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The relation between ECAP measurements and the effect of rate on behavioral thresholds in cochlear implant users

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Running Title: ECAPS and rate of stimulation

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Abstract

It has been shown that electrically evoked compound action potential (ECAP) thresholds are not sufficiently predictive of behavioral thresholds to allow their use as a totally objective method to program a cochlear implant. Previous animal studies have shown that two other ECAP parameters (the ECAP amplitude growth slope and the effect on ECAPs of changing the phase duration (PD) or interphase gap (IPG)), and the way that behavioral thresholds change with increasing rate of stimulation, are associated with cochlear health. This experiment tested the hypotheses that a) the degree to which behavioral thresholds change with rate of stimulation is associated with either or both of those two ECAP parameters, and that b) the accuracy of ECAP thresholds for predicting behavioral thresholds at clinically relevant rates can be increased by including those additional ECAP parameters. Both these hypotheses were confirmed by the data. The ECAP slope was associated with within-subject variation across electrode positions of both behavioral thresholds and the change of thresholds with increasing rate. The effect of changes in IPG or PD on ECAPs was moderately associated with between-subjects variations in both average absolute behavioral thresholds and the average effect of rate on thresholds. The inclusion of the IPG/PD effect to predict average absolute behavioral thresholds for each subject and inclusion of the ECAP growth slope to predict variation in relative thresholds across electrode positions in the same subject led to a significant increase in accuracy of the predicted behavioral thresholds.

Keywords: cochlear implant, electrically evoked compound action potential, rate of stimulation

List of abbreviations:

CI	Cochlear implant
CL	Current level
ECAP	Electrically evoked compound action potential
IPG	Inter-phase gap
PD	Phase duration
pps	Pulses per second
SGC	Spiral ganglion cell
NRT	Neural response telemetry
3IFC	Three interval forced choice
SD	Standard deviation

INTRODUCTION

Studies in guinea pigs have shown both behavioral and electrophysiological correlates of cochlear pathology. Using electrical pulse trains in the cochlea, Pfingst et al (2011) have shown that animals with poor survival of spiral ganglion cells (SGCs) have a reduced effect of rate of stimulation on behavioral thresholds for rates up to 1000 pulses per second (pps). Similarly, several features of electrically evoked compound action potentials (ECAPs) have been correlated with SGC survival. These ECAP features include: the current change required for equal ECAP amplitude when inter-phase gap (IPG) or phase duration (PD) are changed (Prado-Guitierrez et al., 2006; Ramekers et al., 2014); the change of N1 peak latency as IPG or PD are changed (Ramekers et al., 2014); and the N1-P2 amplitude growth slope (Pfingst et al., 2015a; Pfingst et al., 2015b). The use of these ECAP or behavioral measures in human cochlear implant (CI) users to infer SGC survival or cochlear health relies on the assumption that their relation to SGC survival applies in the human case as in the animal case. Some support for this assumption has come from a recent paper by Zhou and Pfingst (2014), who showed that, in bilateral CI users, the ears with the better speech understanding were those that had the greater effect of rate on behavioral threshold. Under the assumption that animal data can be applied to humans, the ECAP and behavioral measures should be correlated with each other in human CI users, since they are both influenced by SGC survival. The present study aimed to first test whether this correlation exists, and then to evaluate whether such a correlation can be used to improve the accuracy of ECAP measures for totally automated programming of cochlear implants.

ECAP thresholds (measured using single pulses at measurement rates of 40 Hz or 80 Hz) are only moderately correlated with behavioral thresholds when the latter are measured using pulse trains of rates relevant to CI programming (generally above 500 pps) (Cafarelli Dees et al., 2005;

McKay et al., 2005; Potts et al., 2007). This moderate correlation is not sufficient for totally objective programming of CIs. In contrast, a relatively good correlation has been noted between ECAP thresholds and behavioral thresholds measured using pulse trains at very low rates (Brown et al., 1998; Brown et al., 1996; Zimmerling et al., 2002). Thus, the poorer correlation between ECAP thresholds and behavioral thresholds at high rates of stimulation compared to low rates is driven by the difference between behavioral thresholds at high and low rates and how this difference varies among CI users. Given that ECAP threshold is highly predictive of low-rate behavioral thresholds, an additional objective measure that could predict the change in behavioral threshold between low rates and the high rates relevant to CI outputs (such as the ECAP features mentioned above, potentially) could be combined with ECAP thresholds to improve the accuracy of automated programming of CIs at high rates.

McKay et al have published a series of papers that developed a model that successfully accounts for a variety of temporal effects in electrical stimulation (McKay et al., 1998; McKay et al., 2010; McKay et al., 2005; McKay et al., 2013a; McKay et al., 2003; McKay et al., 2013b). In this model, the change in behavioral threshold as rate increases depends on three factors: a central temporal integration window, the output of which increases with rate as more stimulus pulses are contained within it; the effect of adaptation, accomodation or refractoriness, which together decreases the number of spikes evoked for each pulse as the interpulse interval decreases; and the relation between current level and spike activity, which is assumed to be a power function over small ranges of current change and is level-dependent. When applying this model to a range of psychophysical phenomena in CI users, McKay et al. have shown that the central temporal integration window derived from normal hearing psychophysics (Oxenham, 2001; Oxenham et al., 1994; Plack et al., 2002) is appropriate to apply to CI users. It was deduced that the central integration mechanism is resistant to the effects of peripheral deafness, and is relatively invariant among different CI users. It follows that the variation between CI users of the effect of rate on threshold can be hypothesized to be significantly contributed to by a combination of the second and third factors (the decrease in spike activity per pulse as rate increases and the current-to-excitation function).

McKay et al (2013b) investigated the degree to which the reduction in activity evoked by each pulse as rate increased differed among CI users and whether this effect could explain a significant amount of the variance in the effect of rate on behavioral threshold. In that study, ECAP amplitudes were measured using a technique whereby the amplitude to the nth pulse in a pulse train was derived by subtracting the response after n-1 pulses from the response after the nth pulse. The ratio reduction in ECAP amplitude compared to that of the first pulse in the pulse train was assumed to be related to the ratio reduction in number of neural spikes evoked by the probe pulse compared to the same pulse in a very low rate pulse train. The ECAP data was then used in the model to predict the effect of rate on behavioral thresholds. The reduction in neural spike activity with increasing rate was expected to be greatest at high rates, as was found, with the ECAP amplitude decreasing on average from around 0.85 of that of the first pulse at 500 pps rate to around 0.35 of the amplitude at 2400 Hz.

The model was successful in using the ECAP data to predict the average behavioral threshold versus rate functions for the subjects in that study, when using previously determined values for the integration window and the current-to-excitation slopes. It was found however that, for rates above 500 pps, both the slope of the threshold versus rate function and the ECAP reduction ratio did not vary very much between subjects. In contrast, most of the variation between low (40 pps) and high (up to 2400 pps) rate thresholds among subjects occurred in the low-rate range of 40 to

500 pps where there would be minimal influence of refractory or accommodation effects. The lack of a correlation between the ECAP amplitude reduction as rate increased and the behavioral threshold changes as rate increased was replicated by Hughes et al. (2014). McKay et al. (2013) concluded that, provided the model assumptions were valid, the variation of the current-to-excitation function among subjects must be a factor that significantly contributes to the variation in the slope of the behavioral threshold versus rate function for rates less than 500 pps. A steeper current-to-excitation function would lead to less current adjustment being needed to equalize neural activity when rate is increased. One possible reason for the low-rate threshold versus rate slope being found to be correlated with SGC density (Pfingst et al., 2011) in guinea pigs is that, when the SGC density is poorer a higher current is needed to evoke threshold hearing, and this higher current could reach more central and tightly packed neural material in the internal auditory meatus in animals with poor SGC survival, leading to a steeper current-to-excitation function when that occurs. Hughes et al. (2014) also tested the hypotheses that the rate that produced maximum alternation in ECAP responses or the rate at which the alternation no longer occurred may also be correlated with the change of behavioral thresholds with rate, but these hypotheses were not supported by the data.

