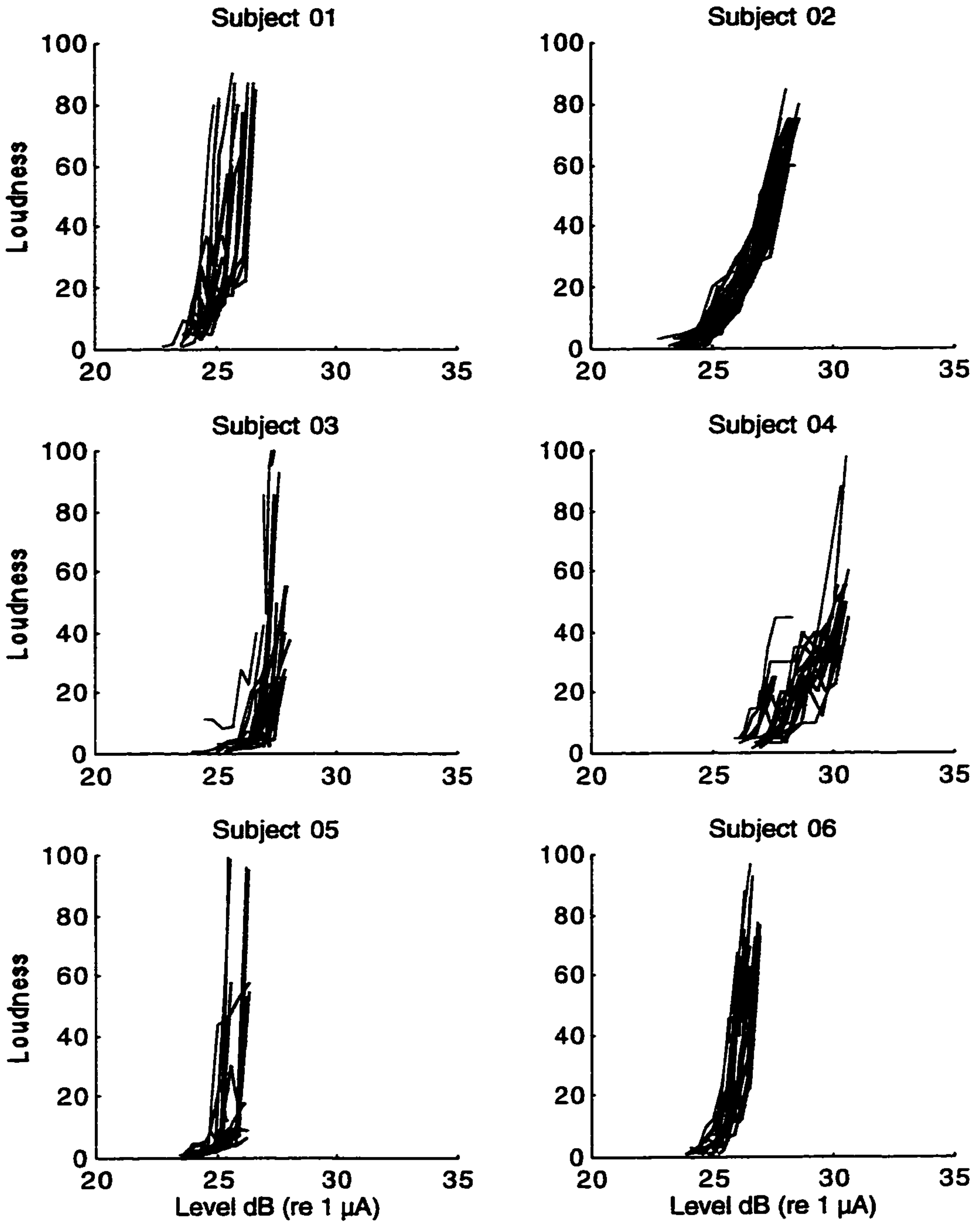

Figure 35. Magnitude estimation as a function of current level at 250 Hz from each stimulating electrode. Panels represent subjects 1-6.

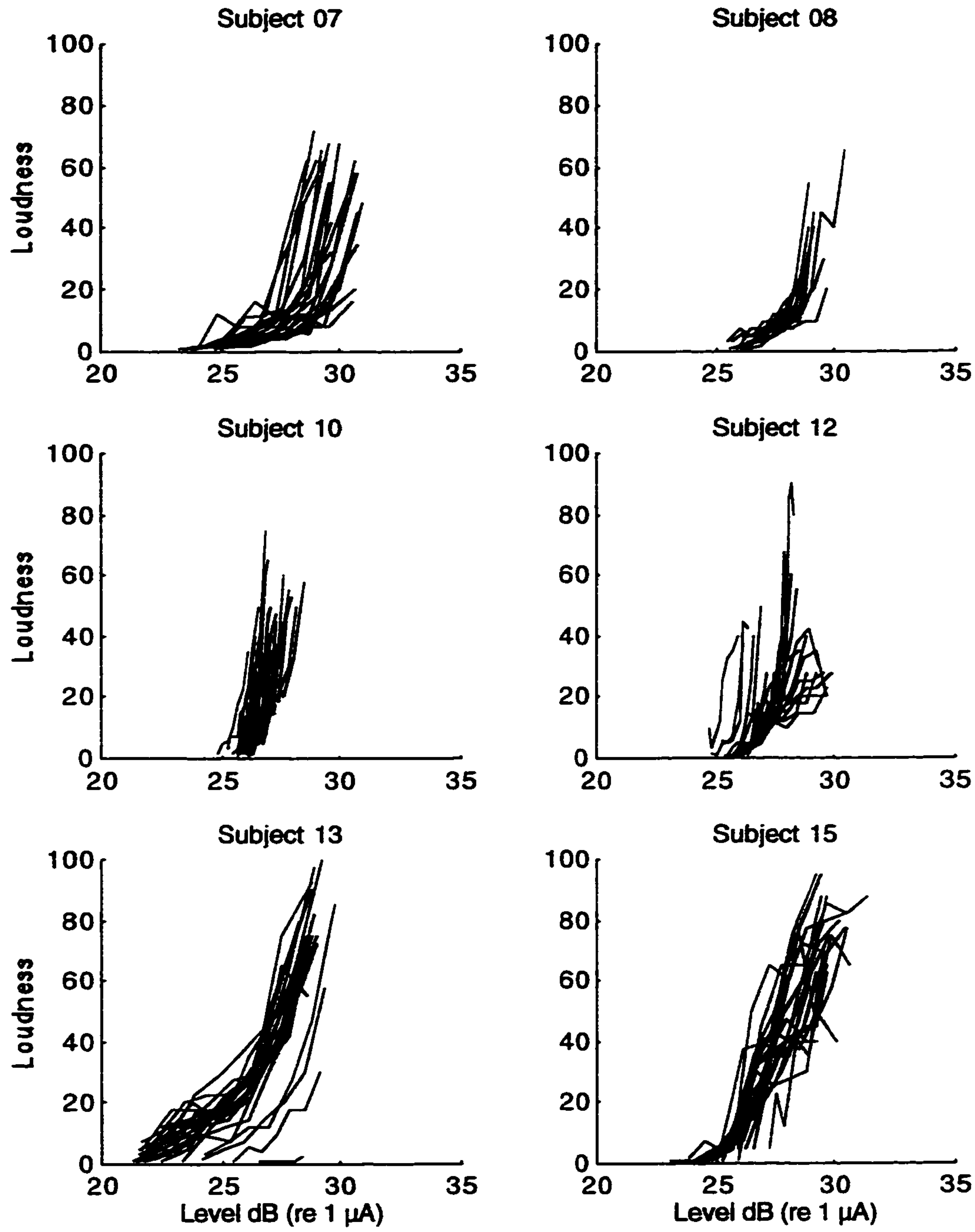

Figure 36. Same as Figure 35 except for subjects 7-15.

