Effects of the Clarion Electrode Positioning System on Auditory Thresholds and Comfortable Loudness Levels in Pediatric Patients With Cochlear Implants

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Objective: To evaluate the effects of using the Electrode Positioning System on psychophysical auditory thresholds, most comfortable loudness levels, and electric auditory brainstem response (EABR) thresholds in children with the Clarion version 1.2 cochlear implant.

Design: Retrospective analysis.

Setting: Academic tertiary care center.

Patients and Methods: Clinical records of a series of 25 children who received the Clarion version 1.2 cochlear implant at the University of Minnesota, Minneapolis, between January 1997 and August 1999 were examined. Measures evaluated were psychophysical thresholds (T-levels) and most comfortable loudness levels (M-levels) obtained at the 3-month posthookup audiologic evaluation and EABR thresholds obtained during implant surgery. Relevant threshold measures were available for 24 patients, 11 of whom had received the Clarion spiral electrode and electrode positioner (EP group) and 13 of whom had received the spiral electrode without positioner (non-EP group). The 3 measures (T-levels, M-levels, and EABR thresholds) were compared across groups. In addition, EABR thresholds were compared with T-levels and M-levels within groups.

Results: Mean T-levels and M-levels were significantly lower for the EP group than for the non-EP group, and interpatient variability for these measures was considerably smaller in the EP group. Electric auditory brainstem response thresholds were not significantly different for EP vs non-EP patients; however, EABR data were available for only a few non-EP patients.

Conclusions: Use of the electrode positioner results in lower T-levels and M-levels in children with the Clarion version 1.2 cochlear implant, consistent with results of previous studies in adults, and reduces across-patient variability for these measures. It is unclear from the present data whether use of the electrode positioner systematically reduces intraoperative EABR thresholds.


In 1998, Advanced Bionics Corporation (Sylmar, Calif) introduced the Electrode Positioning System or “positioner” for use with its Clarion version 1.2 perimodiolar, spiral electrode. The positioner is a wedge-shaped piece of Silastic that is inserted lateral to the spiral electrode in the scala tympani. It is designed to move the electrode array medially toward the modiolar wall of the cochlea, thereby placing electrode contacts closer to residual auditory neurons. Clinical studies in adults have shown that using the positioner reduces electrical auditory thresholds and comfortable loudness levels and increases electrode insertion depth.

The primary purpose of the present study was to evaluate the effects of using the electrode positioner on psychophysical thresholds (T-levels) and most comfortable loudness levels (M-levels) in pediatric patients with the Clarion version 1.2 prosthesis. It was expected that, similar to findings in adults, T-levels and M-levels would be lower in patients who have the positioner compared with those who have the spiral electrode alone. Secondary goals of the study were to compare electric auditory brainstem response (EABR) thresholds for positioner and nonpositioner patients and to compare EABR thresholds with T-levels. Some EABR analyses were limited by the small number of nonpositioner patients for whom EABR data were available.
PATIENTS AND METHODS

Clinical records were examined for a consecutive series of 25 children who underwent surgical implantation of the Clarion version 1.2 cochlear prosthesis at the University of Minnesota, Minneapolis, between January 1997 and August 1999 (Table). Relevant psychophysical measures or EABR thresholds were available for 24 of these patients. Eleven patients underwent implantation with the Clarion spiral electrode and electrode positioner (EP group), whereas the remaining 13 underwent implantation with the spiral electrode alone (non-EP group). Mean (SD) ages of the non-EP and EP groups were 3.2 (1.1) and 4.2 (1.9) years, respectively.

The Clarion spiral electrode has 16 intracochlear electrodes arranged in 8 medial-lateral pairs. All measures in the present study were obtained for the 8 medial electrodes coupled in monopolar mode to a return electrode on the case of the internal receiver-stimulator. Full insertion of the electrode array was achieved in all patients.

The Clarion device supports several speech-processing strategies, including an analog strategy (simultaneous analo-
g stimulation) and an interleaved pulsatile strategy (con-
tinuous interleaved sampler). Most patients in our series were initially programmed in the continuous interleaved sampler strategy. For this reason, T-levels and M-levels were taken from continuous interleaved sampler speech-processing programs established at patients’ 3-month post-
hookup audiologic evaluations. The 3-month point was selected because T-levels and M-levels generally stabilize within 3 months of hookup and because 3-month measures were available for 22 of 24 patients in our sample. The T-levels were obtained with a descending method of limits procedure using Clarion clinical programming software. The M-levels were not measured directly but were established during the first 3 months of device use by progressively raising M-level settings to the maximum levels that were well tolerated by the patient. Psychophysical stimuli were 50-millisecond trains of biphasic pulses with a pulse rate of approximately 600 pulses per second (pps) and a pulse duration of 75 µs/phase.

