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Programming characteristics of cochlear implants in children: effects of etiology and age at implantation

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Abstract

Objective—We investigated effects of etiology and age at implantation on changes in threshold (T) levels, comfortable (C) levels and dynamic range (DR) for cochlear implants (CIs) in children over the first five years of life

Design—Information was collected at 6-months post-activation of CIs, and at 3 and 5 years of age.

Study sample—161 children participating in the Longitudinal Outcomes of Children with Hearing Impairment (LOCHI) study.

Results—Children with neural and structural cochlear lesions had higher T-levels and C-levels as compared to those without these conditions. Parameter settings varied from manufacturer's defaults more often in the former than in the latter group. Investigation of the effect of age at implantation for children without neural and structural cochlear lesions showed that those implanted at ≤12months of age had higher T-levels and narrower DR at 6-months post-activation, as compared to the later-implanted group. For both early- and later-implanted groups, the C-levels at 6-months post-activation were lower than those at age 3 and 5 years. There were no significant differences in T-levels, C-levels, or DR between age 3 and 5 years.

Conclusions—Etiology and age at implantation had significant effects on T-levels and C-levels.

Keywords

children; cochlear implants; programming; etiology; age at implantation

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Introduction

The goal of the cochlear implant (CI) programming procedure is to maximise the speech information available to the user. This is particularly important in infants and young children who are using input from their CI to develop speech and language. An important aspect of programming a CI for any individual is the process of determining appropriate electrical current levels for each electrode to provide the user with a dynamic range from just audible to maximum comfortable hearing sensations (Shapiro and Bradham, 2012). This process, also known as 'Mapping', utilises manufacturer's proprietary software and a hardware interface to program the sound processor. The clinician has access to a range of settings for various electrical parameters through the programming software, enabling customisation of the program to suit the individual's need (Wolfe and Schafer, 2015).

During the Mapping process, several decisions need to be made including: choice of sound coding strategy; stimulation rate; stimulation mode; number of electrodes used (channels); as well as CI device parameters specific to the implant system chosen. CI manufacturers provide default recommendations for setting of these parameters in their proprietary programming software (Boyd, 2010; Vaerenberg, et al., 2014). Other parameters, such as setting the hearing threshold (T) and maximum comfortable (C) current levels for each electrode need to be measured for each individual CI recipient using behavioural and/or objective measures (Hodges et al., 1997; Brown, 2003; Gordon et al., 2004). The difference between T- and C-levels is termed the dynamic range (DR). The range of values selected for the CI parameters by the clinician control the conversion of acoustic signals into electrical stimulation and is referred to as the 'MAP' or listening program. Initial device activation generally occurs 2–6 weeks after surgery. In general, a CI recipient attends about six appointments in the first year after implantation until the values set for specific CI parameters such as current levels are stable; subsequently the MAPs are reviewed annually (Shapiro and Bradham, 2012; Uhler and Gifford, 2014; Vaerenberg et al., 2014). The fitting of an individualised, usable, accurate program is a critical part of the postoperative rehabilitation management program and can significantly influence CI recipient outcomes (Baudhuin et al., 2012; Boyd et al., 2010; Boyle and Moore, 2015; Sainz et al., 2003; Wasowski et al., 2010; Zhou and Pfingst, 2014).

A global survey of CI programming practices across 47 CI centres reported that the most common fitting practice during initial or follow-up CI programming sessions was the check of individual electrode function by measuring their electrical impedances. The second most common practice reported was the setting of T- and C-levels on each electrode to be included in the MAP (Vaerenberg et al., 2014). The authors reported that 'Most, if not all, centres' focus goes to the setting of threshold and the maximum comfortable current levels, to ensure that soft sounds are audible and loud sounds are comfortable and that loudness is balanced across the electrode array'. In adults and older children, T- and C-levels can typically be measured using standard psychophysical behavioural responses to electrical stimuli. In younger children, however, the setting of these levels are more challenging and time consuming (Hughes et al., 2001; Morita et al., 2004). The use of age-appropriate techniques such as behavioural observation audiometry (BOA), visual reinforcement audiometry (VRA) or conditioned play audiometry are utilised to determine these levels

