

Second Quarterly Progress Report

April 1, 2002 through June 30, 2002

Speech Processors for Auditory Prostheses

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submitted by

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1.0 Introduction

Work performed with the support of this contract is directed at the design, development, and evaluation of sound-processing strategies for auditory prostheses implanted in deaf humans. The investigators, engineers, audiologists and students conducting this work are from four collaborating institutions: the Massachusetts Institute of Technology (MIT), the Massachusetts Eye and Ear Infirmary (MEEI), Boston University (BU) and the University of North Carolina at Chapel Hill (UNC-CH). Major research efforts are proceeding in four areas: (1) developing and maintaining a laboratory-based, software-controlled, real-time stimulation facility for making psychophysical measurements, recording field and evoked potentials and implementing/testing a wide range of monolateral and bilateral sound-processing strategies, (2) refining the sound processing algorithms used in current commercial and laboratory processors, (3) exploring new sound-processing strategies for implanted subjects, and (4) understanding factors contributing to the wide range of performance seen in the population of implantees through psychophysical, evoked-response and fMRI measures.

Effort during the second quarter has focused on continued data collection for ongoing studies and on further preparation for upcoming experiments. In particular, psychophysical data collection has begun with three bilaterally-implanted subjects using the software /hardware tools developed during Q1 to enable presentation of highly synchronized pulsatile stimuli bilaterally. In addition, data collection has continued in our study of triphasic waveforms for reducing channel interactions. The results of these studies will be reported in a subsequent QPR. This QPR focuses on our efforts to develop techniques for measuring and analyzing scalp potentials related to intracochlear stimulation and implementing techniques for reducing artifact when measuring intracochlear evoked potentials.

Plans described in QPR1 to develop during Q2 a measure of channel interactions using measures of intracochlear evoked potentials (IEP) have been temporarily delayed in favor of accelerated development of hardware and software tools for use in objectively verifying proper operation of implanted devices *in situ*. These tools also will have the capability for recording brainstem and cortical evoked potentials from auditory pathways in response to electrical stimulation. This shift in emphasis was made to best utilize the skills of a graduate student assistant, Ms. Punita Christopher, who joined the UNC-CH laboratory during Q2. Ms. Christopher is initially involved in circuit board layout and logic design as she transitions into the overall project. Development of IEP measures of channel interactions will resume in Q3.

Details of these ongoing studies and development activities will be included in later QPRs. In this QPR, we describe the field potential and recording tools developed at UNC-CH in collaboration with Advanced Bionics Corporation. Example data collected at MEEI from patients implanted with the Clarion CII system are included. During Q2 the capabilities of this system have been expanded and tested in subjects at MEEI to include electrical artifact reduction using the scaled-template-subtraction method.

2.0 Background

Many factors contribute to the large variations in performance observed among implantees. Important individual differences probably include variations in the anatomy, physiology and distribution of both peripheral VIII nerve fibers and central auditory pathways, as well as variations in general cognitive abilities that mediate speech reception. Variations in device design, including characteristics and placement of the intracochlear electrode array and the sound processing strategy are also of importance.

This view follows from two lines of evidence and reasoning: First, across the broad range of performance that exists among subjects using a given implant system, substantial order is observed among a variety of traditional measures of speech reception (e.g., Rabinowitz, WM et al. 1992). These measures span a continuum from open-set recognition of words in sentences and words in isolation (NU-6), closed-set consonant and vowel identification, and perception of underlying phonetic features. When factors relating the intrinsic properties of such tests are taken into account, relatively high correlations (exceeding 0.85) are found among different speech-reception measures (Rabinowitz, WM et al. 1992). Second, although variability among subjects using a given processing strategy is large, within-subject comparisons of different processing strategies exhibit high correlations in performance. With speech tests that avoid floor and ceiling limitations, correlations near 0.9 are frequently observed (e.g., Dowell et al. 1987; Wilson, BS et al. 1993). Taken together, these results suggest that underlying subject variables, which are independent of processing strategy appear responsible for much of the observed variation in performance. This is also consistent with observations by Rubinstein. et al. (1999) that a majority of the variance associated with speech reception measures made across patients can be accounted for by the duration of their deafness and their preoperative performance on a test of sentence recognition. In addition, given the general similarity of performance distributions across and within patient populations receiving the three major clinical systems, it is likely the case that the anatomy and physiology of individual subjects is a major factor in determining outcome as opposed to electrode or processor design *per se*.