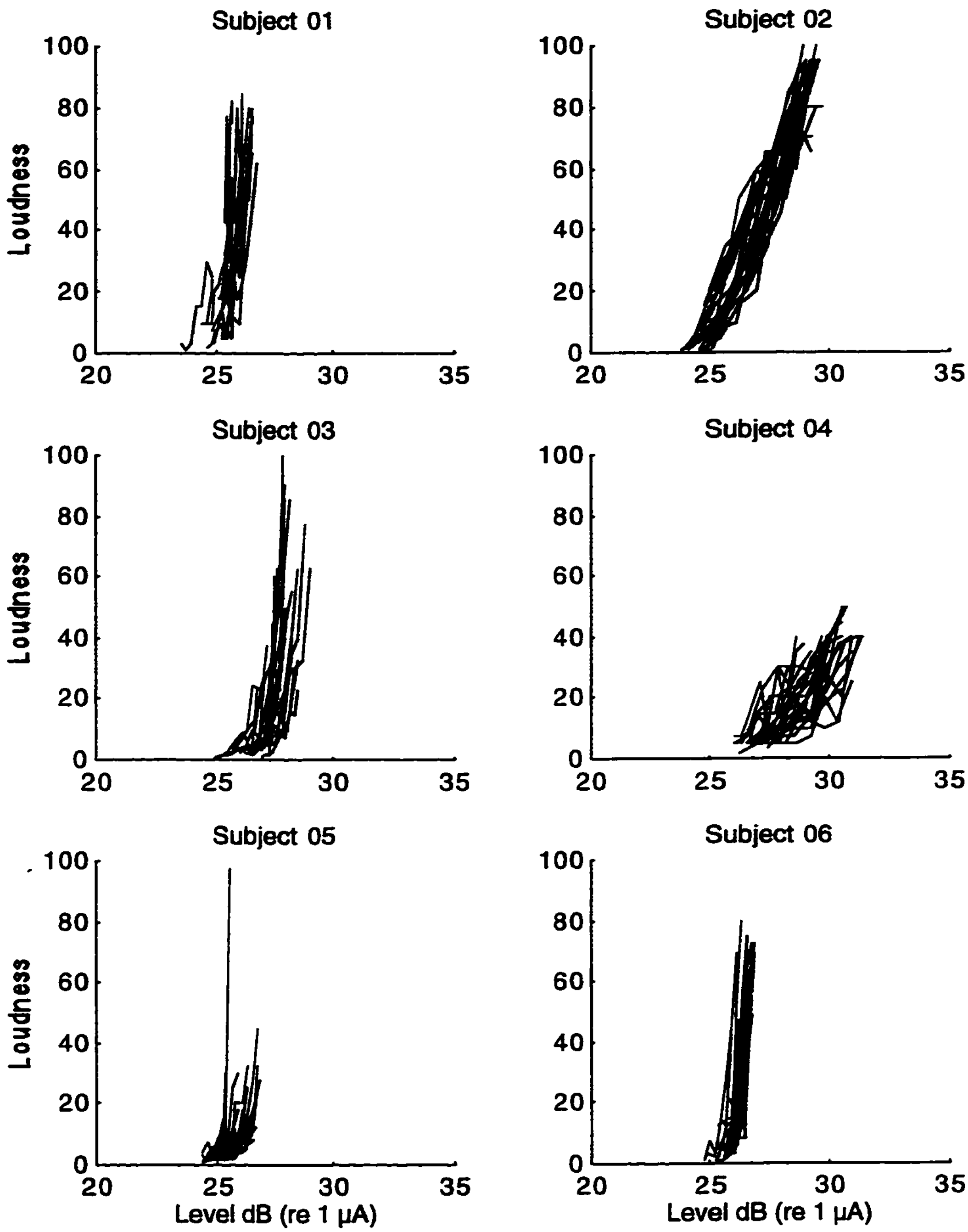

Figure 37. Magnitude estimation as a function of current level at 80 Hz from each stimulating electrode. Panels represent subjects 1-6.

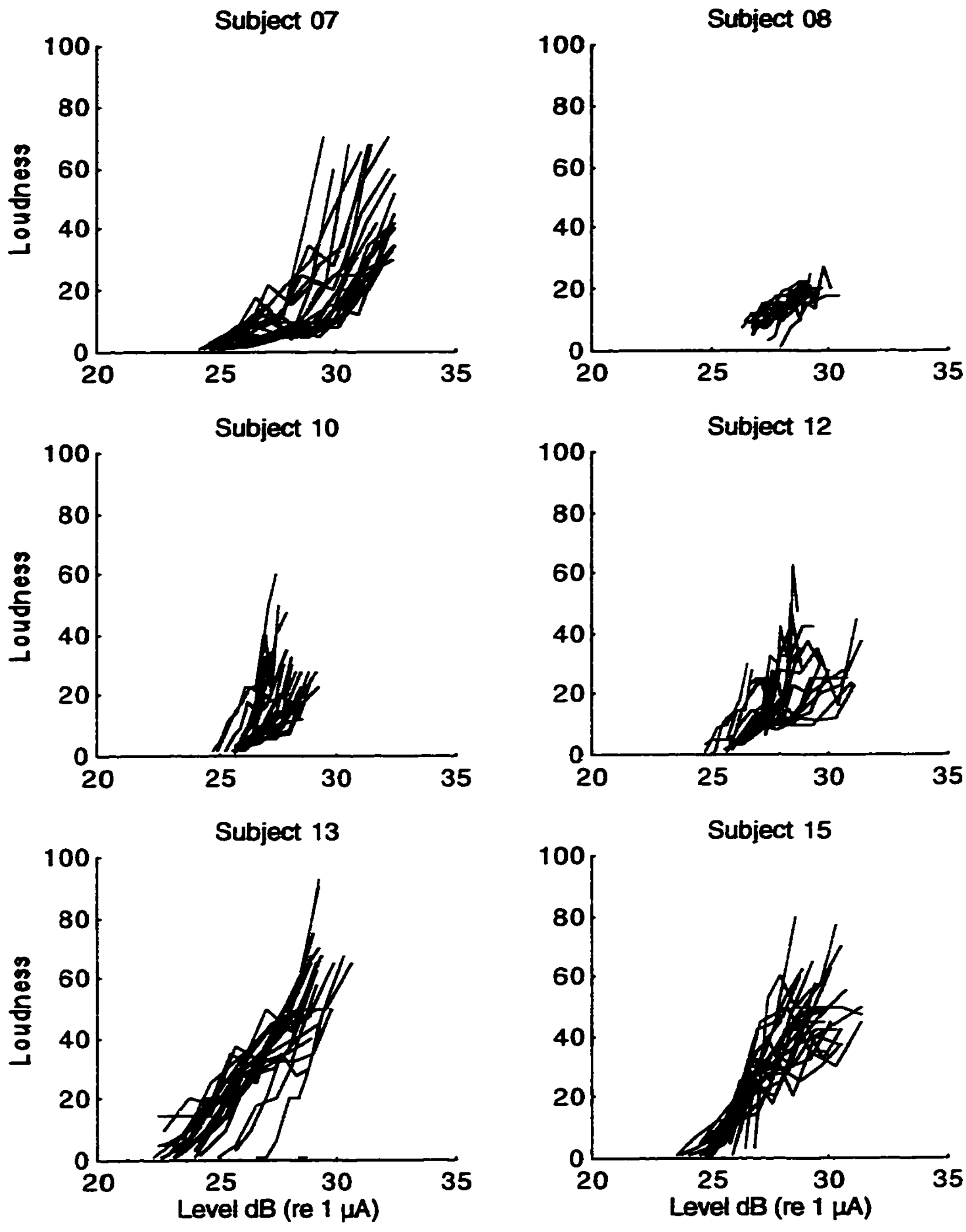

Figure 38. Same as Figure 37 except for subjects 7-15.

In most cases, subjects reported magnitude estimation values near 1 for stimulation at T-level. Subjects rarely reported magnitude estimation values near 100 for stimulation at C-level. Subject 2 at 80 Hz reported high magnitude estimation values at C-levels across all electrodes. Subjects 1, 3, 4, 5, 6 also reported high magnitude estimation values at C-levels, but only at one or a few electrode sites. The electrode sites were not consistently at the basal or apical end of the cochlea, nor were they consistently obtained at 80 Hz or 250 Hz. See Figure 39 - Figure 42.

Rank-order comparisons, using the Wilcoxon Matched-Pairs Signed-Ranks Test, were performed on dynamic ranges and magnitude estimation ranges per electrode at 80 Hz and 250 Hz. At 80 Hz, the dynamic ranges were not found to be significantly different from the magnitude estimation ranges ($p>=0.05$). At 250 Hz the dynamic ranges were less than the magnitude estimation ranges in a significant number of cases ($p<0.01$).

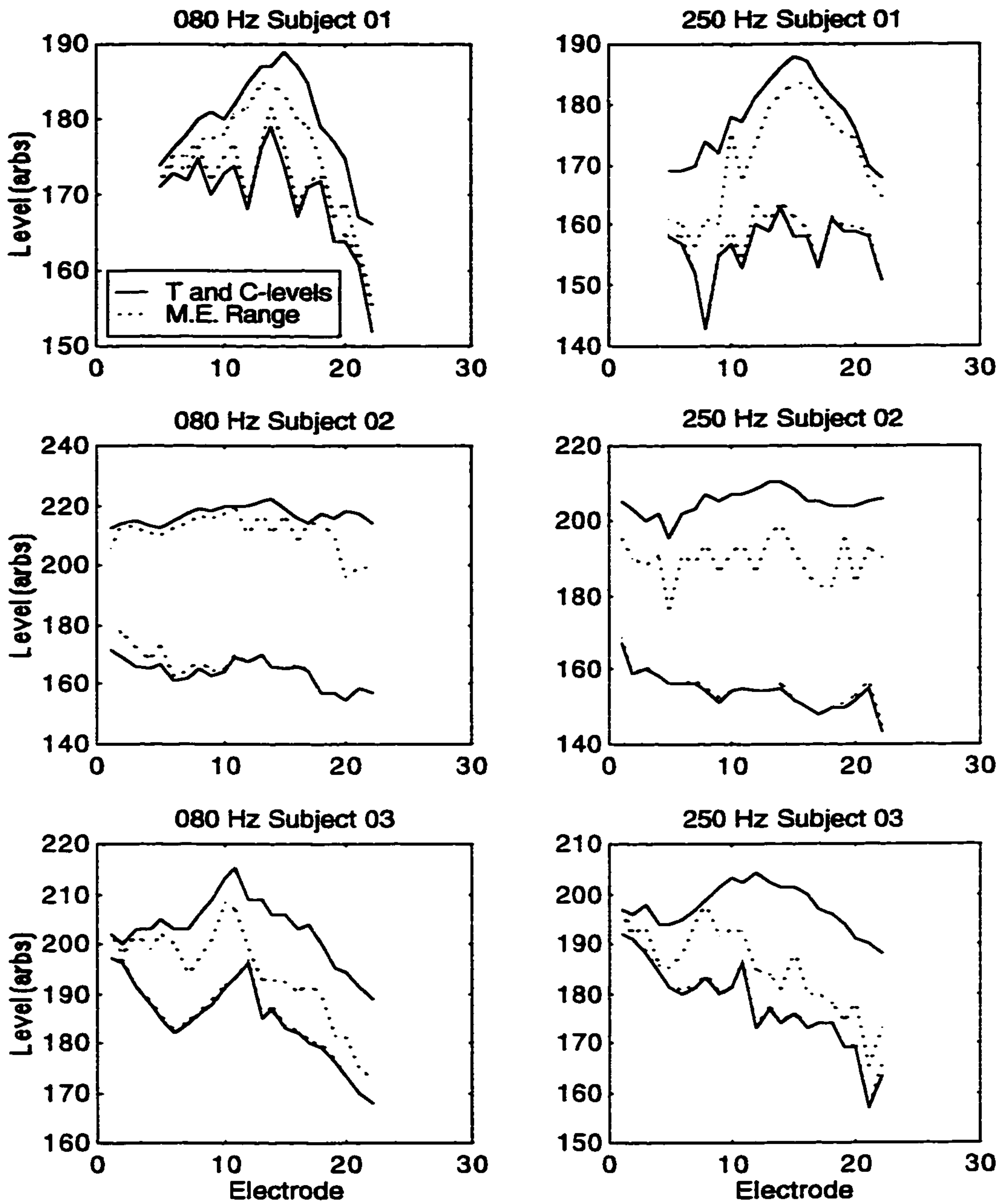

Figure 39. Loudness ranges for subjects 1-3. Left and right columns depict loudness ranges for stimulation at 80 Hz and 250 Hz respectively. Solid lines represent T- and C-levels. Dotted lines show scaled percentage of dynamic range obtained with magnitude estimation.