McKay et al (2013b) concluded that, to improve the objective prediction of high-rate behavioral thresholds using ECAPs, an objective measure additional to ECAP threshold was needed that was correlated with the slope of the threshold versus rate function in the *low rate* region. The potential ECAP features that have been correlated with SGC density, and therefore may be correlated with the threshold versus rate function slope in the low-rate region, are the effects of PD or IPG on ECAPs or the ECAP amplitude growth slope, as described above. In this study, we hypothesized that these features are correlated with the slope of the behavioral threshold versus rate function in the low-rate region, and that these measures can therefore improve the prediction accuracy for high rate behavioral thresholds using a combination ECAP data alone.

1. METHODS

1.1. Subjects

Fifteen adult cochlear implant users were recruited for this experiment. Five subjects were later excluded from the study due to ECAP thresholds being too high for reliable estimates of the effect of PD and IPG to be determined. All remaining subjects were users of the CI24RE or CI512 implants manufactured by Cochlear Ltd. Type of implant, the electrode locations where a full dataset was acquired, duration of time since implantation, duration of severe deafness, and etiology for all remaining participants are shown in Table 1. The project was approved by the Human Ethics Committee of the Royal Victorian Eye and Ear Hospital (14/1180H). All participants provided their informed consent.

1.2. ECAP measurements

ECAP measurements were obtained for each subject via neural response telemetry (NRT) through CUSTOM SOUND EP version 4.0 software provided by Cochlear Ltd. ECAP stimuli were cathodic-leading biphasic pulses. The probe electrode was set, by default, as intracochlear electrodes 1, 4, 7, 10, 13, 16, 19, or 22, in MP1 mode. The recording electrode was 2 electrodes offset from the probe electrode and in MP2 mode. The standard forward masking procedure of Brown et al. (1990) was used to remove artefact, with a masker-probe interval of 500 μs and the masker pulse level set 10 current levels (CLs) above that of the probe pulse. Four IPG/PD pulse combinations were used 1) PD 25 μs IPG 8 μs, 2) PD 40 μs IPG 8 μs, 3) PD 25 μs IPG 40 μs, 4) PD 40 μs IPG 40 μs. NRT recordings were averaged over 50 sweeps. NRT recordings were made at a 40 Hz presentation rate. Amplifier delay, measured from probe stimulus offset, was set to 122 μs and amplifier gain to 60 dB.

Before collecting data for ECAP amplitude growth functions in the four IPG/PD conditions, the 'stimulate only' function of the software was used to determine the CL range from approximate ECAP threshold to maximum tolerable CL for each IPG/PD condition of each selected electrode. In some cases the software indicated that the implant exceeded the compliance level or it was evident that the amplifier was saturated by the stimulus artifact before the maximum tolerable level was reached. In the case of amplifier saturation, a reduced gain of 50 dB and/or an increased amplifier delay (130 μs) was used. Amplifier delay and gain settings were kept constant across the four conditions for any single electrode. If no clear ECAP was evident at a CL lower than the maximum tolerable CL in any one of the four IPG/PD conditions, an alternative probe electrode position was tried. In this way a set of 'usable electrodes' was obtained for each subject. There were a significant number of electrodes found to be unusable using this criterion. Table 1 shows the probe electrodes used for data collection in each subject. Over the ten subjects, 52 electrodes in total were used in the study.

Amplitude growth functions (ECAP N1 to P1 peak amplitude in μV versus stimulus level in CL) were obtained for the four stimulus conditions for each electrode, using up to 7 CLs within the estimated range between ECAP threshold and the maximum useable level. Voltage versus time series data were exported for each NRT recording, with ECAP peaks and amplitudes determined automatically through CUSTOM SOUND EP's peak-picking software.

The data of interest for our study were the CL adjustments needed to equalize ECAP amplitude between the 4 different IPG/PD conditions. To obtain these values, the 4 amplitude growth functions were first plotted. An example is shown in Figure 1 for subject CI9, electrode 12. The functions were truncated at a high and low voltage values to isolate the linear proportions of the functions, and the remaining data were fitted using linear regression (red lines in color). The mean horizontal offsets between the regression lines (in CL) were then calculated for the amplitude range of data that was common to all the four functions (between the horizontal lines – blue in color). The slopes of the linear sections (in μV/CL) were also calculated and averaged over the four IPG/PD conditions for each electrode/subject for further analysis.

ECAP thresholds were calculated from the amplitude growth functions for the [PD = 25 μs; IPG = 8 μs] condition (i.e. the same parameters as for the behavioral thresholds). ECAP threshold was defined as the CL at which the extrapolated linear regression line reached zero μV.

1.3. Psychophysical measurements

Behavioral thresholds were determined using pulse trains of 500 ms duration and rates of 40, 500, 1000, and 2000 pps and using the same probe electrodes as for the electrophysiological measures. The stimulation mode was MP1+2 and IPG and PD were set to typical speech processor settings of 8 and 25 μs respectively. Stimuli were controlled and subject responses recorded, using ImPResS software (developed at Melbourne University in collaboration with the MRC-CBU in Cambridge, UK). The software directly controlled the delivery of the electrical stimulus to the implanted electrodes via a SPEAR research processor (developed at the Hearing CRC in Melbourne). A response box was used to visually represent trial time intervals and to record subject responses. Thresholds were obtained using an adaptive three interval three-alternative forced choice task, in which subjects were asked to select which of three intervals (separated by 500 ms) in each trial contained a sound. A two-down, one-up adaptive procedure was used with a step size of 5 CL until two reversals were obtained and then a step size of 2 CL until a total of 10 reversals were obtained. Threshold was calculated as the mean CL at the final six reversals.

2. RESULTS

2.1. Predicting the effect of rate on behavioral threshold

Figure 2 shows an example of the ECAP waveforms measured for two different conditions - [PD 25 μs IPG 8 μs] (left) and [PD 40 μs IPG 40 μs] - at different probe current levels, illustrating the difference in probe current needed for the same response amplitude in the two conditions. From the four IPG/PD conditions, four different comparisons were made: The effect of changing IPG from 8 to 25 μs with a fixed PD at either 25 or 40 μs; and the effect of changing PD from 25 to 40 μs with fixed IPG of either 8 or 25 μs. For each probe electrode, the means (and standard deviations - SDs) of the CL adjustments to equalize ECAP amplitude for changes in PD and IPG were as follows. The mean adjustment in CL for changing IPG from 8 to 25 μs was 6.98 (SD 1.78) and 9.93 (SD 2.59) at PDs of 40 and 25 μs respectively. The adjustment for changing PD from 25 to 40 μs was 22.39 (SD 1.57) and 25.34 (SD 2.33) at IPGs of 25 and 8 μs respectively. For both the IPG-change effect and the PD-change effect, the mean CL adjustment needed for equal ECAP amplitude was larger when the fixed value of PD or IPG was smaller (Wilcoxon Signed Rank Test, $Z = 6.275$, $p < 0.001$ in both cases). Since all four measures were highly correlated with each other ($r > 0.7$, $p < 0.0001$), a single measure for each subject/electrode was derived for further analysis and for comparison with behavioral data. This measure combined IPG and PD effects and was the current adjustment between the condition with smallest total biphasic pulse duration [PD 25 μs IPG 8 μs] and that with the largest total pulse duration [PD 40 μs IPG 40 μs]. The mean (and SD) of this measure (referred to below as the IPG/PD effect) was 32.32 CL (SD 3.86).