(Zowlan, 2009). In cases where only a few behavioural measurements can be made, interpolation of levels on unmeasured electrodes located between measured electrodes, and the setting of fixed DR across all electrodes or global adjustments of levels may be necessary to create a MAP (Wolfe and Schafer, 2015). Objective measures such as electrically evoked compound action potential (ECAP), auditory brainstem potential (EABR) and stapedius reflex (ESR) are also routinely used in conjunction with behavioural measures to assist with the estimation of both T- and C-levels and can expedite the establishment of a MAP (Gordon et al., 2004). In infants and very young children for whom conditioned behavioural responses are not possible, electrophysiological responses have a dominant role in guiding clinicians in the fitting and setting of T- and C-levels (Zowlan, et al., 2008). In the initial stages of paediatric programming, when limited information is available, clinicians in general take a conservative approach to setting ranges of stimulation, in particular for C-levels (Wolfe and Schafer, 2014; Zowlan et al., 2008). Compared to adults, setting of current levels in children has been reported to take longer to stabilize (Hughes, et al., 2001).

Several studies have investigated changes in T- and C-levels that may occur over time to provide information that may assist with post-operative programming of parameters, management procedures and service provision. Previous paediatric studies have reported that mean T-levels stabilize within the first 3 months to 1 year post-activation and that C-levels stabilize within the first 6 months to 2 years post-activation (Henkin et al., 2006; Hughes et al., 2001; Van Den Abbeele et al., 2012; Vargas et al., 2013; Zwolan et al., 2008). Several studies investigating the setting of T- and C-levels for straight versus perimodiolar electrodes have reported significantly lower mean T- and C-levels for perimodiolar arrays designed with closer placement to the modiolus (Frank et al., 2002, Gordon et al., 2013; Jeong et al., 2015; Telmesani et al., 2015). Current levels have also been reported to vary along the length of the cochlea, with higher mean T- and C-levels recorded in the basal region as compared with medial and/or apical regions (Gordon et al., 2004; Henkin et al., 2003; Raghunandhan et al., 2014; Vargus et al., 2013). Several studies have suggested that these higher mean T- and C-levels in the basal region may be due to the presence of fibrotic tissue or to lesser integrity of the auditory nerve fibres in this region (Henkin et al., 2003; Mosca et al., 2014).

A number of studies have investigated whether etiology may have an effect on T- and C-levels. Compared to patients who do not have cochleovestibular anomalies, higher T- and C-levels have been anecdotally reported in case studies describing series of patients with common cavity, Mondini, cochlear hypoplasia, or enlarged vestibular aqueduct (Coelho and Roland, 2012; Eisenman et al., 2001; Woolley et al., 1998); or hypoplastic cochlear nerve and narrow internal auditory canal (Bradley, 2008; Lee et al., 2012; Valero et al., 2012); or cochlear osteogenesis due to meningitis (Durisin et al., 2014; Eshraghi et al., 2004). Vargas et al. (2013) reported significantly higher mean T- and C-levels in a group of patients with meningitis and cochleovestibular anomalies compared to a group of patients with normal cochleovestibular anatomy. Requirements for higher current levels have been largely attributed to atypical electrode positions and/or target neural cells (Coelho and Roland, 2012; Turrini et al., 1997). A range of accompanying programming issues such as non-auditory stimulation (pain or facial nerve stimulation), inability to obtain an auditory response, and failure to achieve appropriate loudness growth due to electrode compliance

issues have been described. Studies have also reported narrowing of DRs due to the setting of low C-levels to eliminate non-auditory stimulation and pain (Lee et al., 2012; Papsin, 2005). Papsin (2005) reported a statistically significant reduction in DR and increased incidence of facial nerve stimulation in children with common cavity deformity and hypoplastic cochlea as compared to children with normal cochleovestibular anatomy. Most of these studies are retrospective, and include subjects with a wide range of ages at implantation (mean age ranging from 2.9 to 5.8 years). To date, there is limited information on changes in T- and C-levels over time for specific etiological groups in young paediatric cohorts.