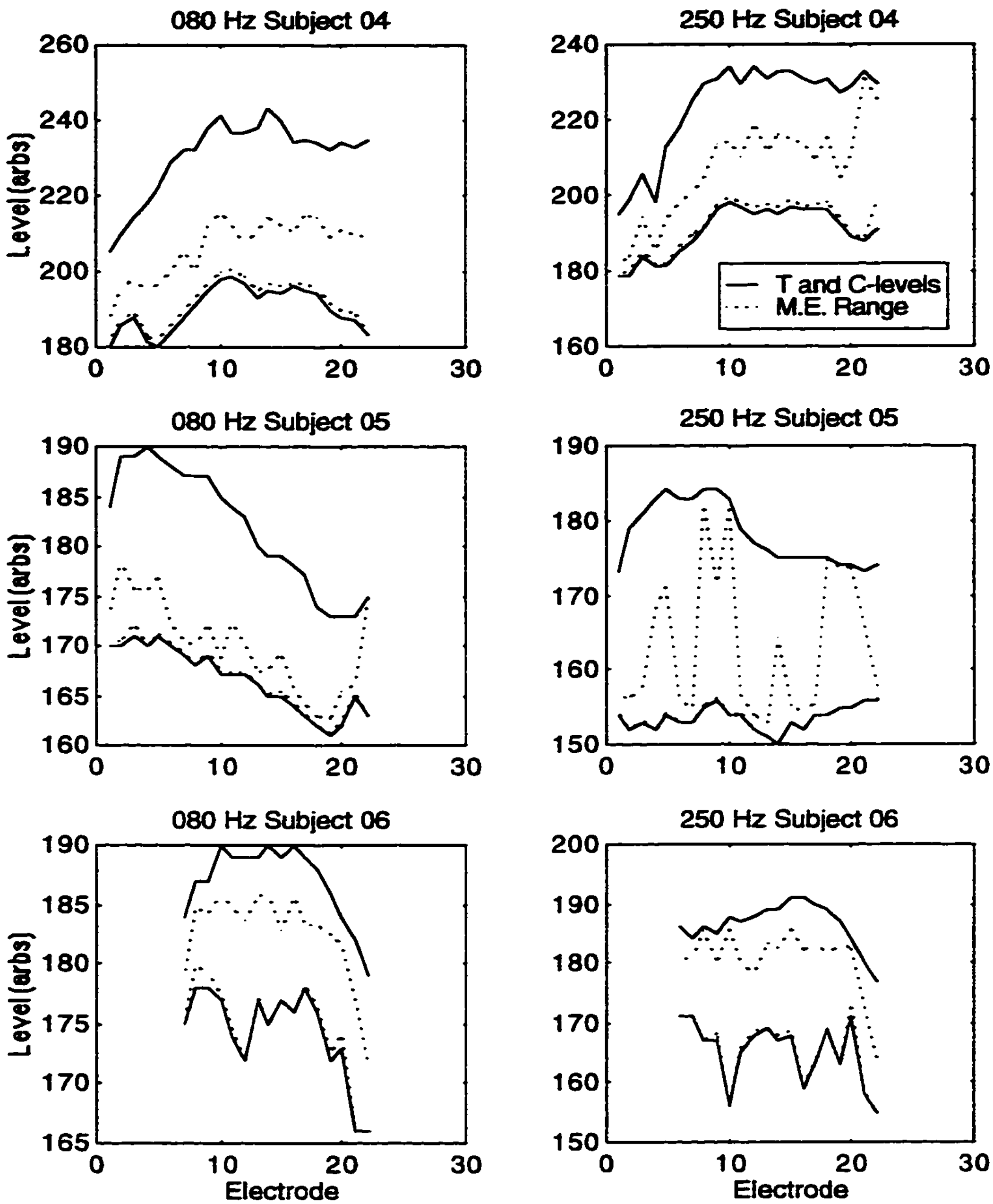

Figure 40. Same as Figure 39 except for subjects 4-6.

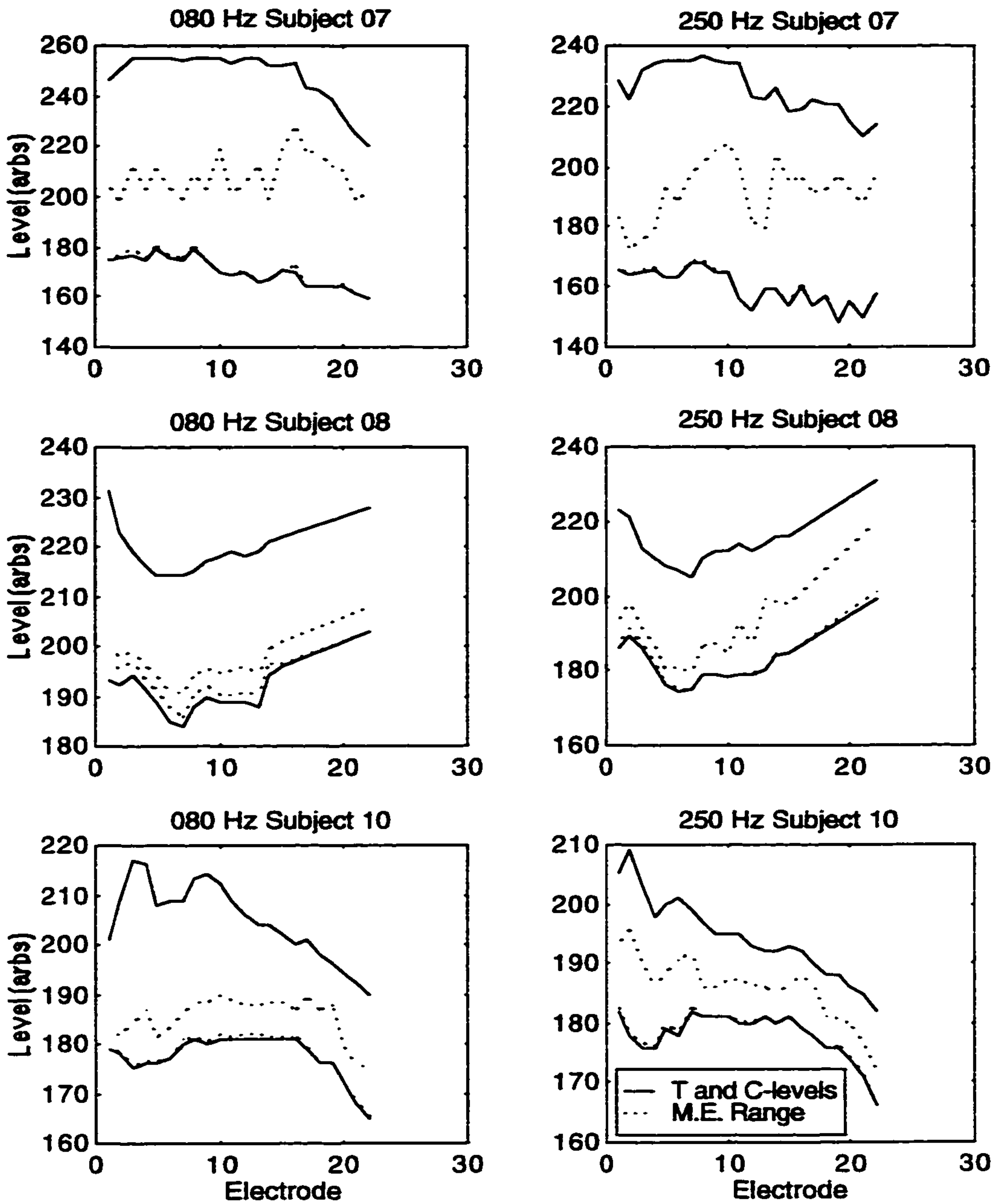

Figure 41. Same as Figure 39 except for subjects 7-10.