Consequently, we hypothesize that improved outcomes may be obtained if speech processor design and fitting address these factors in individual subjects. It is therefore essential that we develop the ability to measure the bases for individual variability within single subjects. This project approaches this problem in multiple ways, including the electrical and physiological assessment of the peripheral cochlea, evaluation of neural responses in the brainstem and cortex using evoked responses, and, where possible, global functional imaging using fMRI. The following section describes our current progress in the electrical and physiological assessment of the cochlear periphery of Clarion C-II patients. Subsequent QPRs will describe progress with other assessment approaches. Combined application of each assessment tool in individual subjects is our ultimate goal, so that a more complete picture of how factors in both the peripheral cochlear interface and the central nervous system influence speech processor design and performance.

3.0 Intracochlear Potential Recording

Functional assessment of the implanted cochlea has long been a goal in cochlear implantation. Although psychophysical measures are often interpreted to infer conditions within the cochlea, they suffer the limitation that other factors involving more central portions the auditory pathways may influence the observations. EABR measures have helped but still are limited given the documented central changes that occur with deafness. Early work with Ineraid patients, whose percutaneous connectors allowed direct connection to the implanted intracochlear electrodes, demonstrated that monitoring of electrical stimulation artifact potentials and evoked neural responses from unstimulated electrode contacts was feasible. Some later generation implant systems feature dedicated on-board instrumentation to facilitate monitoring of the intracochlear environment. The first of these was the Neural Response Telemetry (NRT) feature of the Nucleus cochlear implant system. Work in this project will focus primarily on patients implanted with either the Ineraid percutaneous system or the Clarion C-II transcutaneous system with the Hi-Focus electrode.

Each of these devices offers unique opportunities and challenges to cochlear assessment. The percutaneous connector-linked Ineraid system offers a direct, high-bandwidth connection to the implanted electrode contacts, which allows great flexibility in stimulation and recording instrumentation. However, the typical Ineraid subject has six intracochlear contacts that are spaced four millimeters apart longitudinally and are located along the outer wall of scala tympani away from the spiral ganglion. Consequently, this electrode configuration offers relatively few intracochlear recording contact locations, each with limited spatial resolution. In contrast, intracochlear recording with the transcutaneous telemetry-linked Clarion C-II system is dependent on the onboard recording system integrated into the implanted stimulator. Fortunately, this onboard system is quite capable and is functionally based on the instrumentation we previously developed for direct recording with Ineraid subjects. Collaborator CF in this project has worked closely with Advanced Bionics for the past three years in the implementation of the C-II monitoring system. One potential advantage of this system is the Hi-Focus electrode which provides sixteen contacts spaced on 0.7 mm centers. The electrode array is positioned adjacent to the modiolar wall near the spiral ganglion. The combination of more, closely-spaced, and closely-positioned contacts for recording may provide better spatial resolution in assessing the cochlear environment. The following paragraphs describe the Clarion C-II recording system in greater detail and present new research capabilities implemented in the course of this project.

The Clarion C-II recording system is an integrated, analog potential measurement subsystem for measuring electrical field and evoked neural potentials appearing at unstimulated electrodes during active stimulation. The same hardware system is also used to monitor on-chip test potentials and potentials at stimulated electrodes for impedance measurements. Support software divides the measurement of electrical artifact fields and measurement of neural responses in to two separate tasks named commercially by ABC as

Electrical Field Imaging (EFI) and Neural Response Imaging (NRI), respectively. Both systems are presently research tools and are not employed in standard clinical fitting.

As shown in Figure 1, the basic system consists of specialized recording hardware located onboard the implanted stimulator chip that amplifies, converts and finally transmits recorded data via backward-telemetry to a speech processor. The speech processor acts as a communication link to a personal computer, which in turn controls stimulation and analyses the recorded data.

