

Electric Charge Requirements of Pediatric Cochlear Implant Recipients Enrolled in the Childhood Development After Cochlear Implantation Study

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Objective: To evaluate mapping characteristics of children with cochlear implants who are enrolled in the Childhood Development After Cochlear Implantation (CDACI) multicenter study.

Study Design: Longitudinal evaluation during 24 months of speech processor maps of children with cochlear implants prospectively enrolled in the study.

Setting: Six tertiary referral centers.

Subjects: One hundred eighty-eight children enrolled in the CDACI study who were 5 years old or younger at the time of enrollment. Of these children, 184 received unilateral implants, and 4 received simultaneous bilateral implants.

Intervention: Children attended regular mapping sessions at their implant clinic as part of the study protocol. Maps were examined for each subject at 4 different time intervals: at device activation and 6, 12, and 24 months postactivation.

Main Outcome Measures: Mean C/M levels (in charge per phase) were compared for 4 different time intervals, for 3 dif-

ferent devices, for 6 different implant centers, and for children with normal and abnormal cochleae.

Results: All 3 types of implant devices demonstrate significant increases in C/M levels between device activation and the 24-month appointment. Significant differences in mean C/M levels were noted between devices. Children with cochlear anomalies demonstrate significantly greater C/M levels than children with normal cochleae.

Conclusion: The CDACI study has enabled us to evaluate the mapping characteristics of pediatric patients who use 3 different devices and were implanted at a variety of implant centers. Analysis of such data enables us to better understand the mapping characteristics of children with cochlear implants.
Key Words: C level—Cochlear implant—Electric charge—Pediatric—Mapping.

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Wide variations exist in the performance skills of pediatric cochlear implant patients. Numerous studies have assessed aspects of intervention that may affect performance with a cochlear implant, but very few studies have reported on the mapping characteristics of children

with cochlear implants. The Childhood Development after Cochlear Implantation (CDACI) study (1) provides an ideal data set for evaluating the mapping characteristics of large numbers of children who received cochlear implants from a variety of implant centers.

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Psychophysical responses used to program cochlear implant speech processors are obtained by the audiologist during postoperative programming sessions and primarily include threshold (T), the softest level of sound perceived when an electrode is stimulated electrically, and C/M level, the level where sound is loud but comfortable (C) or most comfortable (M). These values are entered into the patient's map using programming software and analyze the lower (T) and upper (C/M) level of electric stimulation delivered to the implanted electrodes. Threshold and C/M levels can be obtained using behavioral procedures, objective procedures (2–4), or a combination of both procedures.

Setting T and C/M levels can be particularly challenging with young children because they are often unable to provide feedback regarding the loudness of the programming signal. Thus, several programming sessions are usually needed after activation to optimize the settings of the device. During subsequent appointments, the audiologist works with the child to refine the T and C/M measurements until the child hears optimally with the device. Children are then followed regularly to ensure that the levels remain appropriate, to monitor performance with the speech processor map, and to evaluate the integrity of the internal and external equipment.

Little information presently exists regarding the average C/M levels used in children's speech processor maps. Additionally, little data exist regarding how these values change over time. Here, we report psychophysical responses of 188 pediatric cochlear implant recipients prospectively enrolled in the CDACI study. The goals of this specific study were 1) to report average psychophysical responses for a large, heterogeneous population of pediatric cochlear implant recipients; 2) to evaluate differences in psychophysical responses that may be due to type of device or implant center; and 3) to compare mapping characteristics of children with normal and abnormal cochleae. The mapping data provided in this study may be particularly useful to clinicians who do not have access to large data sets because they can be used as a guide for assessing channel availability and C/M level stability during the first 24 months of device use. Additionally, this information may help identify patients with device-specific or other factors in need of additional assessment, may help identify patients with inappropriately mapped speech processors, and may eventually influence the recommended programming strategy or rehabilitative procedure used with such patients.

METHODS

Subjects

Subjects included 188 children who were enrolled in the CDACI study (1) and received cochlear implants from 6 different implant centers: House Ear Institute, Johns Hopkins University, University of Miami, University of Michigan, University of North Carolina at Chapel Hill, and University of Texas at Dallas. All children were enrolled before the age

of 5 years, anticipating implantation within 3 months of enrollment. The mean age of implantation was 28 months, with a range of 7 to 62 months. Pathogenesis of hearing loss included unknown (29%), genetic causes (28%), meningitis (4%), and other causes (39%). Thirty-four percent of subjects experienced a progressive deterioration of hearing loss, 56% experienced a congenital onset, and 6% experienced a sudden hearing loss. The pattern of onset was unknown in 8 (4%) children who were adopted (1).