Figure 3 shows the effect of rate of stimulation on behavioral threshold for the 10 subjects, with data averaged across the electrodes tested for each subject. For each subject/electrode, the change of behavioral threshold with rate was divided into two parts: the difference between 40 pps and 1000 pps; and the difference between 1000 pps and 2000 pps. Since animal studies showed that only low-rate changes (up to 1000 Hz) were correlated with cochlear pathology, it was hypothesized here that only the low-rate threshold changes would be correlated with the IPG/PD effect or the ECAP amplitude growth slope.

Since the data included multiple electrodes in the same subjects as well as multiple subjects, statistical the analysis separated the within-subject effects from across-subject effects. The mean data across electrodes (behavioral threshold changes with rate, ECAP slopes, IPG/PD effects) was calculated for each subject (n = 10) to investigate across-subject effects. To investigate within-subject effects (profile across electrodes), the mean data-value across electrodes for each subject was subtracted from each electrode's absolute data values. Each new data point (n = 52) then represented the value *normalized relative to the mean for that subject*.

Best subsets regression was used to investigate the association between change of behavioral threshold with rate and the three ECAP measures (threshold, slope, and IPG/PD effect). Since the power of the between-subject analysis was rather low (n= 10) compared to the within-subject analysis (n = 52) a loose criterion for significance ($p < 0.2$) was adopted in the former case when interpreting the results, with more emphasis being on the r-squared values.

Table 2 shows the results of the best-subset regressions. The best subset was selected as that with the highest adjusted r-squared. The change of behavioral thresholds between rates of 1000 to 2000 pps was not associated with any of the three ECAP measures for either within- or across-subject data, as hypothesized. The within-subject change of behavioral thresholds between 40 and 1000 pps was significantly associated with the ECAP slope and marginally associated with the ECAP threshold. That is, within each subject, electrodes that had a greater drop in threshold with increasing rate of stimulation were those that had greater ECAP slopes and/or a tendency towards higher ECAP thresholds. The variance inflation factor (VIF = 1.01) indicates that the two factors, ECAP threshold and slope profiles, contributed independently to the regression, and were not correlated with each other (n = 52, r = -0.1, p = 0.48). However, across subjects, the average change in behavioral threshold from 40 to 1000 pps for each subject was best predicted by the IPG/PD effect alone. That is, subjects who showed a greater change of behavioral thresholds between 40 and 1000 pps on average were those that had larger IPG/PD effects.

In summary, subjects with a larger average effect of rate on threshold had a larger average IPG/PD effect, whereas, within each subject, the electrodes with the larger effect of rate on threshold were those that had a relatively greater ECAP amplitude growth slope and relatively higher ECAP thresholds. Both these results are consistent with animal studies that have associated all three measures (ECAP slope, IPG/PD and change of behavioral thresholds with rate) with cochlear health. However the two ECAP measures (ECAP slope and IPG/PD effect) accounted for different types of variance in the behavioral data and were not significantly correlated with each other, either within subjects (n = 52, r = 0.13, p = 0.36) or between subjects (n = 10, r = 0.32, p = 0.37).

2.2. Predicting the profile of behavioral thresholds across electrode position.

Current semi-objective fitting methods measure the ECAP threshold profile across electrode positions and use this profile to predict behavioral level profiles (e.g. Gordon et al., 2004). The absolute current levels for programming the CI are then determined using behavioral methods. In this section we evaluate whether the profile of thresholds across electrode positions can be better-predicted using multiple ECAP measures rather than from ECAP thresholds alone. The profile of behavioral thresholds across electrode positions was calculated for each subject and rate of stimulation by subtracting the mean threshold across electrodes from each individual threshold (similarly to the subject-normalization carried out in section 2.1). Each data point then represented the degree to which threshold at a particular electrode position differed from the mean threshold across electrodes. A best-subsets regression was performed with behavioral threshold profile as the dependent variable and within-subject profiles of the three ECAP measures (ECAP threshold, ECAP amplitude growth slope and IPG/PD effect) as the independent variables.

Table 3 (second row) shows the best predictive model (based on best adjusted r-squared) for each rate of stimulation tested in the behavioral data. The best sets regression found that the ECAP amplitude growth slope profile was a highly significant predictor of the behavioral threshold profile at every stimulation rate tested. At each rate, a combination of two of the three predictors was found to produce the highest adjusted r-squared. For rates of 40, 500, and 1000 pps, a combination of ECAP threshold profile and ECAP amplitude growth slope profile best predicted behavioral threshold profiles, with the contribution of ECAP thresholds reducing as rate increased. Electrodes with greater ECAP slopes and higher ECAP thresholds tended to have higher behavioral thresholds. For 2000 pps, ECAP threshold profile no longer contributed to the best model, and the IPG/PD effect had a mild influence: at 2000 pps, electrodes with a smaller

IPG/PD effect and greater ECAP slope tended to have higher behavioral thresholds. It is of interest to note, since ECAP threshold profiles are currently used clinically to predict behavioral threshold profiles, that the ECAP threshold profile alone (top row) was not significantly correlated with the behavioral threshold profile except at the 40 pps rate. In contrast, the best single-predictor model for the rates above 40 pps was the ECAP amplitude growth slope. Figure 4 illustrates the improvement in predicted behavioral threshold profile for rates of 1000 pps when ECAP growth slope profile was included as a predictor along with ECAP threshold profile (panel B) compared to when ECAP threshold profile alone was used (panel A). Figure 5 shows an example profile of 1000 ppp behavioral thresholds for subject CI3 (open triangles), along with the ECAP threshold profile (filled circles) and the predicted behavioral threshold profile using both the ECAP threshold and slope profiles and using the regression equation in Table 3 (filled squares). The ECAP and behavioral threshold profiles in this subject were quite different in the apical part of the array, and the predicted behavioral profile using both ECAP threshold and slope profiles is closer to the actual behavioral profile than is the ECAP profile.

2.3. Prediction of absolute behavioral thresholds

If ECAPs were to be used for totally objective fitting, ECAP features alone would need to account for a very high proportion of variance in the absolute behavioral thresholds (and also variance in the dynamic range on each electrode). To achieve this goal, the average behavioral threshold needs to be determined for each individual, as well as the profile across electrodes. In this section the predictive value of the combined ECAP measures for absolute threshold determination is evaluated.

The variance across subjects of the across-electrode averaged thresholds was investigated using best subsets regression. Table 4, second row, shows the best model, based upon best adjusted r-squared, for predicting the average absolute threshold (average across electrodes for each subject) from the three ECAP features (also averaged across electrode positions: n = 10). In this analysis, the ECAP amplitude growth slope did not feature in any best model at any stimulation rate. The best model for all rates included both the average ECAP threshold and the average IPG/PD effect. Subjects with higher average behavioral thresholds were those with higher average ECAP thresholds and smaller IPG/PD effect. However, using average ECAP thresholds alone to predict average behavioral thresholds (Table 4, top row) did not account for significant across-subject variation in absolute average thresholds except for the 40 pps rate (p = 0.08). Figure 6 (panel A) illustrates the predicted versus actual average absolute behavioral thresholds using combined ECAP thresholds and IPG/PD effect. It is interesting to note that the average ECAP threshold in the best subsets model always had a coefficient very close to 1 for every rate of stimulation (Table 4). This means that the best predictive model is essentially predicting the *offset* between the average ECAP threshold and the average behavioral threshold, using the IPG/PD effect alone, with the influence of IPG/PD on this offset increasing with stimulation rate (the regression coefficient becomes more negative at higher rates). Figure 6 (panel B) illustrates the predicted versus actual offset for the rate of 1000 pps.