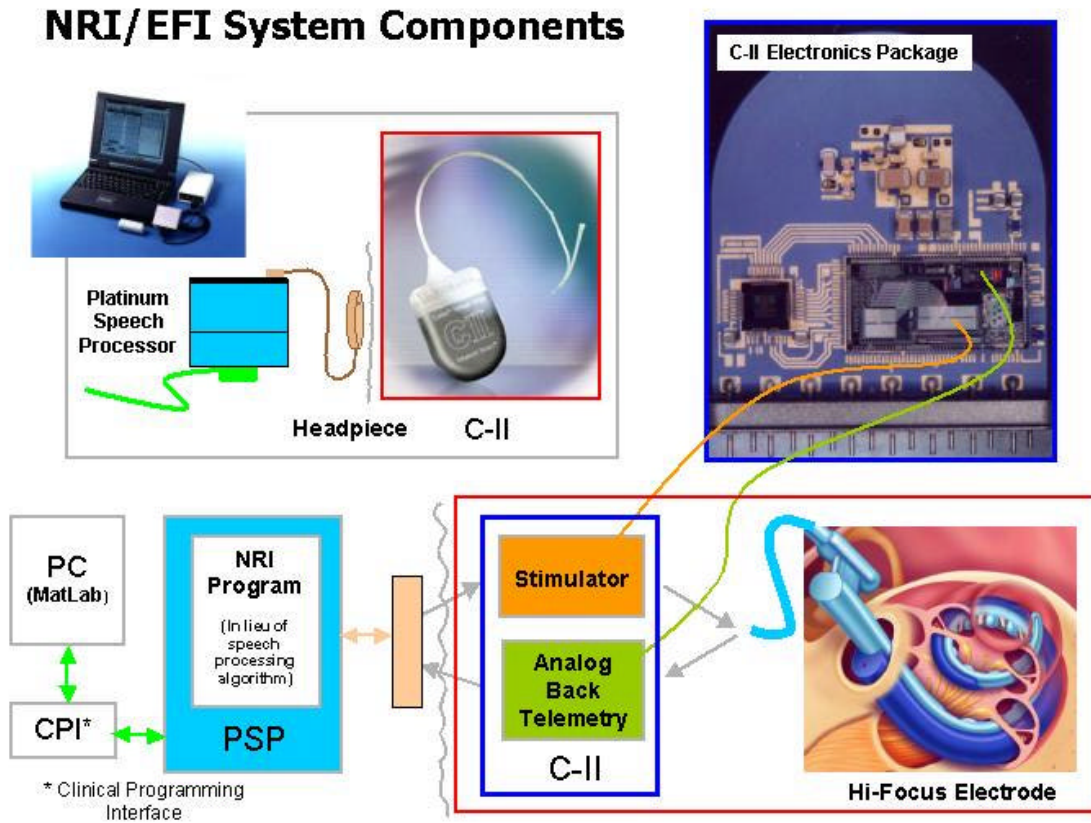


Figure 1

As depicted in Figure 2, the front-end design of the recording system includes a single-channel, high-gain (selectable up to x722), fast-recovery (<20 usec), differential amplifier