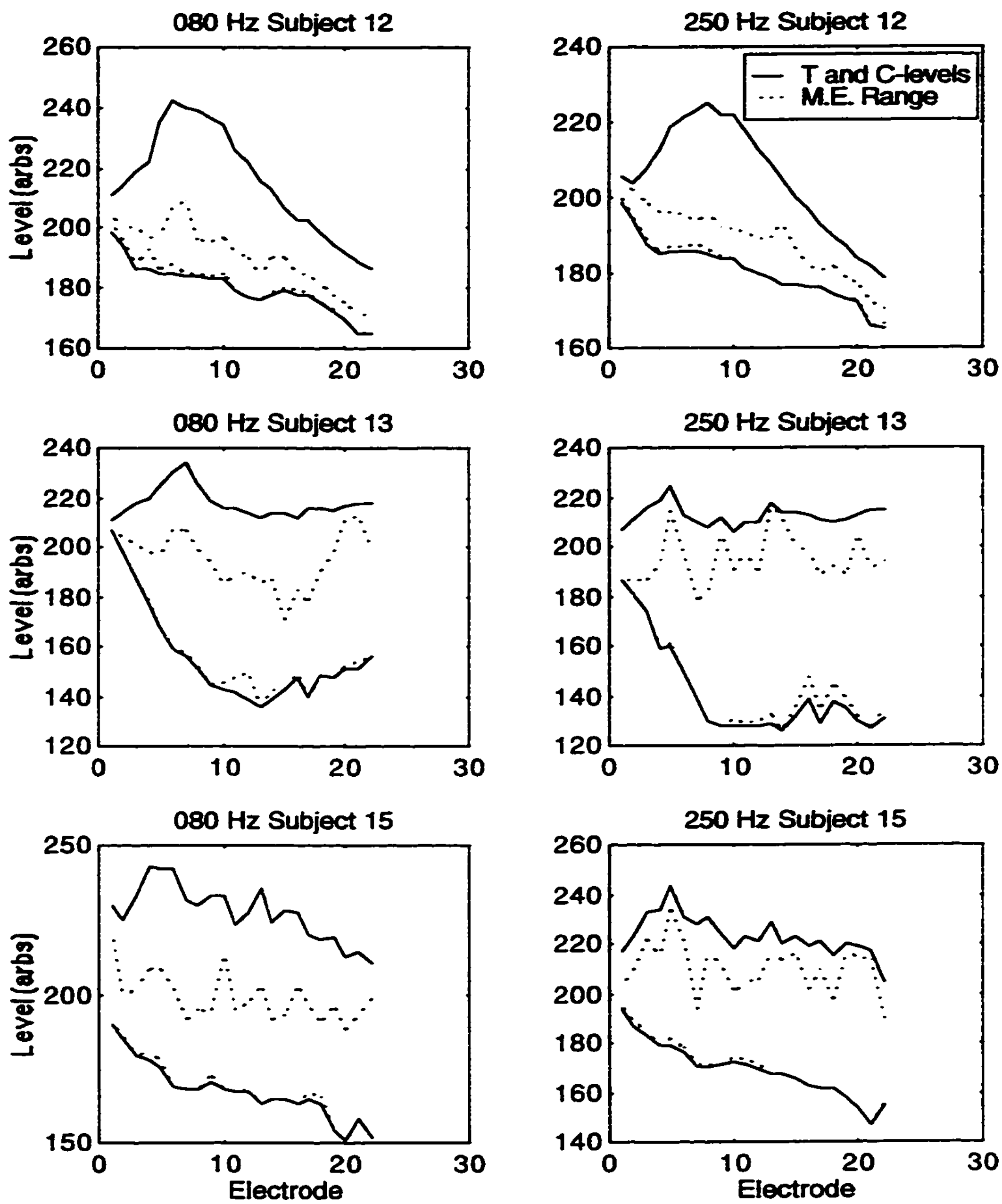

Figure 42. Same as Figure 39 except for subjects 12-15.

CHAPTER 4: DISCUSSION

EXPERIMENT I. EAPS MEASUREDUSING NRT

The purpose of this study was to explore the clinical utility of the EAP in cochlear implant fitting. Specifically, the first goal was to determine if the EAP can be reasonably measured in a clinical setting. The second goal was to determine if EAP data are related to psychophysical loudness measures, speech perception performance and other characteristics of subjects who use the CI24M cochlear implant. Finally, the third goal was to develop an EAP-based cochlear implant fitting protocol to augment behavioral cochlear implant fitting techniques.

Recording EAP using NRT

The EAP can be successfully measured using the NRT capabilities of the CI24M cochlear implant system. EAPs measured in this study had similar waveform morphology, amplitude growth and refractory recovery characteristics to EAPs measured in animals (Brown & Abbas, 1990; Charlet de Sauvage et al., 1983; Nagel, 1974; Stypulkowski & van den Honert, 1984). EAPs measured in this study had similar waveform morphology, amplitude growth and refractory recovery characteristics to EAPs measured by other investigators in humans with the CI24M cochlear implant (Abbas et al., 1999; Brown et al., 1998b) and other cochlear implant systems (Brown et al., 1996; Brown et al., 1990; Finley et al., 1997; Gantz et al., 1994; van den Honert et al., 1997).

EAP recording took approximately two hours per subject for growth and recovery functions on all active electrodes. Results from this study indicate that adequate information can be obtained from fewer recordings. EAPs were stable between recording sessions, indicating that recording a larger number of responses does not significantly improve the growth function. Threshold data obtained from responses near visual threshold did not significantly differ from data obtained from linear estimation of supra-threshold responses, indicating that less detailed growth function data may be adequate for threshold estimation. Recovery functions did not provide additional information relevant to implant fitting psychophysics, indicating further possible reduction in time requirements. Finally, recording from fewer number of electrodes with interpolation may reduce time requirements. However, interpolation should be used with caution, as in some subjects, T- and C-levels can vary over a few electrodes on the array.

If all suggested time-saving procedures were implemented, adequate EAP data for implant fitting may be collected in as little at 15 minutes. Even if EAP data collection required 30 minutes, the efficiency of implant fitting would improve. Characterization of T- and C-levels by traditional behavioral fitting techniques takes more time than that required to obtain adequate EAP data, especially in early fitting sessions of adults, and in the fitting of young children. The rapidity of measurements also allows intraoperative EAP measurement during closure, adding little if any time to the operation. Recording EAPs intraoperatively provides not only the benefit of confirming device function and neural interface, but also the ability to use high masker levels which may not be tolerated by the awake subject.

Waveform morphology

The EAP responses with an additional peak between N_1 and P_1 as seen in the upper right panel of Figure 11, may be a response to dendritic stimulation. As shown in Figure 1, a similar peak was found in animal studies when the EAP was recorded from the auditory nerve at the junction of the nerve trunk and the cochlear nucleus (Stypulkowski & van den Honert, 1984). This morphology has been observed in other humans with the CI24M (Brown et al., 1997). Of the subjects who had this waveform morphology, two and seven both experienced sudden hearing loss in the implanted ear, and subject 12 a progressive hearing loss with residual hearing in the low frequencies. Such hearing histories may be consistent with dendritic survival in the apical region of the cochlea.

Estimating implant fitting psychophysics based on EAP responses

EAP threshold

Across subjects, the EAP threshold was found to be most highly correlated with T-levels measured at 80 Hz, the same presentation rate as EAP measurements. High correlations were also found between EAP thresholds and T-levels assessed using a rate of 250 Hz. This suggests that while it would be ideal to measure EAPs using the same stimulation rates used for behavioral mapping, it is possible to use different stimulation rates for the two measurements. These results are consistent with other studies comparing psychophysical to EAP thresholds in patients using the Ineraid cochlear implant (Brown et al., 1996) and those using the Nucleus CI24M cochlear implant (Brown et al., 1998b). However, unless NRT can use faster EAP stimulation rates, the discrepancy between EAP and behavioral thresholds may increase as faster coding strategies are used in the CI24M cochlear implant.

Across subjects, there were no significant correlations between EAP thresholds and C-levels at 80 Hz or 250 Hz. This is consistent with the loudness psychophysical data. More inconsistencies were found between commonly used clinical psychophysical techniques and magnitude estimation techniques at high stimulation levels than at low stimulation levels.

Individually, significant correlations were found between EAP threshold and either T or C-levels. Significant correlations were sometimes found between EAP threshold and both T- and C-levels. In only one case was there no significant correlation between EAP and T or C-levels. Rarely, also, were correlations stronger between EAP thresholds and psychophysics at 250 Hz than psychophysics at 80 Hz. Loudness estimation at low and high stimulation levels did not predict EAP correlation to T- and C-levels, respectively.

While high correlations were found between EAP thresholds and psychophysical levels, the absolute level of the EAP threshold was not consistently at T-level, C-level or in between. In all subjects, except for three electrodes of subject 12, EAP thresholds were above T-levels. This suggests that in general, stimulation at EAP threshold will result in a perceptible signal. Most of the time, the loudness of stimulation at EAP threshold will not exceed maximum comfortable loudness. However, initial stimulation at EAP threshold may result in a percept above maximum comfortable loudness in some subjects. Behaviorally, levels which exceed maximum comfortable loudness are often lower at initial stimulation than they are after three months of use. Subjects whose hearing loss was sudden consistently had EAP thresholds between their T- and C-levels. These subjects may have had better internal representations of loudness or better nerve survival allowing more natural loudness growth than individuals whose hearing loss progressed over time.

In this study, behavioral threshold and maximum comfortable loudness are the "gold standards" to which EAP thresholds are compared. However, loudness psychophysics are highly subjective measurements based on internal representations. Loudness representations may vary with changes in pitch within subjects and with differing amounts of hearing experience across subjects. Additionally, the psychophysical assessment of loudness and loudness growth can take 30 minutes or more. For some subjects these measurements could be affected by task fatigue or boredom.

Masker levels were also significantly correlated with T- and C-levels. During EAP measurements, the masker level was adjusted so that the stimulation was at a high amplitude but not uncomfortably loud. Subjects who required masker levels near the range of uncomfortably loud stimulation often had masker level profiles which were similar to C-level profiles. T- and C-levels are correlated, which may account for the correlation between masker and T-levels. The masker level may have influenced the absolute EAP threshold. The range of EAP thresholds is more similar to the range of the masker than it is to the range of the psychophysical levels. The range of the EAP threshold and masker levels is smaller than the range of the psychophysical levels.

EAP growth function slope

In this study, correlations were found between the EAP growth function slope and both dynamic range and T-levels. Previous studies have reported positive correlations between the slope of the EAP growth function and the number of surviving spiral ganglion cells in an animal model (Hall, 1990). In human cadavers, the number of spiral ganglion cells is correlated with pre-morbid psychophysical threshold and dynamic range (Kawano et al., 1998). The relationship between EAP growth functions and psychophysical threshold and dynamic range may provide a means to estimate spiral ganglion cell count in living humans. Knowledge of the surviving population of spiral ganglion cells may have an effect on mapping strategies.