Age at implantation has also been reported to affect the setting of T-and C-levels in a few studies. Gordon et al. (2004) reported significantly higher T-levels in a group of 28 infants and toddlers implanted under 3 years of age (0.7–2.9 years) as compared to a group of 24 preschool children (3 to 5.9 years) and 16 school-aged children (6–17 years) using Nucleus CI 24M, CI24R and CI24RE devices (Cochlear Ltd, Sydney, Australia). Behavioural measures for three stimulating electrodes located in basal, medial and apical cochlear segments were obtained using standard, age-appropriate audiometric procedures. There was no significant effect of age at implantation on C-levels or objective measures (ECAP, EABR and ESR) obtained at 2 days after implantation, 1, 3, 6 and 12 months after CI activation. Gordon et al. (2013) reported data from 182 children implanted between 0.7 and 17 years (mean: 6.61, SD: 5.13) showing similar findings as their earlier study It should be noted that while the earlier study included children with cochlear abnormalities, the latter study excluded children with cochlear abnormalities or with partial CI electrode array insertions. The higher T-levels recorded in infants and toddlers as compared to the other groups were largely attributed by Gordon and colleagues to the BOA method used for programming, which was more likely to overestimate levels compared to methods that used conditioned responses. Gordon et al. (2013) also suggested that the finding of higher T-levels in pre-schoolers (3 to 5.9 years) as compared to school-aged children (6–17 years) might be due to immaturities in central auditory areas or in cognitive and attentional centres.

In contrast, Vargas et al. (2013) showed that T-levels in younger children using the Combi 40+ devices (Med-El, Innsbruck, Austria) were significantly lower than those in older children and adults. They reported data on 121 CI users. Patients with a minimum of 6 month’s listening experience with their devices were grouped into three age categories: those implanted between 18 months and 5 years of age; between 5 and 16 years; and between 16 and 63 years. Patients with cochlear abnormalities were excluded. Mean T- and C-levels for the entire electrode array were obtained from MAPs collected at least 6 months after the initial activation. As for the Gordon et al studies, C-levels were not significantly influenced by the age at implantation. The conflicting T-level findings may be related to the clinical methods of programming or to the characteristics of the different cochlear implant systems.

Changes in clinical practice are leading to significant numbers of children receiving a CI under 12 months of age. Currently there is limited information regarding the setting of T- and C-levels in these children compared to those who received a CI after 12 months of age.

The worldwide survey of CI programming practices by Vaerenberg, et al. (2014) suggested that, apart from setting of T- and C-levels, fitting parameters were rarely modified from the default setting in majority of CI recipients. For Nucleus devices, about 6–15% of fittings had modifications to the number of active electrodes; stimulation rate (number of biphasic electrical pulses delivered to an electrode contact per second or pps); number of maxima (largest bandpass filter outputs); and pulse width (duration of each phase of a biphasic electrical phase). The criteria used to identify those CI recipients that may require modifications made to their MAP parameters varied across centres, including the CI recipient's subjective feedback (Vaerenberg et al., 2014) and the presence of cochlear abnormalities (Boyd, 2010). It has been reported that children with cochleovestibular anomalies and hypoplastic cochlear nerve and/or narrow internal auditory canal have wider pulse widths, fewer active electrodes, and slower stimulation rates than others without those abnormalities (Bradley et al., 2008; Dettman et al., 2011; Eisenman et al., 2001; Papsin, 2005). Case studies of these MAP issues have reported 'difficult', 'challenging' and/or 'frequent' programming sessions (Bradley et al., 2008; Coelho and Roland, 2012; Lee et al., 2012; Papsin, 2005; Tucci et al., 1995; Vargus et al., 2013; Woolley et al., 1998;), or suboptimal MAPs (Bradley et al., 2008; Coelho and Roland, 2012; Papsin, 2005; Valero et al., 2012). A number of studies have described the MAP parameter changes in specific etiological groups, however so far, changes in MAP parameters from default setting over time for specific etiological groups in young paediatric cohorts has received limited attention.

Extension of CI candidacy criteria to include infants and those with more complex anatomical cases and additional disabilities has resulted in new programming challenges (Sampio et al., 2011). To date, there is little information on how programming parameters selected relate to etiology or age at implantation in large cohorts of young children. The Longitudinal Outcomes of Children with Hearing Impairment (LOCHI) study provides a unique opportunity to review the clinical CI programming parameters of a relatively large, young paediatric population that has been followed consistently since implantation.