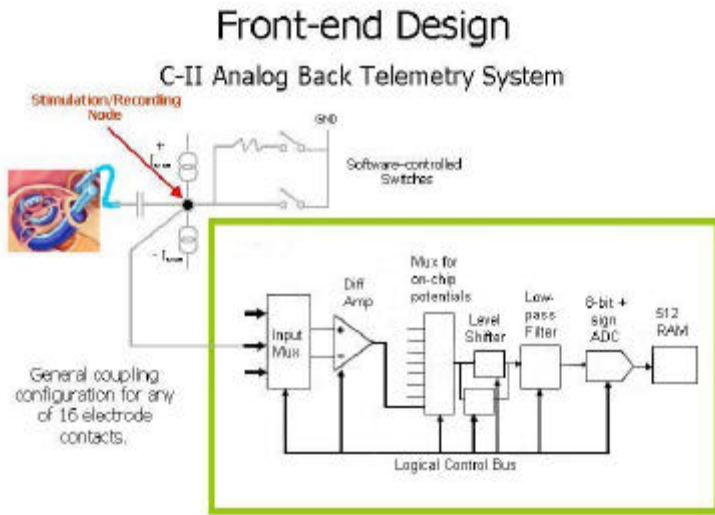


Figure 2

intracochlear electrode sites of the Clarion Hi-Focus electrode, the extracochlear caseband, the on-chip system ground reference, and other on-chip test sites. During active stimulation, data may be collected synchronously over an approximately 8-9 msec time window at a 55 kHz sampling rate (approximately 50 msec window at 10 kHz sampling). Stimulation may occur on one or multiple electrode contacts with monopolar and/or bipolar coupling. Recorded data are stored in a buffer (512 words maximum) within the implanted device and are then transferred via back-telemetry once the data collection buffer is full. Special stimulation and data processing procedures are also employed to minimize inherent system synchronous noise.

When used in the EFI mode to record relatively large artifact potentials on both stimulated and unstimulated contacts during stimulation, the amplifier is operated at low gain (x1- x6) and the diode-clipping feature is disabled.

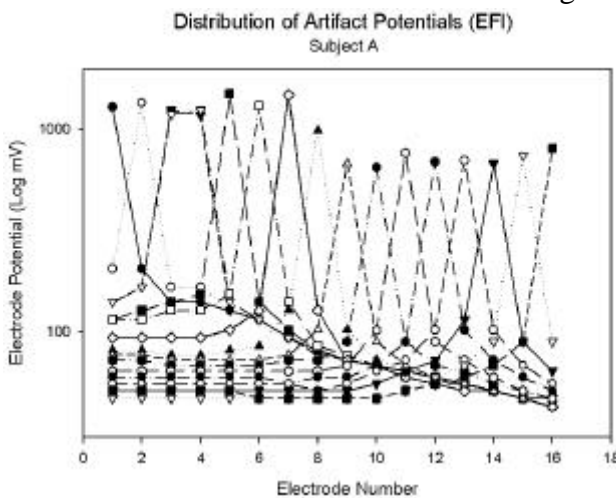


Figure 3

with analog-to-digital conversion (8-bit plus sign @ 10 or 55 kHz sampling rate). Signal clipping in response to stimulus artifact is symmetrically limited about ground potential by high-speed, switching diodes before each gain stage so that that each cascaded gain stage maintains linear, high-speed, non-saturating operation. Input sources to the amplifier may be

selected via multiplexers from any of the 16

Because stimulation is delivered with a current source, the relative magnitude of the potential on the stimulated contact scales directly with electrode impedance, whereas potentials appearing on the unstimulated contacts along the array generally reflect the stimulus electrical field distribution occurring longitudinally within scala tympani. Figure 3 shows artifact potential data collected in C-II Subject A. These

data are plotted on a log scale as a function of recording electrode number (electrode 1 being most apical). For each electrode in the array, the stimulus was applied and potentials were measured sequentially from all electrodes in the array. Consequently, sixteen sets of data are plotted. The data presented in Figure 3 are actually composite data from two recording runs. One run was made at a low amplifier gain to ensure that the largest potentials from the stimulated contacts do not saturate. The other run was made at higher amplifier gain to ensure that the smaller potentials recorded from the unstimulated contacts are well above the ADC's least-significant-bit value. In Figure 3 the solid curve with filled circles shows the data for stimulating on electrode 1. This curve begins with a peak on electrode 1 (indicating the relative electrode impedance of the stimulated electrode), then drops abruptly to lower levels on all of the unstimulated contacts (e2-e16). Potentials on the unstimulated contacts decline from a peak on electrode 2 to a minimum on electrode 16. This progression shows the longitudinal spread of the stimulus field along the electrode array within scala tympani. Each set of data has a peak at the electrode being stimulated with a gradation of potentials from the unstimulated contacts with greater distance from the stimulated contact. There are several points of interest in the data from Subject A. First, the curves for stimulation on electrodes 3 and 4 overlay one another indicating that these two contacts are shorted. The specific location of the short is not known at present. Second, there is an abrupt transition in electrode impedance in the vicinity of electrode 8 with all more apical contacts having elevated impedances as compared to the basal contacts. There may be multiple causes of this impedance increase including, but not limited to, a general change in the conduction properties of scala tympani possibly due to tissue scarring apically, a change in the electrode interface characteristics in the apical region, or smaller than usual effective contact surface area due to contamination or manufacturing defect. Finally, in examining the lower-level potentials from the unstimulated contacts there is a trend to have steeper gradients toward the base than toward the apex as would be expected for the observed conduction properties of scala tympani in favoring current flow toward the base (Girzon, 1987).