In summary, the analysis so far suggests that 1) the ECAP growth function slope accounted for a significant amount of within-subject variance across electrode positions in the behavioral threshold profile at every stimulation rate, with greater slopes predicting relatively higher thresholds, whereas 2) the ECAP IPG/PD effect had the most influence on variance in the across-subject differences in average absolute behavioral thresholds, where higher average absolute thresholds were associated with smaller IPG/PD effects. In both within- and across-subject analyses, the predictive value of ECAP thresholds was limited to low-rate behavioral thresholds. This pattern of results was analogous to that found for the effect of rate on behavioral thresholds. That is, ECAP growth slope was associated with the within-subject variance in the effect of rate on threshold, whereas the IPG/PD effect was associated with between-subject differences in the effect of rate.

3. DISCUSSION AND CONCLUSIONS

3.1. Predicting change of behavioral threshold with rate of stimulation

The results of this study weakly supported our hypotheses that the adjustment of current needed to equalize ECAP amplitude for different IPG and/or different PD was correlated with the change in behavioral threshold between 40 pps and 1000 pps. This correlation lends some support to the proposal that both factors are influenced by cochlear health in humans as has been shown in animal studies (Pfingst et al., 2011; Prado-Guitierrez et al., 2006; Ramekers et al., 2014). The influence of the IPG/PD effect on how thresholds change with rate was further supported by the increasing coefficient of IPG/PD as rate increased in the multiple regression predicting subject-average absolute thresholds (Table 4), while the coefficient of ECAP threshold remained constant across different rates. The mechanisms by which the IPG/PD effect and the change of behavioral thresholds with rate are influenced by cochlear health remain hypothetical, however, but are likely to differ. For example variations in the IPG/PD effect may be due to variations in the health or type of neural material being activated, which in turn may influence the temporal charging characteristics of the neurons and hence the effect of temporal stimulus parameters such as IPG and PD. On the other hand, McKay et al (2013b) have suggested that the relation between cochlear health and the effect of rate of stimulation on behavioral thresholds may be driven, at least on part, by differences in the slope of the current-to-excitation function, which may be steeper at higher stimulus levels when there is poor SGC survival.

The negative correlation between the psychophysical threshold changes with rate and ECAP IPG/PD effects was largely driven by across-subject rather than within-subject variance. The lack of relation to within-subject variance could be due to cochlear health not varying very much across the different electrode positions used in our participants. It may be true in general that across-subject variation in cochlear health is greater than across-cochlear variation, or alternatively, our selection procedure for electrodes to be included in the study (based on good ECAP responses) may have limited the across-cochlear variation in cochlear health. If that were the case, the question of why ECAP slope was able to partially predicted the relative size of the change of threshold with rate across the array (but not the absolute size of the change in subject-average results) would need to be addressed.

In contrast to the IPG/PD effect, the slopes of the ECAP growth functions accounted for within-subject but not across subject variance in the changes in threshold with rate of stimulation in the low-rate region. The fact that the two ECAP parameters (growth slope and IPG/PD effect) accounted for different types of variance (within- or across-subjects, respectively) in the effect of rate on threshold implies that underlying causes of the relationships may differ in the two cases. For example the non-monotonic changes in ECAP slopes seen in animals in the days after implantation (Pfingst et al., 2015a) argue against those changes being due to loss and recovery of SGCs, but more related to changes in neural health status or electrical impedance changes over time. Furthermore, the within-subject profile of ECAP slopes and IPG/PD effects in this study were not correlated with each other ($r = 0.13$, $p = 0.36$, $n = 52$). It is plausible that the ECAP growth slopes would be subject to sources of across-subject variance additional to those contributing to within-subject variance, due to factors such as electrical impedances within the cochlea fluids and other cochlea material. These hypothetical additional sources of across-subject variance (which would have minimal influence on the IPG/PD effect) may have reduced the correlation of ECAP slopes with across-subject differences in the effect of rate on threshold. However, this additional across-subject variance would not explain why only the ECAP slopes, and not the IPG/PD effects predicted the within-subject relative differences in the effect of rate on thresholds. It is possible that within-subject variations in ECAP growth slope are more sensitive to small within-subject variations in cochlear health than within subject variations in IPG/PD effect, but only the IPG/PD effect could demonstrate the larger across-subject variations in cochlear health because of the additional (non cochlear-health-related) across-subject variance in ECAP slopes. Alternatively the correlation between relative within-subject profile of change of thresholds with rate and ECAP slope profile might be driven by factors not related to cochlear health, as further discussed in section 3.2.

Further research is needed to elucidate the mechanisms underlying the association of the ECAP parameters to cochlear health. However, the results support the potential use of the psychophysical or ECAP measures as a proxy for cochlear health in research that aims to determine the effect of cochlear health on outcomes with a CI.

3.2. Predicting behavioral threshold profiles across electrodes and the average absolute behavioral thresholds for different subjects at fixed rates of stimulation.

In a similar pattern to the prediction of the effect of rate on threshold, the within-subject profile of behavioral thresholds across electrode positions at fixed rates of stimulation (Table 3) was best predicted using the ECAP growth slope profile as well as the ECAP threshold profile. For within-subject threshold profiles at fixed rates of 1000 pps and below, electrodes with higher behavioral thresholds than the average level corresponded to those with higher ECAP thresholds and those with greater ECAP slopes. Essentially, greater ECAP slopes were associated with behavioral thresholds closer to the ECAP thresholds (thus higher).

At first sight this result may seem to be in conflict with animal studies that have suggested that greater ECAP slopes are associated with lower absolute behavioral thresholds and better neural survival. However, caution should be exercised when comparing those studies (e.g. Pfingst, et al. 2015a; Pfingst, et al. 2015b) with the current one, as the units used to express the slope the animal studies (μV/μA) differed from that used in this study (μV/CL - CL being a logarithmic unit). It has been argued that changes in stimulus current should always be expressed in ratio or log units, especially when comparing current adjustments in different conditions or ears etc (see discussion in McKay 2012). If two electrodes have the same ECAP growth slope in μV/CL but different ECAP thresholds, the one with the higher ECAP threshold will have a shallower slope when the slope is expressed in μV/μA. Since ECAP and behavioral thresholds are correlated, the relation seen in animal studies where shallower ECAP slope was associated with higher behavioral thresholds, might partly result from the units used as well as, or instead of, any physiological relationship between ECAP slope and SGC survival.

The current unit that the ECAP slope is calculated in has an important influence on how data is interpreted. For example, Schvartz-Leyzac and Pfingst (2016) showed a negative correlation in CI users between average ECAP slope (in linear units of current) and duration of deafness. Although this result could be interpreted to suggest that ECAP slope is positively correlated with neural survival, it is also possible (but not testable in the published data) that the subjects with greater duration of deafness may have had higher ECAP thresholds than those with less duration of deafness (due to poorer neural survival), and that the found correlation may have been driven by the higher absolute ECAP thresholds rather than the ECAP growth slope independent of absolute level.

The question remains of "Why would higher behavioral threshold levels be associated with *greater* ECAP slopes in the present data?" It should be stressed that this result only applied to the *relative* behavioral levels across electrodes, and not the *absolute* levels, and that the regression equation to predict behavioral threshold profile across electrodes included ECAP threshold as well as ECAP slope. The regression suggests that, given a constant ECAP threshold across the array, the absolute behavioral threshold would tend to be closer to the absolute ECAP threshold (i.e. higher) when the ECAP slope is steep. This effect could be independent of SGC status and instead result from the ECAP threshold being a more sensitive measure when the ECAP slope is greater.