EAP recovery function slope

The decay constant of the exponential fit to the recovery functions correlated significantly with T- and C-levels. Correlations were stronger for T-levels than for C-levels, and stronger for 250 Hz than for 80 Hz. Such correlations have not been reported previously. The rate of recovery has been postulated to be a measure of the time required for the neuron to recover from its absolute refractory period (Brown & Abbas, 1990; Brown et al., 1996; Brown et al., 1990; Brown et al., 1998b; Finley et al., 1997; Gantz et al., 1994). Stimulation level has been found to influence the refractory recovery rate. High stimulation levels have been found to result in faster recovery than low stimulation levels (Finley et al., 1997). In this study, recovery functions were measured at high stimulation levels, which often followed C-level profiles. The positive correlation between the recovery slope and psychophysical C-levels is consistent with Finley's findings. However, one might have expected higher correlations to C-levels than to T-levels.

Electrode position

The negative correlations between psychophysical levels and electrode number is consistent with other studies. Electrode number has been negatively correlated with loudness psychophysics and the distance between the center of electrode bands and the center of Rosenthal's canal (Kawano et al., 1998).

Performance and patient characteristics

The rate of recovery from the neural refractory period has been reported to be positively correlated with speech perception performance (Brown et al., 1990; Gantz et al., 1994). Finley et al. (1997) observed that the recovery rate was dependent on stimulation level. However, when patient performance was compared to the recovery rate across a range of stimulus intensities, no relationship was found. These three studies used high-rate speech coding strategies. Subjects in the present study used a low-rate speech coding strategy. If a positive correlation was found with the slower rate, the result would support the results of Brown and Gantz, and the hypothesis that fast-recovering neurons may be a predictor of good performance with the cochlear implant regardless of speech coding strategy. If a negative correlation had been found, it would support the hypothesis that fast-recovering neurons are better suited for high-rate coding strategies, while slow-recovering neurons are better suited for low-rate coding strategies. Such a result would provide rationale for the selection of device and speech coding strategy for a particular patient. If no correlation was found, it would support Finley's hypothesis that the variation of recovery rates may be attributable to stimulation level rather than to underlying physiology. In this study, the recovery rate was not significantly correlated to speech perception performance.

Another significant finding was that the duration of profound hearing loss before implantation was correlated with performance at two weeks post-initial stimulation, but not with performance at three months post-initial stimulation. This indicates that subjects who are implanted shortly after the onset of profound hearing loss only have a speech perception advantage over subjects who have experienced a longer duration of profound hearing loss immediately after stimulation. By three months of use with the implant, subjects with longer duration pre-implant hearing loss perform as well as subjects implanted shortly after onset of profound hearing loss.

Sudden hearing loss was significantly correlated with the psychophysical dynamic range, EAP growth function slopes and T-levels. These three variables are significantly correlated with the number of surviving spiral ganglion cells (Hall, 1990; Kawano et al., 1998). Together these results support the hypothesis that individuals who experience sudden hearing loss have a larger number of surviving spiral ganglion cells than do subjects whose hearing loss is progressive.

Adverse reactions

Two subjects reported buzzing and fullness sensations after EAP measurements. These subjects had the lowest average C-levels of all participants in the study. The cause of these sensations is unknown. It is possible that the buzzing and fullness sensations are the result of tinnitus. It is also possible that immediate cessation of the EAP stimulus after ignoring the EAP stimulation for durations up to three hours may have caused such sensations.

Two subjects reported dizziness the morning after EAP measurements. Vestibular dysfunction has been observed when the cochlear implant is operating normally at comfortable loudness levels. Such occurrences have been reported in one out of 17 randomly selected subjects (Bance et al., 1998), and two out of 11 subjects who experienced prolonged or delayed dizziness post implantation (Ito, 1998). In order to measure EAP, stimulus levels sometimes exceed maximum comfortable loudness levels and are increased to just below painful levels. The stimulus for EAP measurements includes a constant high-level masker, while normal operation of the implant has loudness levels which fluctuate with environmental and speech sounds. It is possible that the constant, higher than normal levels of stimulation used in EAP measurement cause vestibular sensation. In this study, only individuals who experienced vestibular symptoms since implantation noticed this effect.

EAP-based fitting protocol

EAP measurements may be useful for estimation of psychophysical levels. This may simplify and increase the accuracy of cochlear implant mapping, especially in populations where behavioral responses are inconsistent or unreliable. The ability to determine response properties of electrically stimulated neurons for the first time offers the clinician a logical rationale for parameter set manipulations in fitting cochlear implants. Such logical fitting rationales are timely, as the number of parameters which can be manipulated in cochlear implants is increasing rapidly and the population of subjects eligible for cochlear implantation is becoming more diverse.

The contour of the 250 Hz T-levels can be estimated using EAP thresholds. The dynamic range between the T- and C-levels can be estimated using the slope of the EAP growth function. Estimation of the T-level and dynamic range allows the following EAP-based fitting algorithm, demonstrated in Figure 43.

Step 1: Estimate the T- and C-level profiles from EAP data.

The first step in the EAP-based fitting protocol would be to measure EAP growth functions to determine EAP threshold and growth function slope. If EAP measurements can only be taken from a subset of electrodes due to time constraints, they should be measured from electrodes across the entire array so that values for other electrodes can be interpolated. EAP thresholds and slopes of the EAP growth functions are used for each subject to predict T- and C-level profiles, as shown in Equations 5 and 6, and Figure 43 panel A.

$$Tpredict = VisualThreshold \tag{5}$$

$$Cpredict = Tpredict + ((GrowM * GrowFactor) + GrowConstant) \tag{6}$$

The variables *VisualThreshold* and *GrowM* are the EAP visual threshold and slope of the EAP growth function, respectively. *VisualThreshold* and *GrowM* have current level units. Linear regression is used to predict the psychophysical dynamic range from the slope of the EAP growth function. *GrowFactor* and *GrowConstant* are the resulting slope and constant, respectively. The values of *GrowFactor* and *GrowConstant* determined by this study are 1.31 $CL^2/\mu V$ and 26 CL, respectively.

Step 2: Adjust T-level profile to response at threshold.

The next step is to fit the T-level profile to the level of first hearing. This is necessary because the absolute levels of EAP thresholds may correlate with any loudness from threshold to above maximum comfortable loudness. The starting T-level profile, determined from EAP thresholds, is used to set C-levels using the Win-DPS software. T-levels are set at 50 or 100 CL units below the starting C-levels, initially shifted so that maximum stimulation is at a level known not to over-stimulate, such as 100 CL. The C-levels are adjusted with global percentage modifications until the subject reports first hearing to broadband high-level stimulation in live-voice mode. High-level stimulation is required because the T-level profile is set as C-levels in the Win-DPS software. See Figure 43 panel B.

Step 3: Adjust C-level profile to response at maximum comfortable loudness.

The starting C-level profile, calculated by adding the growth function transform to the EAP thresholds shifted to low levels, is used to set C-levels using the Win-DPS software. T-levels are set to 50 or 100 CL units below the starting C-levels, initially programmed at threshold levels from step 2. The C-levels are adjusted with global percentage modifications until the subject reports maximum comfortable loudness to broadband high-level stimulation in live-voice mode. See Figure 43 panel C.

Step 4: Combine T- and C-levels for mapping.

The T-level profile adjusted to threshold loudness is combined with the C-level profile adjusted to maximum comfortable loudness. These levels are mapped into the subject's processor. See Figure 43 panel D.