Further insight into the status of Subject A's cochlea has been obtained using the recording system in the NRI mode. The following paragraphs describe the general operation of the system in recording evoked neural responses and present further preliminary data regarding Subject A.

In the NRI mode the amplifier gain is increased and the diode-clipping feature enabled. Although the recording system design ensures fast-recovery from stimulus artifact overload, there is nevertheless slow decay of the stimulus artifact due to residual charge in the tissue, at the electrode interface, and in the stimulator coupling capacitors. The decaying artifact potential overlaps temporally with the beginning of the short-latency IEP response, resulting in an artifact-contaminated raw data signal. Consequently, additional processing is necessary to recover IEP responses from the raw data records.

The system supports several artifact-reduction processing schemes, including *forwarding masking*, *summed alternation*, and *scaled-template subtraction*. Common to all of these schemes is the strategy of directly or indirectly characterizing the artifact component and subtracting it from a raw data record to leave the neural response

waveform. The *forward masking* method assumes that the response to a probe stimulus immediately following an initial high-intensity “masker” stimulus is pure stimulus artifact and contains no neural response due to neural refraction. This artifact template can then be subtracted from a raw response to the second stimulus alone to obtain the uncontaminated neural response. The success of this method is dependent on how effective the masker is in eliminating neural response to the probe, thus requiring large masker levels.

The *summed alternation* method averages responses elicited by an equal number of stimuli of alternating positive and negative initial polarities. In principle, the averaged response has no net artifact remaining. While this method may be effectively used across a wide stimulus range, the resulting response is a composite of responses to both cathodic-leading and anodic-leading stimuli and is consequently more difficult to interpret. Figure 4 shows a typical IEP response measured using the summed alternation method. This figure illustrates the long-duration residual artifact components that occur with stimulation of a

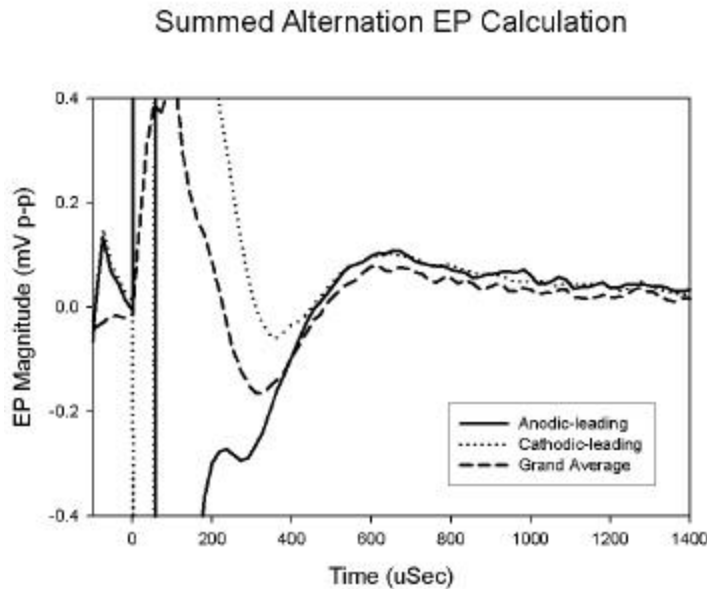


Figure 4

single, fixed-polarity stimulus. Each polarity of stimulation produces a raw signal that decays to the baseline exponentially. When the two components are summed together, the artifact residuals sum to zero leaving the resultant neural response or “grand average” as shown by the dashed line of the figure. Both the forward masking and summed alternation techniques are supported by the current release of research software distributed by Advanced Bionics.