Electric auditory brainstem responses were recorded in the operating room after surgical implantation of the electrode and receiver-stimulator. Stimuli for EABR recordings were single 75-µs/phase biphasic pulses presented at a pulse rate of 10 pps to 21 pps. Responses were recorded differentially between vertex (+) and nape (−) electrodes using a non-
cephalic ground electrode. Threshold was specified as the lowest current amplitude (in clinical units [CU]) at which a repeatable wave V could be visually identified in the traces. Threshold estimates were typically based on 2 waveform recordings per current level, each composed of averaged responses to 500 stimulus repetitions. The EABR data were ex-
cluded if recordings were excessively noisy or if electrode impedances exceeded 20 kΩ at the time of testing. Because recording conditions were suboptimal for many of the ear-
ier (non-EP) patients in the series, acceptable EABR mea-
sures were available for only 4 patients in the non-EP group.

Electric auditory brainstem response recordings were not available for the same electrodes in all patients. Gener-
ally, recordings existed for 1 apical electrode (electrode 1 or 2), 1 or 2 middle electrodes (electrodes 3, 4, or 5), and 1 basal electrode (always electrode 7). To facilitate compar-
isons across patients, electrodes 1 and 2 were combined into an “apical” electrode group and electrodes 3, 4, and 5 were combined into a “middle” electrode group. When data were available for 2 middle electrodes in a given pa-

tient, the 2 threshold estimates were averaged, resulting in a single EABR threshold for the middle electrode.

Findings for M-levels were similar to those described for T-levels. Again, there was considerable overlap in M-
levels for EP and non-EP patients, but variability was much greater for the non-EP group (Figure 3 and Figure 4). Mean M-levels were significantly lower for EP patients than for non-EP patients on all electrodes except electrode 7 (P < .02, Mann-Whitney test). Average M-levels were 292 CU for the EP group and 506 CU for the non-EP group. Thus, mean M-levels were 214 CU lower in the EP group. The M-levels did not vary systematically as a function of electrode number for non-EP patients; how-

ever, for EP patients, thresholds for the most apical (highest number) electrodes were significantly higher than those for the most basal (lowest number) electrodes (P < .05).

EABR THRESHOLDS

Mean EABR thresholds for the EP and non-EP groups were not significantly different at any electrode location (apical, middle, or basal) (Figure 5). The combined data for EP and non-EP patients showed a main effect of electrode location (F = 3.34; P < .05), with the mean thresh-
old for the basal electrode being higher than the mean

olds were significantly lower for EP patients than for non-EP patients on electrodes 1 through 7 (P < .02, Mann-Whitney test), but differences were not statisti-
cally significant for electrode 8, the most basal electrode. Average thresholds across all 8 electrodes were 154 CU for the non-EP group and 86 CU for the EP group. Thus, mean T-levels were 68 CU lower in the EP group. Across-patient variability in threshold measures was considerably larger for non-EP patients than for EP patients, primarily because 2 patients in the non-EP group (patients 3 and 7) demonstrated unusually high thresholds (Figure 1). Thresholds did not vary system-
atically as a function of electrode number in non-EP patients; however, for EP patients, thresholds for elec-
trodes 7 and 8 were significantly higher than those for electrodes 1 through 6.

Excluding the data for the 2 outliers in the non-EP group reduced the mean threshold for this group to 115 CU and resulted in a mean threshold difference of 29 CU between the EP and non-EP groups (Figure 2). Mean thresholds for the modified non-EP group were still sig-
ificantly higher than those for the EP group for elec-
trodes 1 through 6 but were not significantly different than mean EP thresholds for electrodes 7 or 8. The modi-
fied non-EP group demonstrated similar interpatient vari-
ability in T-levels as the EP group.

Most Comfortable Loudness Levels

Most comfortable loudness levels (MCLs) were obtained for all patients. MCLs were defined as the lowest level at which a patient could hear a sound with good quality. Mean MCLs were 64 CU for the EP group and 86 CU for the non-EP group. Thus, mean MCLs were 22 CU lower in the EP group.

Mean EABR thresholds for the EP and non-EP groups were not significantly different at any electrode location (apical, middle, or basal) (Figure 5). The combined data for EP and non-EP patients showed a main effect of electrode location (F = 3.34; P < .05), with the mean threshold for the basal electrode being higher than the mean.