In contrast to within-subject profiles, the across-subject *average absolute* behavioral thresholds (Table 4) were best predicted using the average IPG/PD effect as well as the average ECAP threshold. The IPG/PD effect essentially predicted the *offset* between average behavioral thresholds and average ECAP thresholds. Subjects with greater average IPG/PD effects had average behavioral thresholds that were lower *relative* to the ECAP thresholds. Since the average ECAP threshold is a fixed value for different rates of stimulation, this result is consistent with the earlier result that the IPG/PD effect was the sole predictor of the way that the subject-average behavioral threshold changes with rate. The increasing regression coefficient of IPG/PD with increasing rate (Table 4) directly reflects the decrease in behavioral threshold with rate.

Overall, the results suggest that, to predict absolute behavioral thresholds for all subjects/electrodes, a strategy would be to first use the regression equation in Table 4 (using average ECAP thresholds and average IPG/PD effects to predict the *average* behavioral threshold for each subject) and then to account for *profile* across electrodes by adjusting the threshold prediction up or down for each electrode using the regression equation in Table 3 and the ECAP threshold slope profiles. Table 5 shows the regression of actual behavioral thresholds versus the predicted thresholds using the combined across- and within-subject predictions. It can be seen that the correlation coefficient is greater than for using ECAP thresholds alone, and remains similarly high for higher rates of stimulation. In contrast, the predictions made from ECAP thresholds alone (top line in Table 5) deteriorate significantly as rate increases as expected from previous work. Figure 7 shows the predictive accuracy for 1000 pps behavioral thresholds. Further research is needed to test this prediction strategy on new data.

In conclusion, we have shown that it is possible to improve the predictive value of ECAP measures for totally automated fitting procedures by including both the slopes of the ECAP growth functions and the IPG/PD effects in the predictions. These factors are associated with the way that thresholds change with rate of stimulation and their inclusion in the predictions prevent the loss of predictive power with increasing rate of stimulation seen when using ECAP thresholds alone. Measurement of these two ECAP parameters would be easy to implement in fitting software. However, the potential accuracy of ECAPs for automated fitting, even with the additional factors, remains relatively low. This low accuracy is illustrated by the standard error of the estimates (SEE), which vary from 16 to 24 CL for rates between 500 and 2000 pps. These standard errors are 5-6 CL less than when using ECAP threshold alone (Table 5), but remain higher than ideal for fully automated fitting. Most of this error occurs in predicting across-subject average differences (compare SEE in Figs. 4 and 6) rather than in predicting across-electrode differences within subjects. Nevertheless, the across-subject prediction using IPG/PD may be a useful initial guide to setting absolute levels in a fully automated method. Using cortical evoked responses instead of ECAPs for automatic objective fitting is likely to greatly reduce the prediction error (Visram et al., 2015). Further research is needed to implement efficient and practical use of cortical responses in CI users.

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Table 1. Details of participants in this study.

	Age	Implant type	Electrodes used	Time since implant	Duration of severe deafness	Etiology
CI1	81	CI24RE	5, 8, 13, 17	3 yrs	20 yrs	Noise induced, head injury, progressive
CI2	70	CI24RE	4, 5, 6, 7, 8, 17	7 yrs	20 yrs	Unknown, progressive
CI3	74	CI24RE	3, 4, 7, 10, 13, 16, 19, 22	7 yrs	30 yrs	Possible autoimmune, progressive
CI4	77	CI24RE	22	2.5 yrs	10 yrs	Unknown, progressive
CI6	77	CI512	5, 7, 10, 13, 16, 19, 22	5 yrs	50 yrs	Unknown, possible noise induced, sudden
CI9	54	CI24RE	7, 10, 13, 16, 19	5 yrs	5 yrs	Unknown, possible inner ear infections, sudden
CI11	57	CI24RE	4, 7, 10, 13, 16, 19, 22	7 yrs	51 yrs	Unknown, sudden
CI12	72	CI24RE	7, 10, 13, 16, 19, 22	3 yrs	10 yrs	Possible noise induced, progressive
CI13	64	CI24RE	13, 16, 19, 22	6 yrs	11 yrs	Genetic, noise

						induced, sudden
CI15	44	CI512	6, 5, 4, 2	4 yrs	9 yrs	Unknown, possible genetic, sudden

Table 2. Best subsets regression results for the change in behavioral thresholds with rate of stimulation as predicted by the three ECAP measures (threshold, slope, IPG/PD effect). The best subset was determined as that with the highest adjusted r-squared. For the 1000-2000 pps no significant association was found with the three ECAP measures.

	40-1000 pps	1000-2000 pps
Within subjects (n = 52)		
r^2	0.16	<= 0.02
ECAP T (coefficient, p)	0.2, 0.08	
ECAP slope (coefficient, p)	0.8, 0.01	
VIF	1.01	
Across subjects (n = 10)		
r^2	0.23	<=0.05
IPG/PD effect (coefficient, p)	2.6, 0.16	

ECAP T = ECAP threshold

VIF = Variance inflation factor

Table 3: Prediction of behavioral threshold profiles across electrode positions by ECAP data (n = 52). The top row shows the results of linear regression using ECAP threshold profile alone. The second row shows the results of using both ECAP threshold profile, the IPG/PD effect profile, and the ECAP amplitude growth slope profile together in the best subjects multiple regression. In each case, the best model contained two of the three potential predictors.

	40 pps	500 pps	1000 pps	2000 pps
ECAP T alone, Adjusted r^2	0.156	0.045	0.029	0.000
Coefficient, p	0.573, 0.002	0.326, 0.07	0.266, 0.12	0.129, 0.42
Multiple regression				
Adjusted r^2	0.33	0.24	0.21	0.15
ECAP T: Coefficient, p	0.633, < 0.001	0.384, 0.02	0.320, 0.04	NA
ECAP slope: Coefficient, p	1.600, < 0.001	1.573, 0.001	1.448, < 0.001	1.240, 0.003
IPG/PD effect, Coefficient, p	NA	NA	NA	-0.806, 0.1
VIF	1.01	1.01	1.01	1.01

ECAP T = ECAP threshold

VIF = Variance inflation factor

Table 4: Prediction of average absolute behavioral thresholds using ECAP data (n = 10). The top row shows the results of linear regression using average ECAP threshold alone. The second row shows the results of using ECAP threshold, the IPG/PD effect, and the ECAP amplitude growth slope together in the best subsets multiple regression. In each case, the best model contained two of the three potential predictors.

	40 pps	500 pps	1000 pps	2000 pps
ECAP T alone, Adjusted r^2	0.25	0.06	0.00	0.00
constant	-5	-9	4	-4
Coefficient, p	0.899, 0.08	0.846, 0.25	0.711, 0.45	0.674, 0.53
Multiple regression Adjusted r^2	0.35	0.365	0.241	0.170
constant	36	72	104	105
ECAP T: Coefficient, p	1.032, 0.047	1.104, 0.09	1.030, 0.23	1.021, 0.31
IPG/PD effect, Coefficient, p	-2.012, 0.17	-3.883, 0.06	-4.806, 0.09	-5.235, 0.11
VIF	1.04	1.04	1.04	1.04

ECAP T = ECAP threshold

VIF = Variance inflation factor

Table 5. Prediction of actual behavioral thresholds for combined subjects/electrodes (n = 52). Each line in the table shows the results of linear regression of the predicted versus actual behavioral thresholds at each rate. The first line uses ECAP threshold alone as the predictor. The second line uses the two regression equations from Table 4 (to predict average thresholds for each subject) and Table 3 (to predict adjustment from this average value to account for across-electrode profile).