We have used the summed alternation approach to measure neural responses in Subject A. The upper panel of Figure 5 shows the growth of the intracochlear neural responses recorded from an electrode two contacts apical to the indicated stimulating contact. Evoked potential magnitude is plotted as a function of stimulus intensity for stimulation on electrodes 5, 7, 10 and 15. The growth of the neural response is highly variable, depending on the stimulating electrode location with the largest responses seen with stimulation of more basal electrodes. The single pulse stimulation ranged from threshold to loud perceived levels, unless otherwise limited by other percepts. Stimulation on either contact 5 or 7 produced relatively small response growth over an acceptable stimulus range. Responses could not be obtained on electrodes 1 or 3 at acceptable stimulus levels. The lower panel of Figure 5 shows approximate psychophysical measures obtained in a quick non rigorous survey obtained at the beginning of testing to establish acceptable stimulus ranges. The top horizontal bar indicates the stimulus levels at which

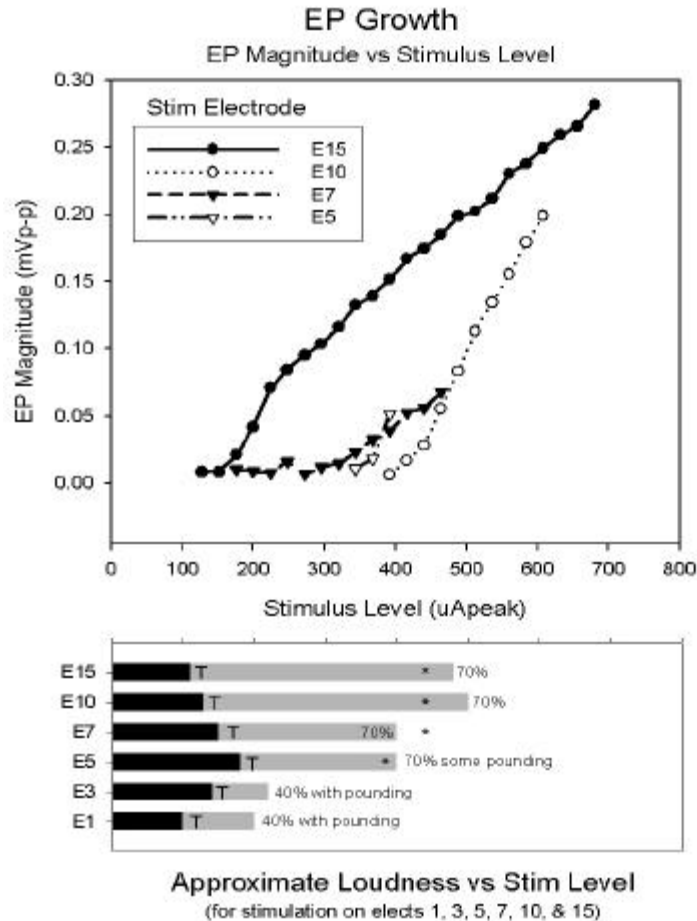


Figure 5

threshold (T) and comfortable (about 70% on a 100% scale) loudness occurred for stimulation on electrode 15. The abscissa is the same as that for the growth plots in the upper panel. For EP growth measures on electrodes 7, 10 and 15, stimulation ranged up to a maximal acceptable level (approximately 90%). On electrodes 1, 3, and 5, stimulation was limited by the occurrence of an uncomfortable “pounding” sensation felt in the ear. The pounding and hearing sensations were clearly distinct from one another. The notation at the end of each bar indicates the perceived loudness at the maximal acceptable stimulus level. For electrodes on which the stimulation range was not limited by somatic sensations, there appears to be a reduction in dynamic range (T to 70%) with more apical stimulation. The “*” symbols on the first four bars indicate the stimulus levels used on electrodes 5, 7, 10 and 15 for the measures described in the next paragraph.