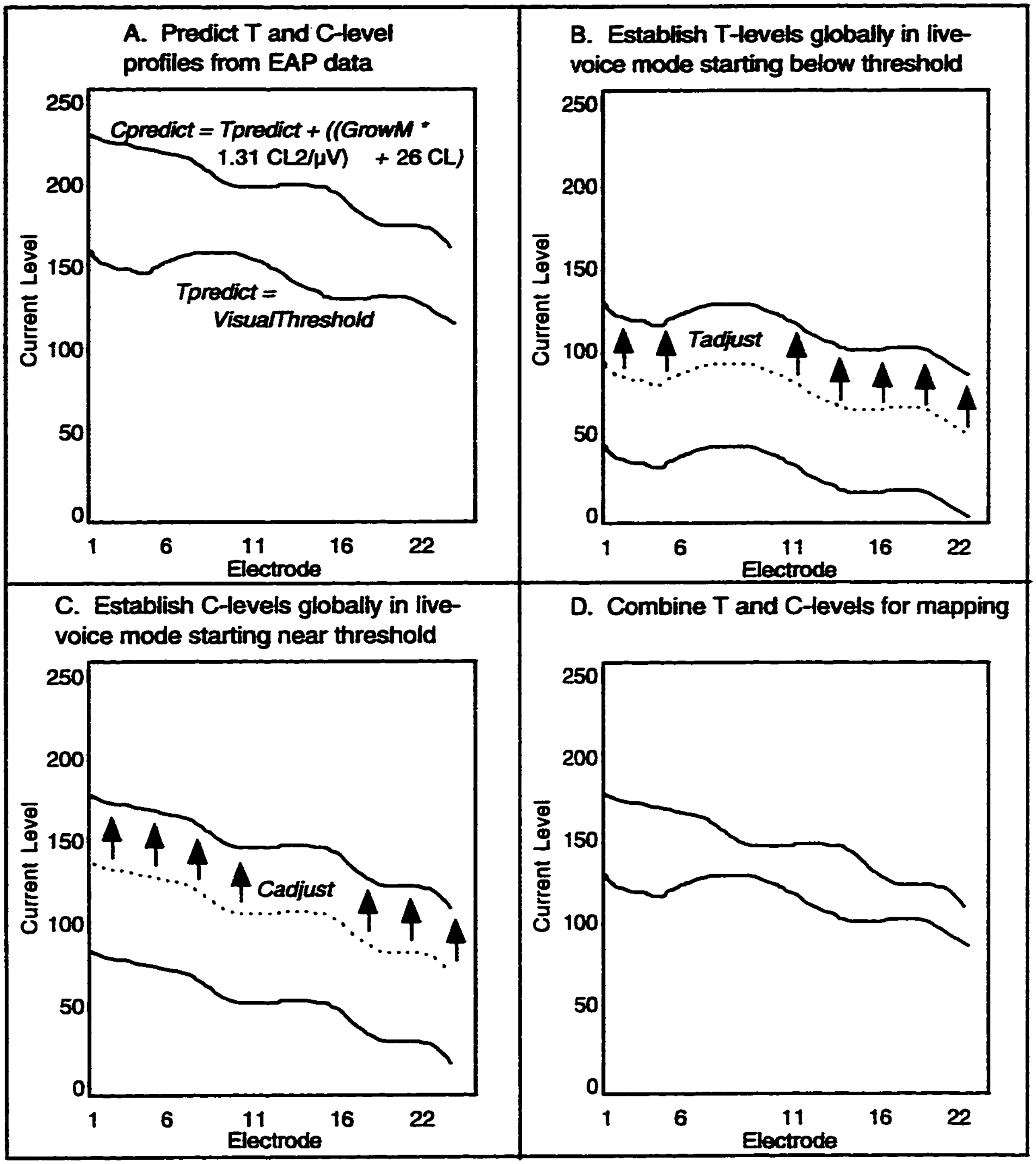

Figure 43: EAP-based fitting protocol. In panel A, T- and C-level profiles are estimated using EAP data. In panel B, the predicted T-level profile is increased to perceptual threshold in response to broadband high-level stimulation in live-voice mode. In panel C, the predicted C-level profile is increased to perceptual maximum comfortable loudness in response to broadband high-level stimulation in live-voice mode. In panel D, T- and C-levels are combined for cochlear implant mapping.

The intensity of broadband noise used to adjust T- and C-levels is determined by the input operating range, which is a function of the sensitivity setting. For the CI24M implant, sensitivity can be set from 0 to 20. Each increase in the sensitivity level decreases the input level by 1.5 dB. The dynamic range of input levels is 32 dB. At a sensitivity setting of 10, the C-level where the automatic gain control becomes active is 74 dBSPL (microphone located one meter from the sound source). Therefore, when fitting the cochlear implant with the EAP-based protocol, if the sensitivity setting were set at 10, T-levels and C-levels would be established with a 74 dBSPL broadband live-voice signal. If the sensitivity setting were set to 20, T-levels and C-levels would be established with a 59 dBSPL signal.

Ideally, steps 2 and 3 would be combined so that predicted T- and C-level profiles could be programmed into T- and C-levels, and adjusted globally with current level modifications in response to broadband stimulation in live-voice mode. However, using the current Win-DPS software, global levels can only be modified in percentage steps of the dynamic range instead of modifications in absolute levels. With percentage modification, dynamic ranges determined by the mathematical transform of the EAP growth function are altered.

The EAP-based fitting protocol was used to estimate T- and C-levels for subjects in this study. The predicted and psychophysical T- and C-levels are shown in Figure 44 and Figure 45. The threshold and maximum comfortable psychophysical loudness judgements which would be determined in steps 2 and 3 of the EAP-based fitting protocol were estimated using the T- and C-levels established by each subject.

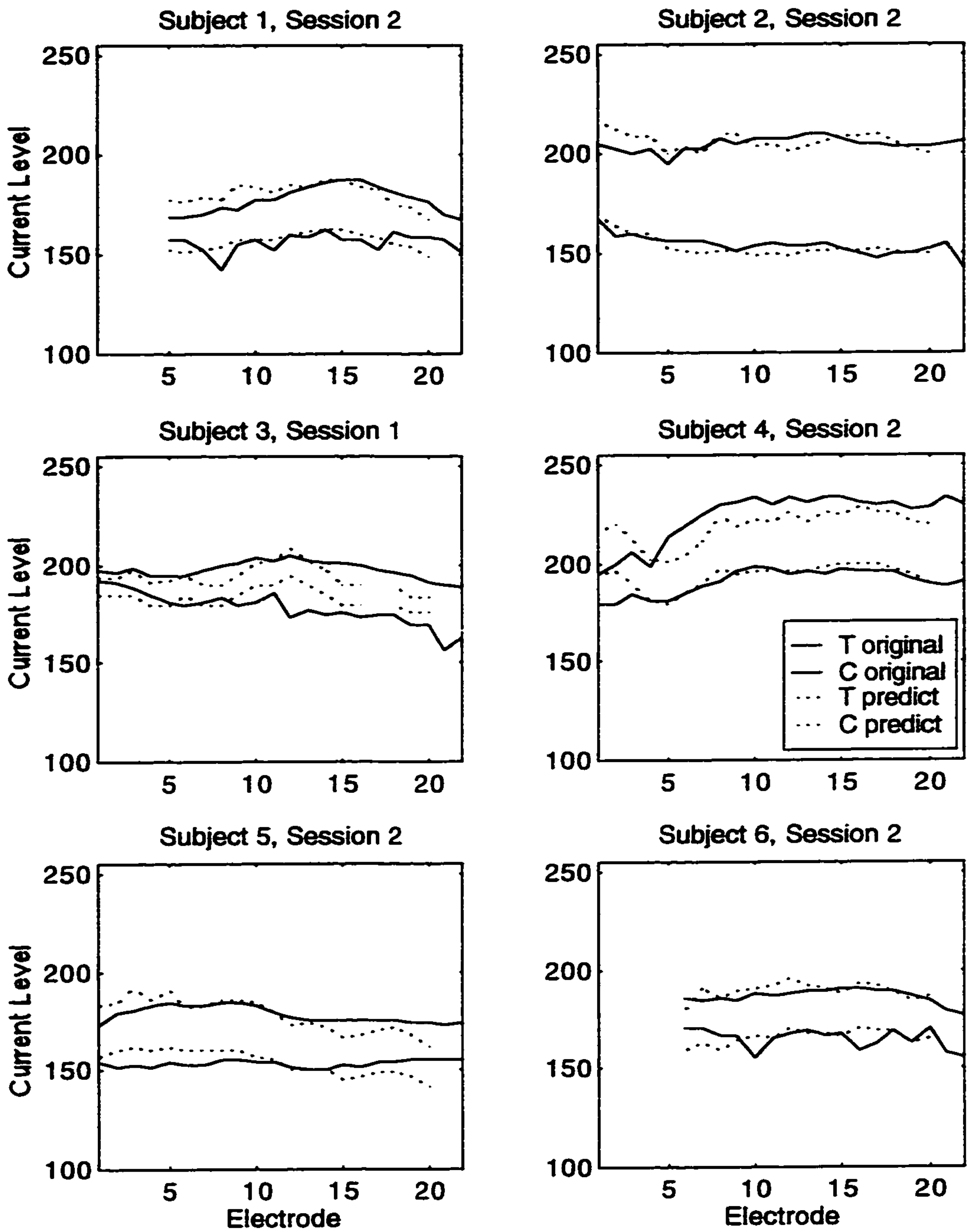

Figure 44. Comparison of traditional and EAP-based T- and C-levels for subjects 1-6.

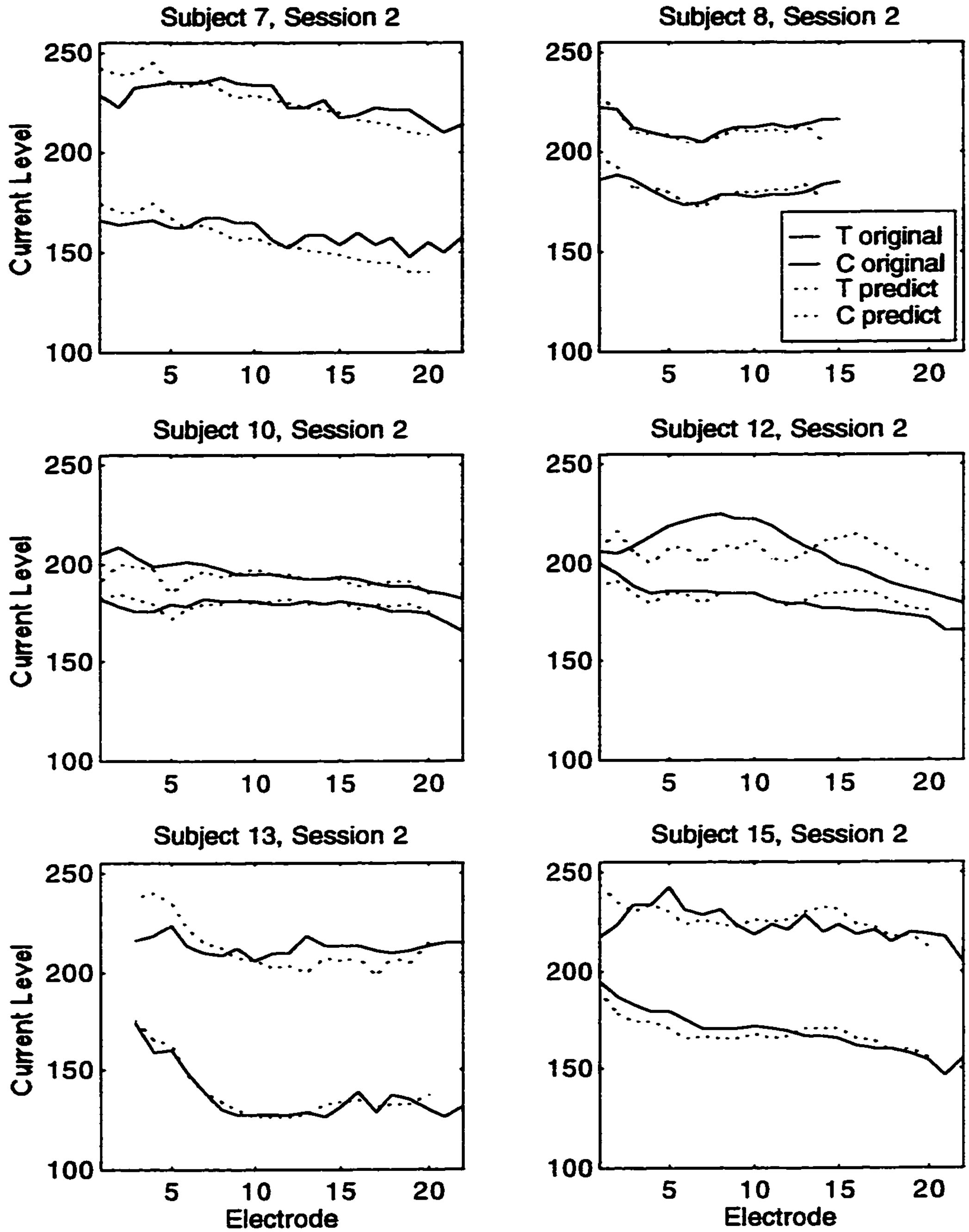

Figure 45. Same as Figure 44 except for subjects 7-15.