	40 pps r, p SEE (CL)	500 pps r, p SEE (CL)	1000 pps r, p SEE (CL)	2000 pps r, p SEE (CL)
ECAP T alone	0.57, <0.001 15.7	0.45, <0.001 21.2	0.38, 0.006 26.2	0.32, 0.02 30.2
Combined within- and across-subject predictions	0.70, <0.001 13.7	0.71, <0.001 16.7	0.70, <0.001 20.72	0.65, <0.001 24.3

SEE = Standard Error of the Estimate

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Figure Legends

Figure 1. Schematic of method to determine CL adjustment to equate ECAP amplitude between stimulus conditions, using data of CI9, electrode 19. The ECAP growth functions were truncated to isolate the linear portions of the functions, which were then fitted with linear regression (red lines in color). The mean horizontal offsets between the regression lines were calculated over the range of amplitudes common to all functions (between horizontal lines).

Figure 2. ECAP recordings (raw data with spline interpolation) of CI12, E16 in condition [PD 25 µs IPG 8 µs] (left), and in condition [PD 40 µs IPG 40 µs] (right), annotated with CL of the stimulus.

Figure 3. The effect of rate of stimulation on behavioral threshold for the 10 subjects, with data averaged across the electrodes tested for each subject. Symbol shapes represent different subjects.

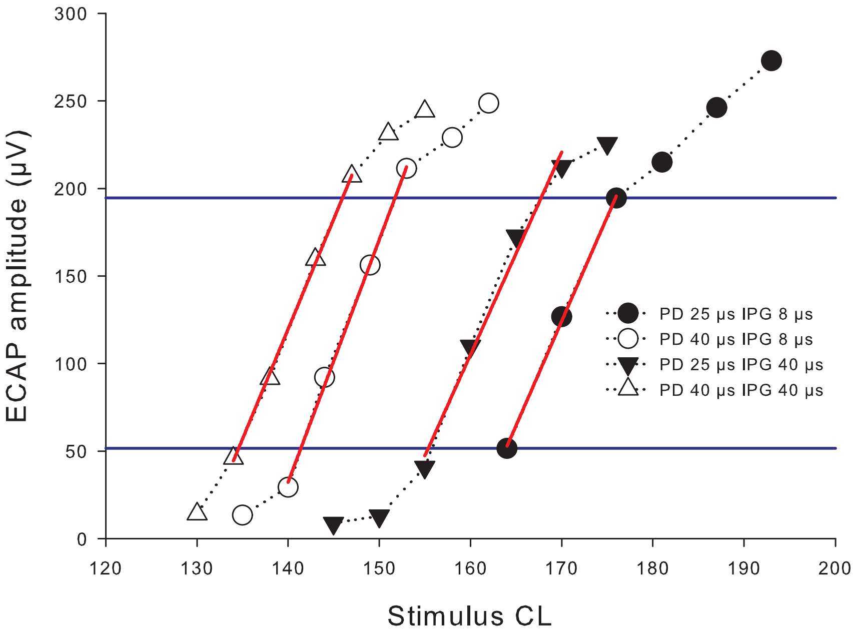
Figure 4. A) Predicted 1000-pps behavioral profile (difference in CL between threshold and across-electrode average threshold for each subject) versus actual threshold profile using ECAP threshold profile alone as the predictor. B) As in panel A, but using both ECAP threshold profile and ECAP growth slope profile as predictors. SEE = standard error of the estimate. Symbol shapes represent different subjects.

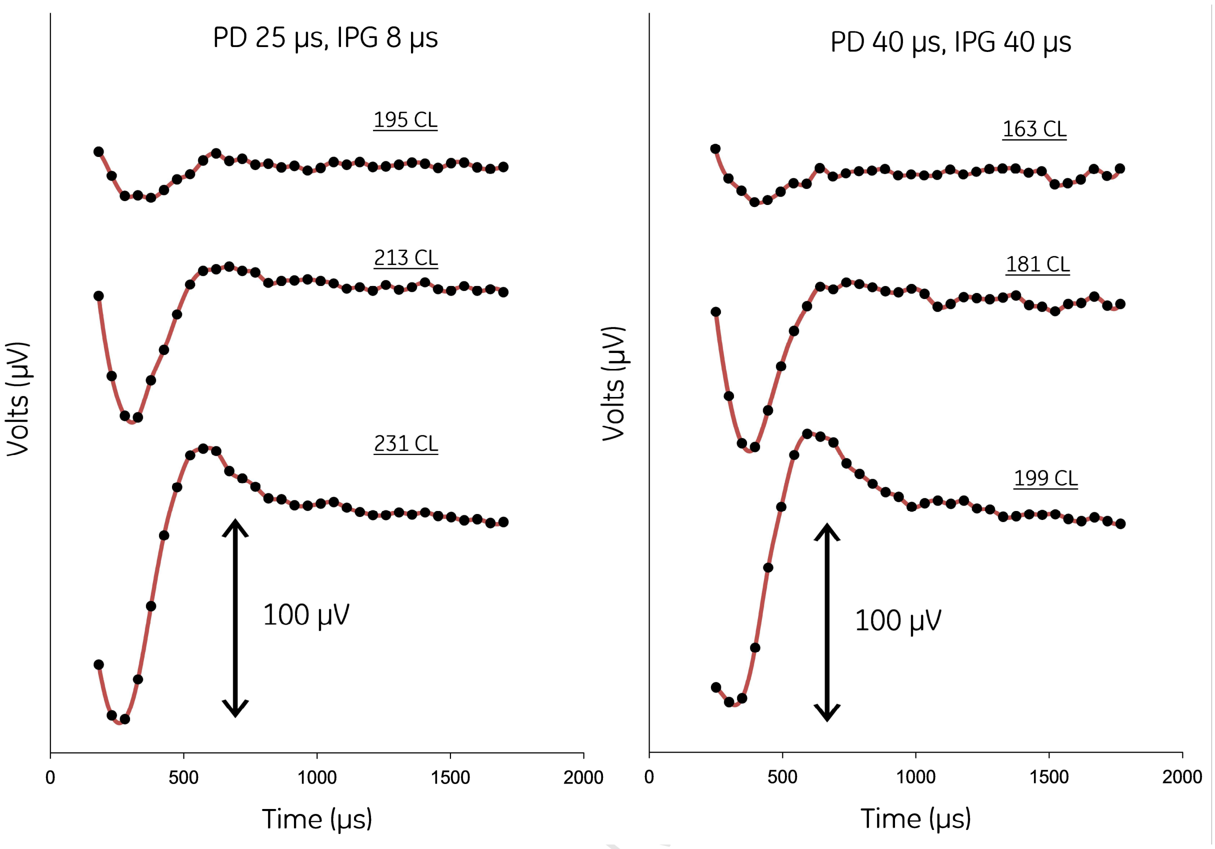
Figure 5. Profiles across seven electrode positions for subject CI3 and rate of 1000 pps. Behavioral and ECAP threshold profiles (black open triangle and closed red circles, respectively)