The LOCHI study is a prospective, population-based study that was aimed to investigate the relationship between age at intervention and speech, language, functional and psychosocial outcomes of children with hearing loss in Australia (Ching et al., 2013). The participants are a cohort of about 450 children born between 2002 and 2007 in three states of Australia (New South Wales, Victoria and Queensland) who were fitted with hearing aids by Australian Hearing (AH) before three years of age (Ching et al., 2013). The children's outcomes were assessed using a combination of standardized tests and validated measures, which included both direct, age-appropriate assessments and parent reports. Evaluations occurred at 6 and 12 months after initial device (hearing aid or CI) fitting, and then when the children were 3 and 5 years of age. Information about demographic characteristics and audiological characteristics are collected at the same intervals. This paper draws on CI parameters collected as part of the study. The data collected at 6 months after CI activation, and then at 3 and 5 years of age were analysed to investigate the effects of etiology and age at implantation on changes in T- and C-levels and DR over time. The parameter settings of the CIs used by the cohort at 5 years of age and over time are described in relation to

manufacturer default settings. This study was conducted under the approval and oversight of the institutional human research ethics committee.

The aims of the study were to investigate changes in T- and C-levels and DR over the first 5 years of life in children using cochlear implants. Specifically, we examined changes over time for: 1) different etiology groups; and 2) different age at implantation groups. Our secondary aim was to compare the programming parameters used in children's CIs to manufacturer default values to increase understanding about current clinical practice.

Method

Participants

The participants included children enrolled in the LOCHI study at 5 years of age, who have received a CI before 3 years of age. All CIs are Nucleus devices (Cochlear Ltd, Sydney, Australia).

Clinical programming practice

All children had their CI sound processors programmed at their respective Cochlear Implant Centres, independent of this study. In general, T- and C-levels are measured using standard, age-appropriate, audiological behavioural techniques. BOA, VRA or conditioned play audiometry are utilised, depending on a child's developmental abilities. In cases where only a few behavioural measurements can be made, interpolation of levels on unmeasured electrodes located between measured electrodes, and the setting of fixed DR across all electrodes or global adjustments of levels are some techniques used to create a MAP. Objective measures such as ECAP, and EABR are also routinely used in conjunction with behavioural measures to assist with the estimation of both T- and C-levels. In infants and very young children for whom conditioned behavioural responses are not possible, including those with cognitive deficits, electrophysiological responses have a dominant role in guiding clinicians in the setting of T- and C-levels. In the initial stages of paediatric programming when limited information is available, clinicians in general take a conservative approach to setting current levels, in particular for C-levels.

For all other programming parameters, the CI clinics typically use the default parameter settings recommended in the Cochlear programming software at initial device activation and routine follow-up sessions. In general, modifications to parameter defaults are made only when deemed necessary by clinician and based on an individual's need. Cochlear software has 'HearingMentor' to provide guidance and tips for troubleshooting and adjustment of parameters for clinicians.

Procedure

Data collection—The children's CI information was collected at six months after initial cochlear activation, at 3 years, and 5 years of age; according to the LOCHI study protocol. Information about the CI device type, sound processor model and Cl MAP parameters for each of the children was obtained at each time interval.

Calculation of T-levels and C-levels—T-level and C-level in clinical units (CU), which are defined by the Cochlear Ltd programming software, are determined by the delivered electric charge per phase (current amplitude × pulse width). The delivered current amplitude (in μA) differs between the CIC3 (CI24M or CI24R) and CIC4 (CI24RE) implant types. In addition, the pulse width (μs/phase) was not the same across children. We therefore calculated the delivered charge per phase for T- and C-levels, and report these in dB (re: 1 nC). Using tables supplied by Cochlear Limited (Busby, personal communication), CU were converted to current amplitude (μA), and then multiplied by pulse width to calculate charge-per-phase. The relationship between current CU and charge dB is linear. Table1 gives an example of the calculations used for both a CIC3 and CIC4 implant type with pulse widths of 25 μs and clinical units of 200 CU.