Because the EAP growth function is correlated with threshold and dynamic range variables which in turn are correlated with spiral ganglion cell counts, the EAP growth functions can be used to select a subset of electrodes in coding strategies such as CIS. If EAP growth functions indicate that only a small region of the cochlea spanned by the electrode array has high densities of surviving spiral ganglion cells, the CIS coding strategy is indicated. Conversely, if EAP growth functions indicate wide regions of neural survival, the SPEAK or Advanced Combination Encoder (ACE) strategies are warranted.

This study strongly supports the use of an EAP-based cochlear implant fitting protocol. An EAP-based cochlear implant fitting protocol has several advantages over the current method of fitting cochlear implants. The EAP-based implant fitting protocol only requires two loudness judgements from the subject, as opposed to 44 loudness judgements with the traditional method. Many subjects have difficulty making these repetitive loudness judgements. Judgements can be difficult because the subject is instructed to only compare the loudness of stimulation, ignoring the pitch. The EAP-based fitting protocol allows adjustment in live-voice mode. The traditional fitting protocol relies on loudness judgements from stimulation of individual electrodes. For many implant users, the perceived loudness of stimulation on individual electrodes is different from the perceived loudness of stimulation using all electrodes (live voice). It is consistent to fit the cochlear implant in the manner closest to how the implant is used during normal operation. Finally, EAP-based decision criteria for the selection of coding strategy is likely superior to chance.

EXPERIMENT II. LOUDNESS PSYCHOPHYSICS FOR DEVICE FITTING AND LOUDNESS GROWTH

Discrepancies between results from different loudness measures

Subjects were instructed to report a magnitude estimation value of one when stimulated at the level they had previously determined as their T-level, and a value of 100 when stimulated at the level they had previously determined as their C-level. The average magnitude estimation value for stimulation at the T-level was close to the expected value. However, the average magnitude estimation value for stimulation at the C-level was only half of the expected value. This discrepancy between loudness perception based upon stimulation at equal stimulus intensities indicates either that subjects are unable to reliably perform loudness judgements or that unknown differences exist in the manner loudness is estimated using the two psychophysical methods. For some cochlear implant users who have little hearing experience, the concept of loudness is difficult to understand. This difficulty is often confounded when loudness estimates are compared across electrode, which may differ in pitch.

It is doubtful that the loudness discrepancy is due to inexperience with the standard method of determining T- and C-levels. Subjects had at least three months experience with cochlear implant fitting and each had established T- and C-levels in a manner very similar to the method used in this study at least six times. In addition, criteria for determining each T- and C-level required two consistent responses before proceeding. However, subjects had no experience with loudness magnitude estimation techniques before this study and responses were the average of two stimulations at each level. The lack of training with magnitude estimation procedures could be a source of the loudness discrepancy, though loudness estimation for normal hearing listeners does not require training (Stevens, 1971). The effects of training have not been studied for loudness magnitude estimation procedures in deaf subjects with electrical stimulation. In normal hearing listeners, only one or two judgements per stimulus is required for adequate loudness magnitude estimation (Stevens, 1971). Previous loudness magnitude estimation studies using deaf subjects receiving electrical stimulation used more averages per level (Shannon, 1983; Shannon, 1985). However, in these studies loudness growth was quantified on single electrodes.

Thresholds decrease as a function of increasing stimulation frequency of electric biphasic pulse trains with constant pulse durations (Shannon, 1985). This is likely because charge per unit time increases with stimulation frequency (Eddington et al., 1978; Shannon, 1981). In this study, thresholds and maximum comfortable loudness levels at 80 Hz were not consistently higher than levels at 250 Hz. Stimulation at 80 Hz and 250 Hz can cause different pitch percepts, as described by some subjects in this study and shown in previous studies (Blamey et al., 1995; Clark et al., 1987). This discrepancy suggests that subjects either had difficulties performing loudness judgements when stimuli have different pitches or difficulty with the psychophysical task of determining T- and C-levels.

Thresholds and maximum comfortable loudness measures have been shown to be statistically higher when using a keyboard procedure than when using procedures which use a control knob (i.e. method of adjustment) for cochlear implant fitting. Average keyboard-obtained threshold levels exceed knob-obtained thresholds by 0.83 dB, and maximum comfortable loudness levels by 0.88 dB, though standard errors are large (Skinner et al., 1995). In this study, the keyboard procedure is similar to magnitude estimation in that discrete pulse trains were presented. This is unlike the knob procedure, which is similar to the procedure used to obtain T- and C-levels in this study, where a continuous signal is presented. Due to the exponential growth of loudness measured by magnitude estimation techniques, extrapolation by one decibel in some cases would result in values near 100, as can be seen in Figure 37 and Figure 38. However, this compensation may not be adequate in all cases.

When determining the T- and C-levels, subjects were presented with continuous ascending and descending stimulation levels. With the magnitude estimation procedure, stimulus intensities were presented in a random order. This may be an additional source of discrepancy between loudness estimation techniques.

FUTURE STUDIES

This study explored the clinical utility of the EAP in cochlear implant fitting, demonstrating that the EAP can be reasonably collected in a clinical setting, and that EAP data are related to psychophysical loudness measures and likely neural survival. In addition, an EAP-based implant fitting protocol was developed. Finally, this study exposed a discrepancy in loudness when measured with different techniques. Results suggest the need for further research.

Clinical acceptance of and performance tracking using EAP-based fitting protocols.

Cochlear implant fitting techniques have evolved independently at implant centers worldwide. A number of factors contribute to the apparent lack of consistency. The relative novelty of cochlear implant services and rapidly changing technology have not allowed enough time for organized studies of fitting efficacy. This is hindered in many centers by small subject populations where performance variability is too great for statistical analysis. Typical graduate programs training Audiologists do not require coursework which addresses the complex interactions of electrical stimulation of the cochlea. Fitting protocols are largely determined by manufacturer suggestions, reflecting software capabilities rather than logical fitting procedures. Nevertheless, cochlear implant users have enjoyed a high degree of success, though reasons for this success may be poorly understood. Because of this success, Audiologists may be reluctant to accept fitting protocols based on physiological data. Studies exploring the clinical acceptance of consistent fitting procedures which would include EAP-based decision criteria are needed. Studies which examine both the short-term and long-term efficacy of various cochlear implant fitting techniques are also necessary. Only with these data can one technique be shown to be more effective than another.

Further studies of loudness growth

The discrepancy between the ascending and descending loudness judgements with the stimulus control knob and loudness magnitude estimation techniques should be explored in more depth. It is possible that discrepancies are simply due to the techniques involved in this study rather than fundamental difference between constant ascending and descending stimulation and presentation of stimuli at random levels. Techniques to be explored would include expanding the range of stimuli used in magnitude estimation based on subject responses. Also allowing subjects the freedom of selecting any value instead of a fixed range between one and 100 may improve results near endpoints. The effects of training with loudness estimation techniques should also be explored so that subjects have similar experience with each.

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VITA

EDUCATION

UNIVERSITY OF WASHINGTON Seattle, WA
Department of Speech and Hearing Sciences
Doctor of Philosophy in Audiology 1999
Dissertation: *The Electrically Evoked Whole-Nerve Action Potential: Fitting Applications for Cochlear Implant Users*
Advisor: Richard Folsom, Ph.D.
Dissertation advisor: Susan Norton, Ph.D.
Certificate of Clinical Competence in Audiology June 1998

JOHNS HOPKINS UNIVERSITY Baltimore, MD
Center for Hearing Sciences
Master of Science in Biomedical Engineering August 1994
Winner of Research Competition
Thesis: *Auditory-nerve response to speech sounds in partially deafened cats*
Thesis advisor: Eric D. Young, Ph.D.