Each curve of Figure 6 shows the spatial distribution of neural responses from unstimulated electrodes to a constant, comfortable stimulus level on a fixed stimulating electrode. Evoked potential magnitudes are plotted as a function of recording electrode position, holding the site of stimulation constant. Data are shown for stimulation on electrodes 5, 6, 7, 10 and 15. EP data are not measured from the contact being stimulated. Single pulse stimulus level was held relatively constant across electrodes (384 uA for E5

and E6; 440 uA for E7, E10 and E15) as indicated by the “*” in the lower panel of Figure 5. As seen with the growth functions of Figure 5, the largest responses are measured with basal stimulation and the neural responses are observed to peak in the vicinity of the stimulating contact. In contrast with stimulation in the apical region, the responses are small and do not demonstrate a strong peaking around the stimulating contact.

This preliminary cochlear assessment of Subject A is interesting from several perspectives. The artifact potentials suggest that Subject A’s electrode array and intrascalar electrical environment may be altered from what is expected for most subjects. The neural response and psychophysical data suggest that the ability to stimulate neurons in the apical region may be compromised. This may be due to a combination of several

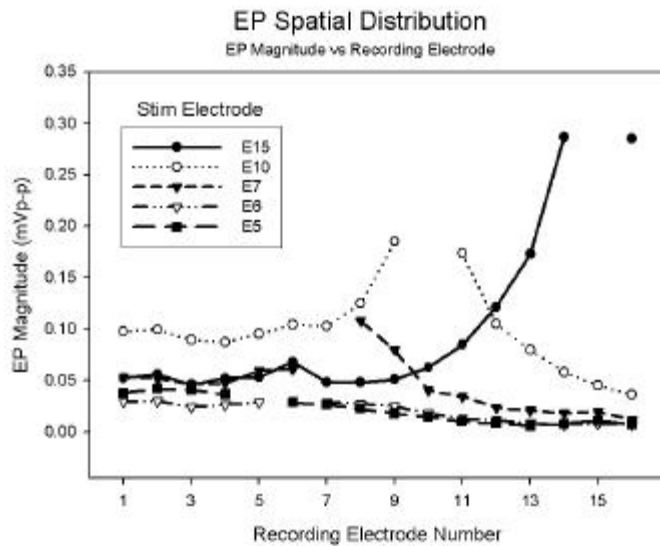


Figure 6

strategies that address these intracochlear factors are key goals for this project. The goal in this QPR has been to illustrate the types of data and the potential utility of intracochlear potential measures. Future QPRs will report more detailed studies with this and other subjects using additional tools in development.

As co-developers of this platform with ABC, we have (during Q2) expanded the software to support the *scaled-template subtraction* method. This method involves averaging records using a fixed-polarity, suprathreshold test stimulus, followed by subtraction of a derived template of the residual artifact from the average record to obtain an artifact-free evoked potential. The derived or scaled artifact template is obtained by reducing the stimulus to a sub neural threshold level and averaging the pure artifact. The artifact is then arithmetically scaled to the test stimulus level and subtracted from the averaged response. Figure 7 shows the essential components of this procedure to obtain the evoked neural response to an anodic-leading biphasic pulse. The suprathreshold stimulus was delivered at 392 uA on electrode 15. The response was recorded from electrode 13. The subthreshold record was obtained with a 128 uA stimulus. Consequently, the scaling factor

for the subthreshold record was 3.06 ($=392/128$) to derive the scaled template. This method assumes linearity of the measurement system, which is, in general, the case. Figure 8 compares EP results obtained with the summed-alternation and the scaled-template methods. The neural responses to anodic- and cathodic-leading stimuli differ in both latency and magnitude. The summation of these two components is the same result as that obtained by the summed alternation method (Figure 4). Advantages of the scaled-template approach are that responses to complex stimulus trains of any polarity may be obtained and additional insight into the underlying biophysical mechanisms may be available. Future QPRs will report on our studies using this methodology.