Calculation of mean T- and C-levels for basal, medial, and apical segments—T- and C-levels were recorded for all electrodes, and mean values for three cochlear segments were calculated. Apical segments were defined as all active electrodes allocated to the input frequency range of 188 Hz to 1063 Hz. Medial segments included all active electrodes allocated to the input frequency range of 1063 Hz to 3063 Hz. Basal segments were all active electrodes allocated to the input sound frequency range of 3063 Hz to 7938 Hz. In a Nucleus CI with all electrodes activated (22 channels), these frequency ranges correspond to the following electrode allocation across cochlear segments: basal (Electrode 1 or E1 to E7); medial (E8 to E14); and apical (E15 to E22). This categorization was based on the clinical fitting default recommendations provided in programming software (Custom Sound 4.4) for frequency-to-electrode allocation tables (FAT) for the Nucleus® Freedom™ and Nucleus® 6 sound processors (Cochlear Ltd). The approach adopted in the paper takes into account the clinical scenario in programming with regard to the default software frequency-to-electrode allocation for any number of active electrodes. As electrodes become deactivated, the frequency bandwidth of each channel becomes wider but the overall input frequency range remains the same (Wolfe and Schafer, 2015). The approach allowed all participants, including those using CI systems with multiple electrodes being deactivated (e.g. those with cochleovestibular anomalies), to all be included in the analysis.

Data analysis—Descriptive statistics and analysis of variance (ANOVA) were used to compare across groups and time intervals. The statistical analysis was done using Statistica v.10 (Statsoft Inc., 2011) All analyses used two-tailed tests, with statistical significance set at $p < 0.05$.

To investigate the effect of etiology on changes of CI parameter settings over time, children were grouped into 1) those diagnosed with auditory nerve deficiency, 2) those with cochlear lesions (including common cavity, Mondini, cochlear hypoplasia), 3) those with large vestibular aqueduct syndrome, 4) those with auditory neuropathy spectrum disorder, 5) those with additional disabilities (including autism spectrum disorder, cerebral palsy, developmental delay, disorders of vision, speech output, syndromes, medical disorders), and 6) all other children (unknown etiology, genetic factors and cytomegalovirus infection).

To investigate the effect of age at implantation on changes in CI parameter settings over time, children were grouped according to whether they received their first CI at ≤12 months

or later. As auditory nerve deficiency, cochlear lesions and meningitis have been known to affect CI parameter settings (Lee et al., 2012; Papsin, 2005; Valero et al., 2012; Vargus et al., 2013) independent of age at CI, children with these characteristics were excluded from this analysis.

To examine the extent to which CI parameter settings in the present cohort vary from manufacturer's default settings, we focused on pulse width, stimulation rate, number of active electrodes, and number of maxima; as these have been known to be modified often in programming practice (Bradley et al., 2008; Eisenman et al., 2001; Papsin, 2005; Vaerenberg, et al., (2014). Descriptive statistics were used for this comparison.

Results

Data from 161 children participating in the LOCHI study are reported in this paper. The demographic characteristics are shown in Table 2. The mean age at activation of the first CI is 22.1months (SD: 13.5; Range: 5.3 to 59.6). Ninety-three children had bilateral CIs (12 simultaneously and 81 sequentially). For sequential implantation, the mean time interval between the first and the second CI was 16.6 months (SD:11.6, Range: 2 to 48). All children used a Nucleus device (Cochlear Ltd). The mean and standard deviation (SD) of T- and C-levels of CIs at 5 years of age are provided in Table 3, separately for each etiology group. Table 4 provides information about the CI type, sound processor and MAP parameters.

Effect of etiology

The effect of etiology on changes in T-levels, C-levels and DR over time was investigated for 108 children (130 ears). Data collected at 6-months post-activation of CIs, at age 3 years and at 5 years were analysed. When a child had a 6 months post-activation of CI assessment interval that overlapped with his/her 3 years of age assessment interval (1 data point), they were excluded from this longitudinal analysis.

T-levels—Figure 1 shows the T-levels as recorded along the electrode array at three different segments for the six etiological categories over time. As shown, T-levels for children with auditory nerve deficiencies (Etiology group or EGp 1) were consistently higher than for other etiological categories, and this was found across all three cochlear segments.