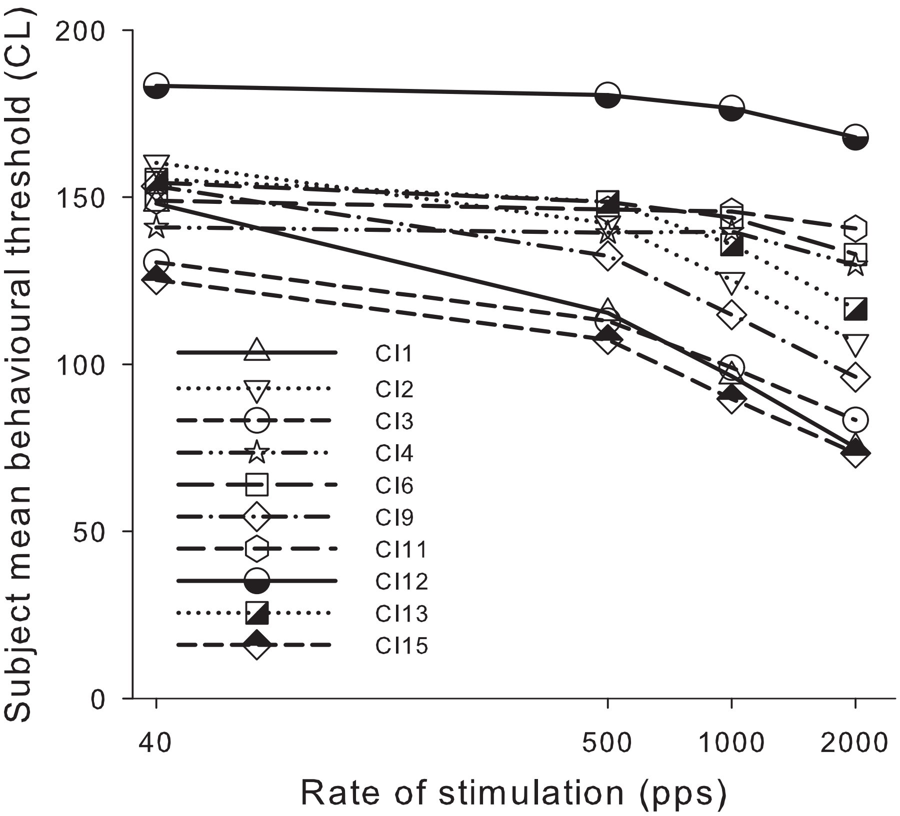
are shown, along with the prediction of behavioral threshold profile (closed blue squares) using both ECAP threshold and slope profiles and the regression equation shown in Table 3.

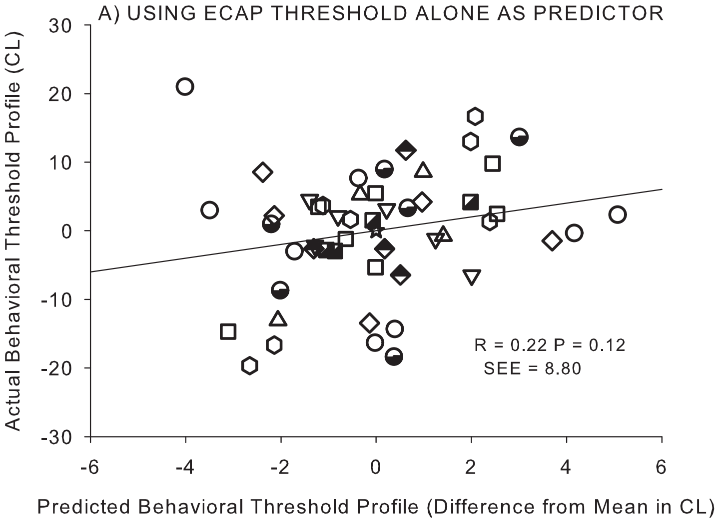
Figure 6. Predictions of average behavioral thresholds (across electrodes) at 1000-pps rate. Panel A: prediction of absolute thresholds using ECAP thresholds and IPG/PD effect. Panel B: prediction of offset between ECAP the behavioral thresholds using IPG/PD effect alone. SEE = standard error of the estimate. Symbol shapes represent different subjects.

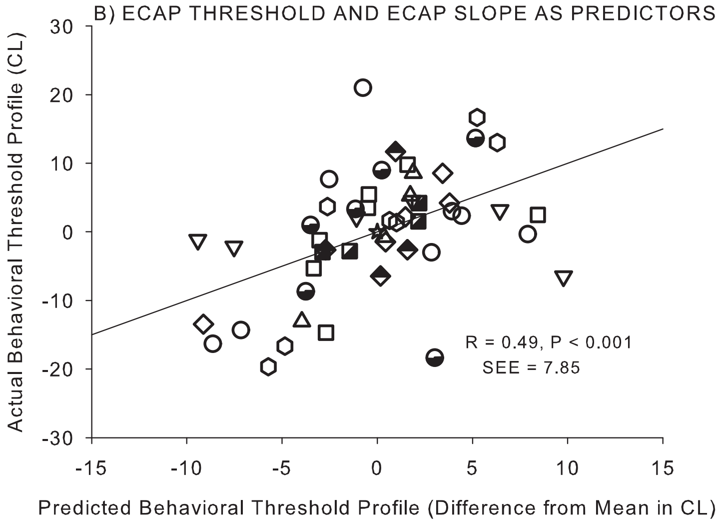
Figure 7. Predictions of actual behavioral thresholds (subjects and electrodes) at 1000-pps rate. Subjects are denoted by symbol type.