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Mean EABR thresholds for the EP and non-EP groups were not significantly different at any electrode location (apical, middle, or basal) (Figure 5). The combined data for EP and non-EP patients showed a main effect of electrode location (F = 3.34; P < .05), with the mean threshold for the basal electrode being higher than the mean.
threshold for the apical electrode (P<.05). Thresholds for the apical and middle electrodes and for the middle and basal electrodes were not statistically different.

In EP patients, mean EABR thresholds fell approximately halfway between 3-month T-levels and M-levels (Figure 6). This indicates that, on average, current levels associated with EABR thresholds would produce audible but not overly loud sound sensations when presented at the pulse rate (approximately 800 pps used by the continuous interleaved sampler speech-processing strategy. For individual EP patients, the relationship among T-levels, M-levels, and EABR thresholds was variable. Electric auditory brainstem response thresholds were between 3-month T-levels and M-levels for 21 electrodes tested in 8 patients but exceeded M-levels for 9 electrodes in 4 patients.

The 4 non-EP patients for whom EABR data were available demonstrated a similar relationship between psychophysical measures (T-levels and M-levels) and EABR thresholds as that described for EP patients (Figure 7). For non-EP patients, EABR thresholds fell between 3-month T-levels and M-levels for 11 electrodes in 4 patients but exceeded M-levels for 2 electrodes in 2 patients.
Psychophysical thresholds reported herein for EP and non-EP patients are similar to those reported by Osberger et al. Similar to the present findings, Osberger et al. showed that mean T-levels were 30 to 60 CU lower in EP patients compared with non-EP patients. However, unlike the present study, they found that threshold reductions were largest for basal electrodes (electrodes 7 and 8). A second study of positioner effects in adults by Lesinski-Schiedat et al. reported no change in mean T-levels with the positioner and showed low mean thresholds (approximately 50 CU) in EP as well as non-EP patients. In agreement with the present findings, both studies reported lower M-levels for EP patients than for non-EP patients. In general, results of these adult studies and the present study in children suggest that use of the electrode positioner lowers electrical operating ranges and reduces interpatient variability in T-levels and M-levels. Lesinski-Schiedat et al. also evaluated EABR thresholds on electrode 4 in their adult patients. They found significantly lower EABR thresholds for EP patients compared with non-EP patients, although T-levels were not significantly different for the 2 groups in their study. We did not observe a similar difference in EABR thresholds at any electrode location; however, EABR data were available for only a small number of non-EP patients in our series.

The variable relationship between T-levels and EABR thresholds observed in this study has been reported in several studies.
eral previous studies primarily involving adults. It is well established that EABR thresholds do not accurately predict T-levels, although the 2 measures are strongly correlated. Differences in psychophysical and EABR thresholds are primarily related to the use of faster stimulus presentation rates for psychophysical programming of the implant speech processor compared with the slower rates required for EABR testing. Differences between psychophysical and EABR thresholds vary across patients because of individual differences in temporal integration, and this precludes use of a simple correction factor to align EABR thresholds and T-levels. The present data show that T-levels and M-levels are relatively invariant when an electrode positioner is used with the Clarion spiral electrode and suggest that initial programming of the speech processor could use a common stimulus level in most EP patients. In this case, intraoperative EABR recordings might not be needed for purposes of T-level estimation but would still be useful for confirming an auditory response to electrical stimulation and for evaluating electrode placement in patients with aberrant cochlear anatomy.

A limitation of the present study was that our ability to assess the effect of using an electrode positioner on EABR thresholds was restricted by the variability of EABR measures within patient groups and by the small number of non-EP patients for whom EABR data were available. This effect could have been better studied by comparing EABR thresholds obtained intraoperatively before and after placement of the electrode positioner in EP patients. Such a within-patient comparison would have allowed each patient to serve as his or her own control, thereby reducing or eliminating the problem of interpatient variability.

**CONCLUSIONS**

Use of the electrode positioner decreases T-levels and M-levels in pediatric patients with cochlear implants and substantially reduces the variability of such measures across patients. It is unclear whether EABR thresholds measured at the time of implant surgery are reduced through use of the electrode positioner. Such a result was not observed in this study; however, EABR data were limited to only 4 patients in the non-EP group.

Use of the electrode positioner does not seem to consistently alter the relationship between EABR thresholds and psychophysical operating range (T-levels and M-levels). On average, EABR thresholds fall between T-levels and M-levels; however, the relationship between EABR thresholds and T-levels and M-levels varies considerably across individual patients.

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