Analyses of variance (ANOVA) using T-levels at basal, medial and apical segments as dependent variables, time interval (6-months post-activation, age 3 years, age 5 years) as repeated measures, and etiological category (auditory nerve deficiency, cochlear lesions, LVAS, ANSD, AD, others) as categorical variables showed that the main effect of etiology was significant ($F[5,123] = 5.26$, $p < 0.001$). The main effect of cochlear segment was also significant ($F[2,246] = 12.91$, $p < 0.001$). There were no other significant main effects or interactions. Post-hoc analyses using Bonferroni corrections revealed that on average, the basal, medial, and apical segment charge levels of the auditory nerve deficiency group were significantly higher as compared to those with additional disabilities ($p = .009$, $p = 0.0007$, $p = 0.01$ respectively), or those in the 'others' category ($p = 0.003$, $p = 0.008$, $p = 0.012$).

C-levels—Figure 2 shows changes in C-levels over time at different cochlear segments for 6 etiology groups.

ANOVA using C-levels at basal, medial and apical segments as dependent variables, time interval (6-months post-activation, age 3 years, age 5 years) as repeated measures, and etiological category (auditory nerve deficiency, cochlear lesions, LVAS, ANSD, AD, others) as categorical variables showed that the main effect of etiology was significant ($F[5,123] = 8.06$, $p < 0.001$). The main effects of time interval (F[**2, **246] = 3.35, p = 0.04) and cochlear segment were also significant ($F[2,246] = 13.31$, $p < 0.001$). There were no other significant interactions. Post-hoc analyses using Bonferroni corrections showed that C-levels for those children with auditory nerve deficiency were significantly higher from those with LVAS ($p = 0.02$), ANSD ($p = 0.014$), additional disabilities ($p < 0.001$), or 'others' ($p < 0.001$). On average, the group with cochlear lesions was also significantly higher from that with additional disabilities ($p = 0.002$) and 'other' ($p < 0.001$). Post-hoc analyses of the effect of time interval revealed that on average, the C-levels at 6-months post-activation were significantly lower as compared to those at age 3 and 5 years ($p <0.001$), but there was no significant difference between the C-levels at age 3 and at 5 years ($p > 0.05$). Post-hoc tests of the effect of cochlear segment showed that on average, higher C-levels were recorded in electrodes in the basal segment as compared to electrodes in the medial segment ($p = 0.002$), but were not different from apical electrodes. In addition, the medial segments had significantly higher charge level, on average, than apical segments.

DR—The DR was calculated by taking the difference between T-levels and C-levels, expressed in terms of dB (re: 1 nC). Figure 3 shows changes in DR over time at three cochlear segments for 6 etiology groups. Table 5 gives the overall DR averaged across all electrodes for the 6 etiology groups across the three measurement time points, at 6-months post-activation of CIs, at age 3 years and at 5 years.

ANOVA using DR as dependent variable, etiology as categorical variable, and cochlear segment and time interval as repeated measures showed that the main effect of cochlear segment was significant ($F[2,246] = 3.078$, $p = 0.047$). There were no other significant main effects. The interaction between cochlear segment and etiology was significant ($F[10,246] = 1.944$, $p = 0.04$). Post-hoc analyses revealed that for children with auditory nerve deficiency at age 5 years, the DR for electrodes in the basal segment was significantly lower as compared to DR on electrodes in the apical segment ($p = 0.012$). There were no other significant effects.

Effect of age at implantation

Data from 88 children who provided information at all 3 time intervals (n =98 ears) were analysed to investigate the effect of age at implantation on changes in T-levels, C-levels, and DR over time. As indicated in the Methods section, we excluded, *a priori*, data from children with auditory nerve deficiency (n=7 ears), cochlear lesions (n =10 ears), meningitis (n=3 ears) and recurrent mastoiditis (n=1) from this analysis. Of the 98 ears, 43 ears had an implant activated at or before 12 months of age (early-implanted), and 55 ears had an implant activated after 12 months of age (later-implanted). At 3 years of age, the early

implanted group had a mean duration of CI experience for 28.2 months (SD: 2.4; Range: 24.0 to 34.1), and the later implanted group had a mean duration of CI experience for 18.7 months (SD: 5.3; Range: 7.6 to 28.5 months).