Four of the 188 children enrolled in the study received simultaneous bilateral cochlear implants, bringing the total number of ears evaluated to 192. Device for implantation was determined by the parents and the implanting center. One hundred three children received a Nucleus device (CI24RCS, 74; CI24RCA, 25; CI24RST, 3; Freedom, 1), 58 children received an Advanced Bionics device (CII/HiFocus, 48; 90K/HiFocus, 10), 1 child received simultaneous bilateral Advanced Bionics devices (90K/HiFocus, 2), 23 children received a MedEl Combi 40+ device, and 3 children received simultaneous bilateral MedEl Combi 40+ devices. Preoperative computed tomographic scan or magnetic resonance imaging revealed that 170 children (173 ears) had normal cochlear anatomy, whereas 18 children (19 ears) had abnormal cochlear anatomy. Of these 19 ears, 16 presented with incomplete partition of the cochlea, 2 demonstrated cochlear hypoplasia, and 1 had a common cavity. Ten of the ears with abnormal cochleae were implanted with a device manufactured by Advanced Bionics, 6 were implanted with a Nucleus device, and 3 were implanted with MedEl devices. Additional information regarding the CDACI study may be found in the publication of Fink et al (1).

Psychophysical Responses

Participants were observed for programming of their speech processor and for evaluation of speech perception (N. Y. Wang, unpublished data, 2007) and speech/language skills at baseline, and at 6, 12, and 24 months after device activation. Each clinic had extensive experience programming pediatric cochlear implant recipients before the onset of the study. Mapping procedures used by the clinic were analyzed on a case-by-case basis by the managing audiologist and included traditional behavioral procedures, objective electrophysiologic measures, or a combination of the 2 procedures.

In most clinics, the upper level of stimulation is referred to as the "C" level for the Nucleus device and as the "M" level for the Advanced Bionics and MedEl devices. After setting the C and M levels, live speech was presented, and, if needed, levels were modified until speech stimuli seemed appropriate and evoked no discomfort. Because the final C and M levels were based upon an observed reaction to speech as "comfortable and adequately loud," it was thought that minimal differences existed between the subjective loudness of the C and M levels. Thus, for this study, the upper level of loudness is referred to as the C/M level.

Speech processor maps were examined for each subject for each timeframe. For each active electrode in use by subjects, C/M measurements were converted to units of charge per phase (nC) using formulas provided by the implant manufacturers. Each formula is provided in Table 1. For ease of viewing by clinicians, some of the mean measurements were then converted back to clinical units (Tables 2 and 3).

Measurements from 3 areas of the electrode array were summarized for comparative analysis. Electrodes 1 to 5, 6 to 11, and 12 to 16 were used for the apical, middle, and basal areas, respectively, for the Advanced Bionics arrays. Electrodes 16 to

TABLE 1. Formulas used to convert from clinical units to charge per phase (nC)

Advanced Bionics
CII using SCLIN 2000: clinical M level (μA) × pulse width / 1,000
CII using Soundwave software: clinical HiRes or soundwave unit/ 0.0128 / 1,000
Nucleus, current (μA) × pulse width / 1,000
MedEl, clinical M level (μA) × pulse width / 1,000

The current value was dependent on internal device and speech processor. Nucleus devices use arbitrary clinical units. Cochlear Americas provided spreadsheets that enabled us to convert the data from Nucleus clinical units to current (μA). These data were then converted to charge (nC) using the formula provided in the Table.

22, 9 to 15, and 1 to 8 were used for the apical, middle, and basal areas, respectively, for Nucleus devices. Electrodes 1 to 4, 5 to 8, and 9 to 12 defined the apical, middle, and basal areas, respectively, for the MedEl devices.