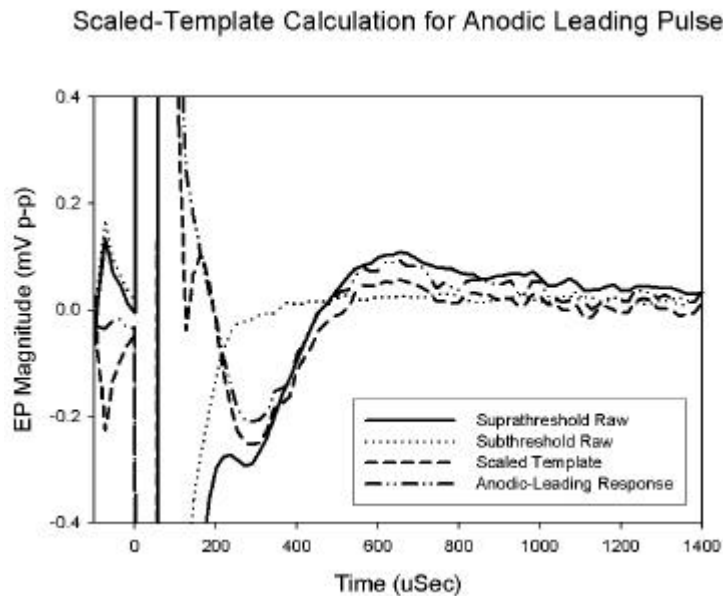


Figure 7

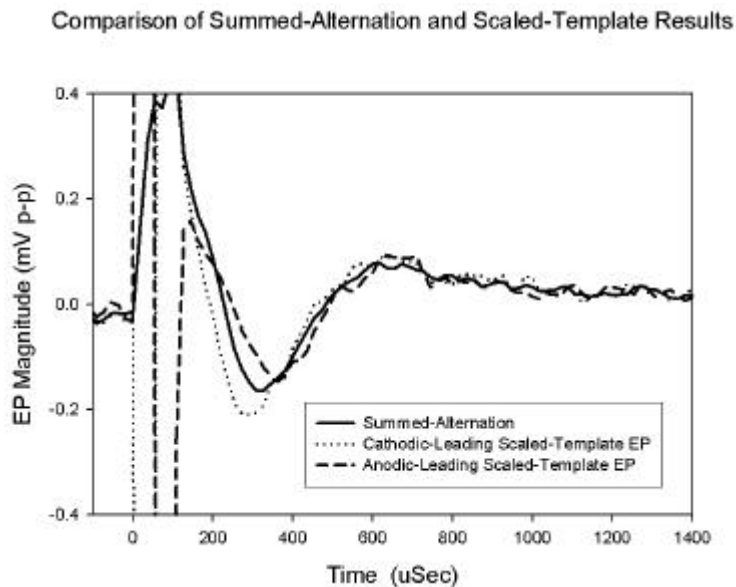


Figure 8

Work Planned for Quarter 3

Next Quarter we plan to continue work directed at reducing channel interaction in high-rate stimulation by the use of triphasic stimulation waveforms. The acute testing of speech reception in Ineraid subjects using CIS sound-processing strategies where the band envelopes modulate trains of triphasic pulses was essentially completed in Q2. In Q3, we hope to complete testing a second group of Clarion C-II subjects with CIS triphasic strategies. The speech reception of these CIS strategies will be compared with the classic CIS strategy modulating biphasic pulse trains in both of these groups.

We also plan to continue the psychophysical testing of the three local subjects who have bilateral implants. These initial experiments explore techniques for selecting interaural electrode pairs for bilateral stimulation. This work is important because all of the bilateral psychophysical testing (ITD and ILD sensitivity) and the design of sound-processing strategies for bilateral stimulation will build on these results.

Following final validation of the IEP measurement tools describe earlier in this QPR, a survey of Clarion C-II subjects at MEEI will be conducted to examine the magnitudes and general variability of the spatial distributions of IEP responses across a range of subjects with differing speech reception outcomes.

Once modifications of the IEP software at UNC-CH to enable measures of channel interactions have been completed, an initial group of selected subjects at MEEI for whom previous threshold and suprathreshold psychophysical measures of channel interaction have been obtained will be studied using IEP methods. These studies should begin by the middle of Q3. In the medium and long term, interaction measures based on the IEP method will be compared to those measured psychophysically. We expect these comparisons to be interesting because the IEP techniques will reflect only the most peripheral factors influencing interaction while the behavioral measures will also include those contributed by more central processing.

Work will continue at UNC-CH to develop recording tools for electrically-elicited surface artifact potentials and evoked response measures. Once the safety and accuracy of these tools has been validated using bench measures, subject trials will begin at MEEI during Q3.

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