T-levels—Figure 4 shows the mean T-levels at three time intervals for the two age at implant groups of children.

ANOVA using T-levels as dependent variable, age at implantation as a categorical variable (early vs later), time interval (6-months post-activation, age 3 years, age 5 years) and cochlear segment (basal, medial, apical) as repeated measures revealed that the main effect of age at implantation was significant ($F[1,96] = 5.65$, $p = 0.02$). The interaction between time interval and age at implantation was significant ($F[2,192] = 7.59$, $p < 0.001$). Post-hoc analyses revealed that T-levels were significantly higher for the early-implanted group as compared to the later-implanted group at 6-months post-activation, but not at 3 or 5 years of age. There were no other significant main effects or interaction.

C-levels—Figure 5 shows the mean C-levels for the two age at implantation groups of children across the three time intervals (6-months post-activation, age 3 years and age 5 years).

ANOVA using C-levels as dependent variable, age at implant as categorical variable, and cochlear segment and time interval as repeated measures showed significant main effects of age at implant ($F[1,96] = 4.25$, $p = 0.04$), time interval ($F[2,192] = 5.59$, $p = 0.004$), and cochlear segment ($F[2,192] = 23.15$, $p < 0.001$). There were no significant interactions. On average, the C-levels at 6-months post-activation of CIs were significantly lower than those recorded at age 3 or 5 years, whereas there was no significant difference in mean C-levels recorded for age 3 and age 5 years. Across both age at implantation groups, electrodes in the basal segment of the cochlea had lower C-levels than those located in medial and apical segments.

DR—Figure 6 shows the mean overall DR (averaged across all electrodes) for the children grouped according to their age at implantation across the three measurement time intervals.

ANOVA using DR as dependent variable, age at implantation as categorical variable, cochlear segment, and time interval as repeated measures showed that the main effect of time interval was significant ($F[2,192] = 3.47$, $p = 0.03$). In addition, the main effect of cochlear segment was significant ($F[2,192] = 4.06$, $p = 0.02$). There was significant interaction between time interval and age at implantation ($F[2,192] = 3.05$, $p = 0.049$). Post-hoc tests revealed that the DR at 6-months post-activation for the early-implanted group was significantly narrower (6.4 dB [SD 2.1]) as compared to the later-implanted group (mean 7.1 dB [SD 1.8]). There were no other significant interactions. Across both groups, DRs recorded for electrodes in the basal segment of the cochlea were narrower as compared to electrodes in the medial segments.

Parameter settings: Default versus non default

The secondary aim of this study was to compare the settings for pulse width, stimulation rate, number of active electrodes and number of maxima used in children's devices with the manufacturer's default settings. The comparison was made for each of the 6 etiology groups. In addition, the proportion of default vs non-default values for each of the 4 parameters were examined for the early and later-implanted groups. Whilst the majority of CI fitting parameters were rarely modified from the manufacturer's software recommended default setting for 5 years, a small proportion of children did have modifications made to their MAPs (see Table 4).

Proportion of non-default settings for 6 etiology groups—Figure 7 shows the percentage (%) of MAPs that have non-default settings for pulse width, stimulation rate, number of active electrodes, and number of maxima.

As shown in Figure 7, children with auditory nerve deficiency showed the highest percentage of non-default settings for pulse width (100%) and stimulation rate (range: 43–86%) at all three time intervals. The group of children with cochlear lesions showed the highest percentage of deactivated electrodes (range: 60–70%), followed by the group of children with auditory nerve deficiency (range: 43–57%) over time. The percentage of non-default parameter settings also increased over time for stimulation rate and number of active electrodes for both of these groups. There were also considerable variations in the number of maxima from default recommendations, generally in the direction of an increase in the number of maxima.

Proportion of non-default settings for early vs later implanted groups—Figure 8 shows the percentage (%) of MAPs set to the non-default settings for pulse width, stimulation rate, number of active electrodes, and number of maxima.