Data Analysis

Analysis of variance was used to analyze if mean C/M levels differed for the basal, middle, and apical areas of each type of implant device. Additionally, mean C/M levels obtained for each device were examined to determine if values changed significantly over time and to determine if the measurements

TABLE 2. Mean C/M levels in nC and clinical units for Advanced Bionics, Nucleus, and MedEl devices obtained on subjects with normal cochleae at device activation and 6, 12, and 24 mo postactivation

	Advanced Bionics	Nucleus	MedEl
Activation			
No. subjects	50	95	26
Mean (clinical units)	135	169	339
Mean (nC)	10.62	9.27	9.05
Minimum	6.25	2.43	2.66
Maximum	19.73	23.41	13.63
SD	2.80	3.58	3.10
6 mo			
No. subjects	48	92	26
Mean (clinical units)	206	201	750
Mean (nC)	16.11	16.66	20.04
Minimum (nC)	8.27	8.39	6.68
Maximum (nC)	24.98	53.84	30.83
SD	3.80	7.03	4.80
12 mo			
No. subjects	45	93	22
Mean (clinical units)	219	207	845
Mean (nC)	17.15	18.43	22.57
Minimum (nC)	8.27	8.21	7.44
Maximum (nC)	30.25	64.52	37.47
SD	4.21	9.18	6.60
24 mo			
No. subjects	47	87	25
Mean (clinical units)	224	207	917
Mean (nC)	17.49	18.39	24.48
Minimum	8.79	6.37	8.42
Maximum	28.07	58.89	74.84
SD	4.00	8.34	12.34

The clinical unit measurements assume different pulse widths for each device. Advanced Bionics assumes a CII device with pulse width of 10.8, Nucleus assumes a pulse width of 25, and the MedEl measurement assumes a pulse width of 26.7.

nC indicates units of charge per phase; SD, standard deviation.

TABLE 3. Mean C/M levels in nC and clinical units for Advanced Bionics, Nucleus, and MedEl devices obtained on subjects with abnormal cochleae at device activation and 6, 12, and 24 months postactivation

	Advanced Bionics	Nucleus	MedEl
Activation			
No. subjects	10	6	3
Mean (clinical units)	128	171	351
Mean (nC)	10.00	9.71	9.38
Minimum	5.86	8.02	8.85
Maximum	14.55	35.17	10.05
SD	2.90	9.24	.609
6 mo			
No. subjects	9	6	3
Mean (clinical units)	217	243	818
Mean (nC)	16.99	35.35	21.84
Minimum (nC)	8.67	11.71	18.61
Maximum (nC)	26.64	55.85	26.43
SD	5.77	14.82	4.08
12 mo			
No. subjects	9	6	3
Mean (clinical units)	237	238 (pw, 50)	857
Mean (nC)	18.54	47.93	22.69
Minimum (nC)	8.83	11.94	20.48
Maximum (nC)	37.93	79.07	26.43
SD	8.55	28.96	3.25
24 mo			
No. subjects	9	4	3
Mean (clinical units)	235	237 (pw, 50)	835
Mean (nC)	18.38	46.42	22.29
Minimum	6.01	11.03	16.04
Maximum	37.70	85.59	26.86
SD	9.41	33.76	5.60

The clinical unit measurements assume different pulse widths for each device. Advanced Bionics assumes a CII device with pulse width of 10.8, Nucleus assumes a pulse width of 25 at device activation and 6 mo and a pulse width of 50 at 12 and 24 mo, and the MedEl measurement assumes a pulse width of 26.7.

nC indicates units of charge per phase; SD, standard deviation; PW, pulse width.

differed for the 3 different types of devices (Advanced Bionics, Nucleus, and MedEl). Mean C/M levels were analyzed for each implant center for each time frame and were also compared. Lastly, mean C/M levels of children with and without cochlear anomalies were compared.

RESULTS

Basal Versus Middle Versus Apical Areas of the Electrode Array

Mean C/M values for basal, middle, and apical electrodes obtained at the 4 test intervals were analyzed for each type of implant. Analysis of variance revealed no significant difference between C/M levels for basal versus middle versus apical electrodes ($p < 0.05$) for any of the 3 devices at any time interval. Thus, average C levels (based on an average of C/M measurements of the entire array) were used in subsequent analyses.

Changes in C/M Levels Over Time

Average C/M levels obtained for all 3 devices at the 4 different test intervals are provided for children with

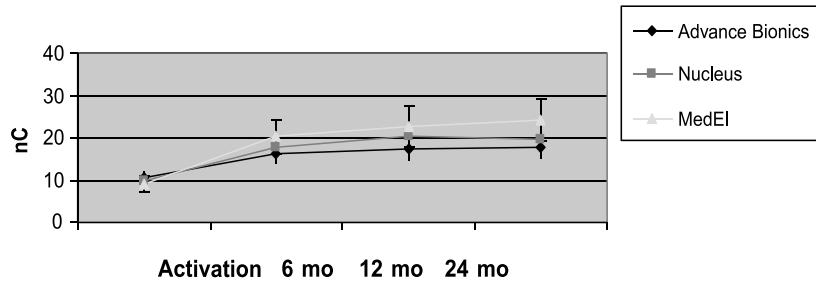


FIG. 1. Mean C/M levels for each device averaged across all subjects with normal cochleae.

normal cochlea in Table 2 and for children with abnormal cochlea in Table 3. The greatest change in C/M levels took place between device activation and the 6-month postactivation visit for all devices. Repeated-measures analysis of variance revealed that all 3 devices demonstrated significant changes in average C/M values during the interval from activation to 24 months ($p < 0.001$).