DARTMOUTH COLLEGE Hanover, NH
Bachelor of Arts in Engineering June 1992
High Honors
Thesis: *Effects of fusion characteristics on ultrahigh-molecular weight polyethylene used in total joint prostheses*
Lyon Université II, French Language study abroad Winter 1990

CLINICAL EXPERIENCE

UNIVERSITY OF WASHINGTON Seattle, WA
Department of Otolaryngology 1997 - 1998
- Fitting, behavioral and physiologic testing, and rehabilitation of patients with cochlear implants

Children's Hospital, Department of Audiology 1995 - 1996
- Behavioral and physiologic testing, and hearing aid and cochlear implant fitting in children

Speech and Hearing Clinic 1994 - 1996
- Aural rehabilitation
- Adult physiologic and behavioral hearing assessment, and hearing aid fitting

Department of Otolaryngology 1996
- Electronystagmography

Child Development and Mental Retardation Center 1995
- High risk infant follow up hearing assessment

WORK & RESEARCH EXPERIENCE

UNIVERSITY OF WASHINGTON Seattle, WA
Department of Otolaryngology 1997 - 1998
George Gates, M.D., E. Sue Sanborn, Ph.D.
- Responsible for research and clinical activities in cochlear implant team

Department of Bioengineering 1997
Francis Spelman, Ph.D., Ben Clopton, Ph.D.
- Conducted electrophysiologic and computer modeling research related to cochlear implant design

Children's Hospital, Department of Audiology 1995 – 1996p
Susan Norton, Ph.D.
- Conducted behavioral, physiologic and acoustic research in Audiology

Department of Speech and Hearing Sciences 1994 - 1997
Lynne Werner, Ph.D., Wesley Wilson, Ph.D.
- Responsible for the laboratory aspect of Hearing Science and Instrumentation courses

JOHNS HOPKINS UNIVERSITY Baltimore, MD
Eric Young, Ph.D., Center for Hearing Sciences 1992 - 1994
- Conducted surgery and neurophysiologic recording in animal models for research and instructional purposes

DARTMOUTH COLLEGE Hanover, NH
Collis Miniversity 1989 - 1992
- Taught beginner and intermediate sign language classes to students and faculty

GREEN MOUNTAIN LIONS CAMP FOR THE HEARING IMPAIRED Camp Winape, VT
Nature Director Summers 1991 - 92
- Responsible for all nature-related activities at camp for the Deaf and hearing impaired

CITY UNIVERSITY OF NEW YORK GRADUATE CENTER New York, NY
Arthur Boothroyd, Ph.D., Department of Speech and Hearing Services Spring 1990
- Conducted feasibility studies of servo motors to follow speech parameter variations in a tactile "shape" display with the goal of constructing a new tactile hearing aid
- Programmed interactive, animated test procedures for hearing impaired children

MARY IMOGENE BASSETT HOSPITAL RESEARCH INSTITUTE Cooperstown, NY
Joseph S. Bertino, Jr. Ph.D., Department of Pharmacology Summers 1988 - 92
- Developed pharmacokinetic data analysis and simulation programs utilizing the *TurboC* language
- Responsible for statistical analysis of 1,500 patient data set to be used in pharmacy studies

PUBLICATIONS & PRESENTATIONS

1. Franck KH, Norton, SJ. (1999). The Electrically Evoked Whole-Nerve Action Potential: Fitting Applications for Cochlear Implant Users. Poster at the 22nd Midwinter Research Meeting of the Association for Research in Otolaryngology. St. Petersburg Beach, FL.

2. Franck KH. (1998). Clinical Applications of Neural Response Telemetry. Presented at Cochlear Corporation's N24 Training Workshop. Seatac, WA.

3. Franck KH, Sanborn ES, Norton SN. (1998). Objective Measures in Cochlear Implant Fitting. Presented at the 2nd Annual Prentice Bloedel Research Day of the University of Washington. Seattle, WA.

4. Franck KH, Sanborn ES. (1998). Cables and Cords - Plugging In Without Blowing Up. Presented at Ears Hearing & Beyond, The Second Annual Citizen's Conference of the Virginia Merrill Bloedel Hearing Research Center. Seattle, WA.

5. Miller RL, Schilling JR, Young ED, Franck KR. (1997). Representation of the Vowel /eh/ in the Auditory Nerve of Cats with a Noise-Induced Hearing Loss. In W. Jesteadt (Ed.), *Modeling Sensorineural Hearing Loss* (pp. 35-48). New Jersey: Lawrence Erlbaum Associates.

6. Miller RL, Schilling JR, Franck KR, Young ED. (1997). Effects of Acoustic Trauma on the Representation of the Vowel /ε/ in Cat Auditory Nerve Fibers. *Journal of the Acoustical Society of America*, 101(6), 3602-16.

7. Norton SJ, Harrison WA, Mascher KE, Franck KH. (1997). Effects of brief exposure to intense sound on distortion product otoacoustic emissions and behavioral thresholds in humans. Poster at the 20th Midwinter Research Meeting of the Association for Research in Otolaryngology. St. Petersburg Beach, FL.

8. Franck KR. (1995). Universal Infant Hearing Screening Protocol. Presented at Beijing Medical Union College. Beijing, China.

9. Miller RL, Schilling JR, Franck KR, Young ED. (1995). Representation of the Vowel /ε/ in the Auditory Nerve of Cats with a Noise-induced Hearing Loss. Poster at Modeling Sensorineural Hearing Loss meeting at Boys Town National Research Hospital. Omaha, NE.

10. Franck KR. (1994). Auditory Nerve Response to Speech Sounds in Partially Deafened Cats. Presented at the 14th Annual Speech Research Symposium of the Center for Speech Processing of the Johns Hopkins University. Baltimore, MD.

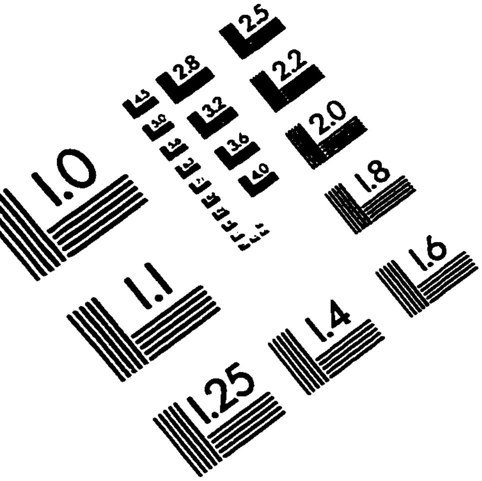
11. Franck KR, Bertino JS Jr. (1994). KINI: A One Compartment Intravenous Pharmacokinetic Analysis Program. *Computer Programs in Biomedicine*, 42,157-165.

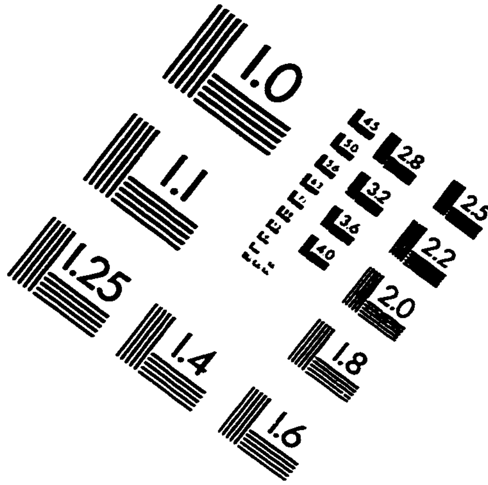
12. Bertino JS Jr., Booker LA, Franck PA, Jenkins PL, Franck KR, Nafziger AN. (1993). Incidence of and Significant Risk Factors for Aminoglycoside-Associated Nephrotoxicity in Patients Dosed Using Individualized Pharmacokinetic Monitoring. *Journal of Infectious Diseases*, 167,173-9.

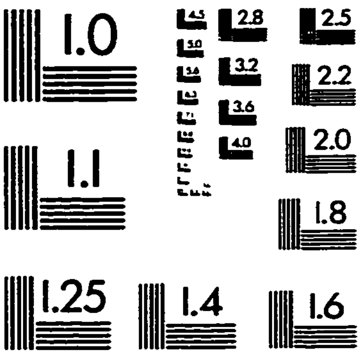
CONFERENCES ATTENDED

- 10th Annual Convention of the American Academy of Audiology. Los Angeles, CA. April, 1998.
- 1997 Conference on Implantable Auditory Prostheses. Asilomar Conference Center, CA. August, 1997
- 19th Midwinter Research Meeting of the Association for Research in Otolaryngology. St. Petersburg Beach, FL. February, 1996.
- 6th Symposium on Cochlear Implants in Children. Miami, FL. February, 1996.
- Citizen Ambassador Program: Education of the Deaf and Hard of Hearing Delegation to the People's Republic of China and Korea. June, 1995.
- The Alexander Graham Bell Association for the Deaf Biennial International Convention. Rochester, NY. June, 1994.
- 14th Annual Speech Research Symposium of the Center for Speech Processing of the Johns Hopkins University. Baltimore, MD. June, 1994.
- 17th Midwinter Research Meeting of the Association for Research in Otolaryngology. St. Petersburg Beach, FL. February, 1994.
- 5th Symposium on Cochlear Implants in Children. New York, NY. February, 1994.
- 24th Annual Neural Prosthesis Workshop. Bethesda, MD. October, 1993.
- 23rd Annual Meeting of the Society for Neuroscience. Washington, DC. 1993.

IMAGE EVALUATION TEST TARGET (QA-3)







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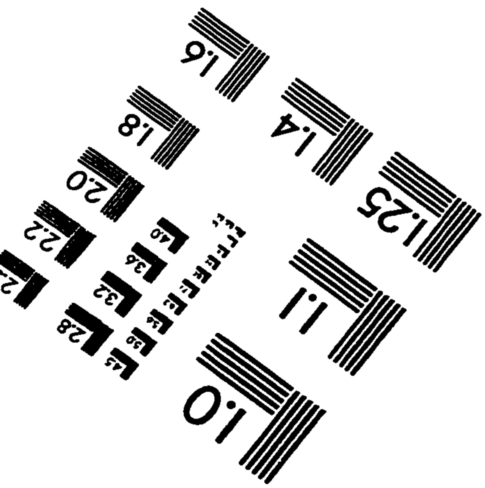

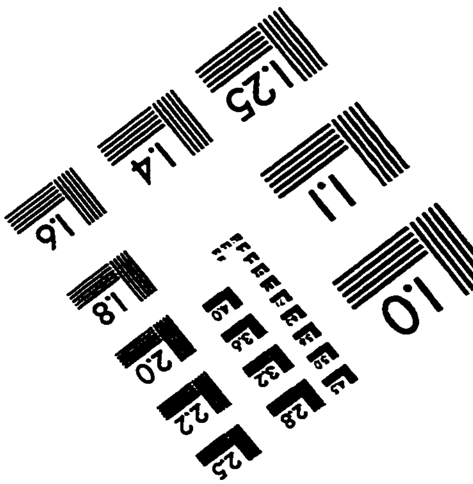

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