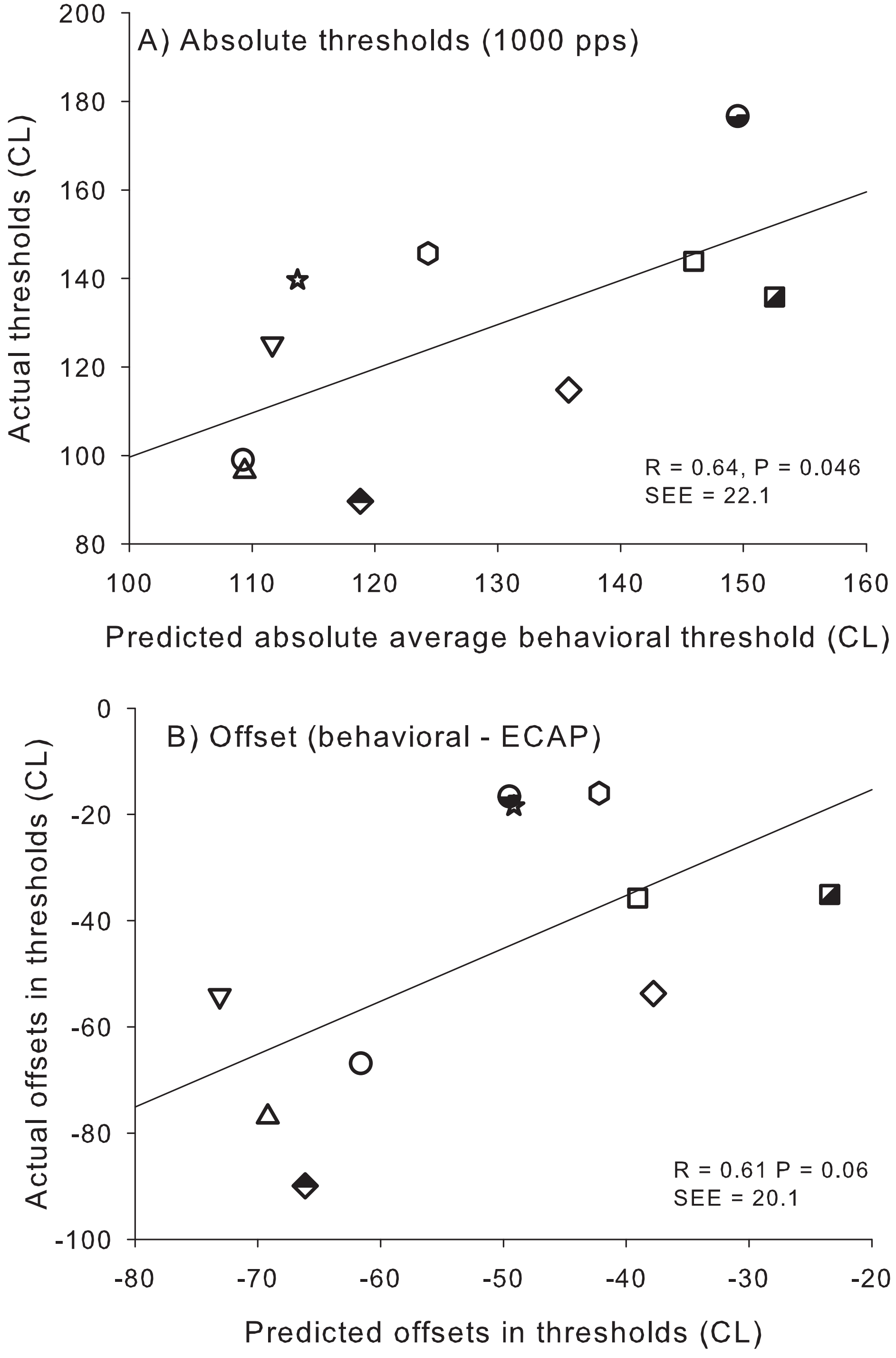

ECAP amplitude (µV)
300
250
200
150
100
50
0
120
130
140
150
160
170
180
190
200
Stimulus CL
PD 25 µs IPG 8 µs
PD 40 µs IPG 8 µs
PD 25 µs IPG 40 µs
PD 40 µs IPG 40 µs

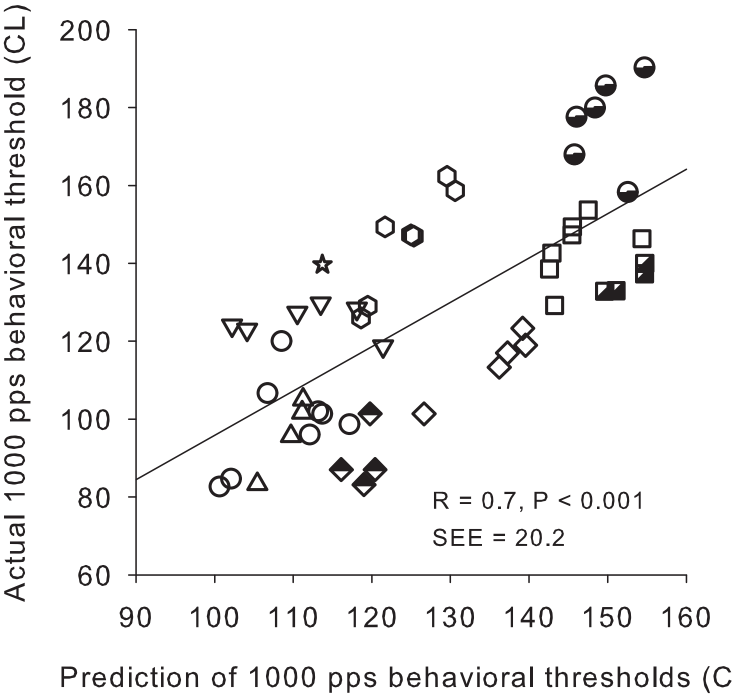

PD 25 µs, IPG 8 µs
195 CL
213 CL
231 CL
100 µV
Volts (µV)
0
500
1000
1500
2000
Time (µs)
PD 40 µs, IPG 40 µs
163 CL
181 CL
199 CL
100 µV
Volts (µV)
0
500
1000
1500
2000
Time (µs)

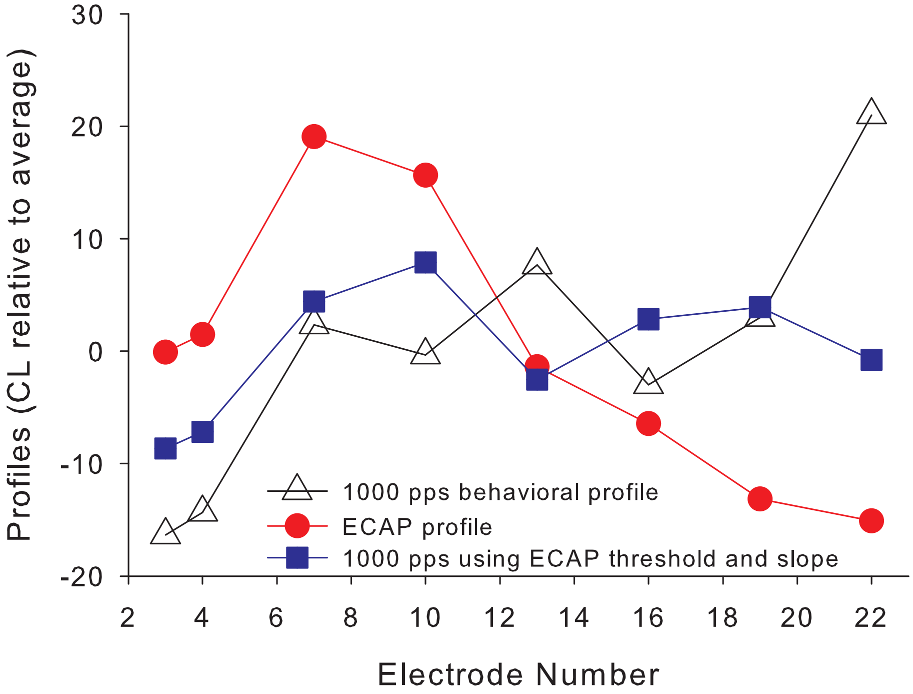

Subject mean behavioural threshold (CL)
200
150
100
50
0
40
500
1000
2000
Rate of stimulation (pps)
CI1
CI2
CI3
CI4
CI6
CI9
CI11
CI12
CI13
CI15


A) USING ECAP THRESHOLD ALONE AS PREDICTOR
Actual Behavioral Threshold Profile (CL)
30
20
10
0
-10
-20
-30
-6
-4
-2
0
2
4
6
Predicted Behavioral Threshold Profile (Difference from Mean in CL)
R = 0.22 P = 0.12
SEE = 8.80


B) ECAP THRESHOLD AND ECAP SLOPE AS PREDICTORS
Actual Behavioral Threshold Profile (CL)
30
20
10
0
-10
-20
-30
-15
-10
-5
0
5
10
15
Predicted Behavioral Threshold Profile (Difference from Mean in CL)
R = 0.49, P < 0.001
SEE = 7.85


A) Absolute thresholds (1000 pps)
Actual thresholds (CL)
200
180
160
140
120
100
80
100
110
120
130
140
150
160
Predicted absolute average behavioral threshold (CL)
R = 0.64, P = 0.046
SEE = 22.1
B) Offset (behavioral - ECAP)
Actual offsets in thresholds (CL)
0
-20
-40
-60
-80
-100
-80
-70
-60
-50
-40
-30
-20
Predicted offsets in thresholds (CL)
R = 0.61 P = 0.06
SEE = 20.1


Actual 1000 pps behavioral threshold (CL)
Prediction of 1000 pps behavioral thresholds (CL)
200
180
160
140
120
100
80
60
90
100
110
120
130
140
150
160
R = 0.7, P < 0.001
SEE = 20.2


30
20
10
0
-10
-20
Profiles (CL relative to average)
2
4
6
8
10
12
14
16
18
20
22
Electrode Number
1000 pps behavioral profile
ECAP profile
1000 pps using ECAP threshold and slope

Highlights

- The effect of rate on hearing threshold is predicted by ECAP measurements
- ECAP amplitude growth slope predicts within-subject differences
- The effect on ECAP of interphase gap or phase duration predicts subject differences
- Including these ECAP measurements significantly improved prediction of thresholds
- Objective cochlear implant fitting using ECAP can be improved