Differences Between Devices

Analysis of variance was used to compare the mean C/M levels (in nC) for the 3 different devices (Fig. 1). Mean C/M levels were similar for the 3 different devices at device activation. Differences between devices begin to emerge at the 6-month postactivation interval and continue 24 months postactivation. Analysis of variance revealed a significant effect of device ($p < 0.05$) when these measurements were compared over time. The MedEl device demonstrated greater increases in C/M levels over time than the Advanced Bionics and Nucleus devices. The distribution of devices was not equally spaced across the 6 different implant centers. Thus, it is possible that the differences noted between devices

were influenced by differences in the procedures used by clinicians to set the C/M levels.

Differences Between Centers

Mean C/M levels obtained for all subjects (independent of device) implanted at each of the 6 different implant centers were combined to obtain mean data for each center. These levels (in nC) are displayed in Figure 2. Analysis of variance indicated that each site demonstrated significant change in C/M levels over time ($p < 0.001$). The primary type of device implanted varied from center to center. For example, Center 1 primarily implanted Nucleus devices, whereas Center 2 primarily implanted Advanced Bionics devices. Thus, the comparison of C/M levels for the various centers may be confounded by device. However, univariate analysis of variance across sites and by device revealed that when device type was adjusted, differences between sites were not statistically significant ($p < 0.05$).

Abnormal Versus Normal Cochlea

Mean C/M measurements (in nC) for children with normal and abnormal cochleae at the 4 time intervals

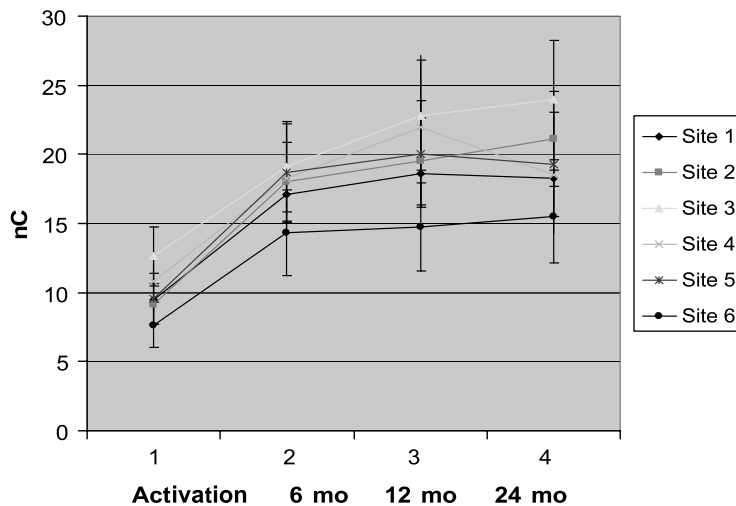


FIG. 2. Mean C/M levels for each site.

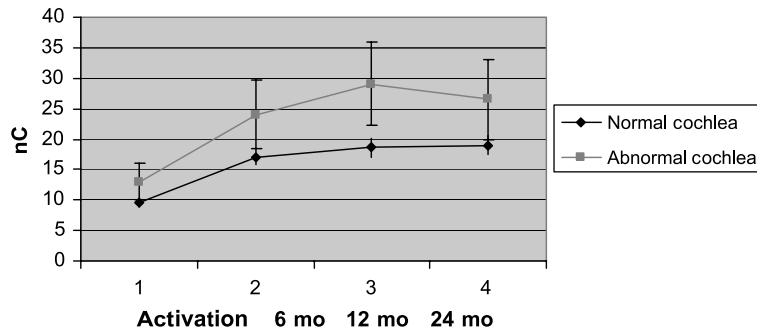


FIG. 3. Mean C/M levels for children with normal and abnormal cochleae.

are presented in Figure 3. Both groups of children demonstrated significant changes in C/M levels over time ($p < 0.001$). At all 4 time intervals, t tests revealed that children with cochlear anomalies demonstrated significantly higher C/M levels than children with normal cochleae ($p < 0.0001$).

DISCUSSION

Previous examination of psychophysical responses had suggested that stimulus level may affect electrode-place discrimination with multichannel cochlear implants (5–7). Thus, assessment of electric requirements to achieve C/M levels may provide insight into variation in outcomes on psychophysical tasks and enhance the information base that clinicians can refer to when programming cochlear implants in children. The present observational study in such a large cohort provides observations that are generalizable and reflect the real-world practices of multiple clinical providers.

This study provides mean data for most comfortable listening levels for a large group of pediatric subjects using contemporary Nucleus, Advanced Bionics, and MedEl multichannel cochlear implants. We observed generally similar patterns of growth in current to achieve acceptable C/M levels across devices. Overall, the 3 device types exhibited similar measurements despite differences in the dimensions and configurations of the arrays and differences in the size and distribution of contacts along the different arrays. The presence of a marginally significant increase in C/M levels over time associated with the MedEL device remains uncertain. Such differences will continue to be monitored during subsequent years of the CDACI study.

Information reported here provides clinicians with data that can be used to identify patients whose values fall outside a range of normal. Such information enables one to better understand the mapping characteristics of such patients and may alert clinicians to interrogate the processor maps and further examine device integrity when measurements fall outside this range. It is possible that such patients have received inappropriately programmed maps or simply that the patient requires more or less

current than other individuals to hear with a cochlear implant.

Future studies from this cohort of subjects will examine the predictive value of C/M levels as an intervening variable in forecasting performance with a cochlear implant. It is possible that such measures will have greater influence on clinical management of patients such as influencing selected programming strategies. Additionally, greater insight into the electric parameters needed to achieve auditory stimulation may be used by clinicians as they analyze the most appropriate type of rehabilitative intervention for the child.

Determination of precise C/M levels can be difficult, particularly with very young children. It is common practice for clinicians to knowingly set C/M levels conservatively low at device activation. These values are then gradually increased during subsequent programming sessions as the child gains experience with sound. Additionally, to facilitate widening of the dynamic range that occurs over time, many clinicians provide recipients with maps that have subsequent increases in C or M levels (subsequently “louder” maps). When this occurs, parents are instructed to gradually move their child up to the louder programs. This common practice at many implant centers reduces the number of programming appointments needed soon after implantation. Such clinical practice is reflected in our data set in the large increase in C and M levels that occurred in between device activation and the 6-month programming appointment. Although C/M levels gradually increased over time, the steepest change in mean C/M values occurred within the first year of use for all 3 devices and for all 6 implant centers.

Previous examination of mean C levels (8) revealed significant differences between children with Nucleus devices whose implants were programmed at 2 different centers. Examination of mean C/M levels for the 6 centers involved in this study also revealed differences between the mean values for each center. However, when the effect of device choice was controlled (different centers implanted different ratios of the 3 devices), these differences were not statistically significant.

It is important to evaluate differences between centers because procedures used to set C/M levels can vary from

center to center and from clinician to clinician. Future maps from these subjects will provide generalizable, normative information and will document longitudinal changes in C/M measurements. Such evaluation will provide insight into possible differences that exist between implant clinics and may shed light on factors that contribute to performance with a cochlear implant.

Results of the comparison of C/M values for children with normal and abnormal cochleae revealed expected differences. Many children with abnormal cochleae are particularly difficult to program because stimulation of the electrodes may result in facial nerve stimulation or anomalous voltage compliance. Cochlear dysmorphia may require specific programming steps to retain electrode activity (such as expanding the pulse width or changing the speech processing strategy). In some instances, the problem electrode(s) may need to be removed from the patient's map. Such clinical management strategies are often prompted by high current levels required to elicit an auditory response. Examination of electric profiles across electrodes can be particularly useful with such challenging cases because inexperienced clinicians may be hesitant to deliver signals at such intense levels particularly if they have never encountered a patient who requires such levels to hear. Data provided in this study indicate that significantly higher current levels may be required if the patient presents with a cochlear anomaly.

The speech processor maps of children enrolled in the CDACI study will continue to be collected and evaluated in subsequent years. We plan to further evaluate the role that electric parameters play in enhancement of verbal

communication. Future studies will include examination of the relationship between C/M levels and performance on speech perception and speech/language measures, as well as continued examination and comparison of mean C/M levels as a function of device, implant center, and cochlear status.

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