For pulse width, stimulation rate, and number of electrodes used, the proportion of non-default parameter settings are similar between the early- and later-implanted groups. However, the proportion of non-default settings for the number of maxima appeared to be higher for the early-implanted than for the later-implanted group.

Discussion

This study reported on the CI programming parameters of 161 children who were using CIs by 3 years of age in the LOCHI study (Ching et al., 2013). We investigated changes in T-levels, C-levels, and DR from 6 months post-activation of CI to 5 years of age. The effects of etiology and age at implantation on these changes were reported. In addition, the proportion of MAPs that used settings for pulse width, stimulation rate, number of active electrodes, and number of maxima that varied from the manufacturer's default settings was described to increase understanding about current clinical practice.

Effect of etiology on T-levels, C-levels, and DR

Averaged across three measurement time intervals of 6-months post-activation, age 3 years and age 5 years, T-levels and C-levels for children with auditory nerve deficiency were

found to be set significantly higher than for the group of children with additional disabilities or for those children in the ‘other’ category (comprising children with unknown, genetic factors and CMV). Mean C-levels for 7 children with auditory nerve deficiency were significantly higher than all other etiological categories except those children with cochlear lesions. Consistent with previous studies that reported that high C-levels for children with cochlear lesions (Vargus et al., 2013; Wooley, et al., 1998), mean C-levels for the cochlear lesions etiological category were significantly higher than those children with additional disabilities or those in the ‘other’ etiological category (comprising children with unknown, genetic factors, congenital cytomegalovirus (CMV) infection). These findings suggest that when clinicians are programming MAPs for children with auditory nerve deficiency or cochlear lesions, they should be aware that higher T-levels or C-levels might be required as compared to MAPs for children without those conditions. As shown in Figs 1 to 3, there is considerable individual variability (as depicted by the 95% confidence intervals) in children with auditory nerve deficiency, cochlear lesions, and LVAS, compared to children without these conditions.

When creating a MAP for children with auditory nerve deficiency or etiologies involving cochlear lesions or LVAS, clinicians might choose a programming approach that is less reliant on interpolation of levels, fixed DR or global adjustment techniques as compared to approaches used for children without those conditions.

This study extends previous retrospective studies on CI parameters of children by tracking changes in CI parameters set at 6-months post-activation to age 3 years and then 5 years in a population-based cohort; showing that on average, there were no significant changes in DR across the specified time period (duration of CI use ranged from 31 months to 55 months, median: 46.4 months). It appears that the DR has stabilised by the measurement point at 3 years of age (mean duration of CI experience was 25.1 months, SD: 9.7; Range: 7.6 to 52.0). It may be expected that by 3 years old, reliable behavioural responses to electrical stimulation may be obtained for most children to facilitate optimal setting of CI parameters.

Averaged across all etiology groups, mean C-levels were significantly lower at 6-months post-activation of CI, compared to C-levels at age 3 and 5 years. This is likely due to clinical programming practice of remapping to increase C-levels over time. There was no significant difference in C-levels between 3 and 5 years of age, suggesting that the C-levels remained stable over this time. To the authors’ knowledge, no study has examined changes in C-levels beyond 2 years after implantation. The main effects of cochlear segment and higher mean T- and C-levels found in the basal segment as compared with medial and/or apical regions were also consistent with previous findings (Gordon et al., 2004; Henkin et al., 2003; Raghunandhan et al., 2014; Vargus et al., 2013).

Effect of age at implantation on T-level, C-level and DR

For children who received a CI before 12 months of age, there was a consistent reduction in recorded T-levels and an increase in C-levels between the 6-months post-activation time period and 3 years of age. This was not observed in the later-implanted group of children. Consequently, the DR at 6-months post-activation was significantly narrower than that at 3 years of age for the early-implanted group, but not for the later-implanted group. This

necessarily resulted in a narrower DR observed for the early-implanted group as compared to the later-implanted group, at 6-months post-activation. However, there were no significant difference in T-levels or C-levels or DR between 3 and 5 years of age, both for the early- and the later-implanted groups. The setting of higher T-levels for the early-implanted group as recorded at the first two measurement time intervals may be related to the greater reliance on BOA that overestimates threshold levels in clinical practice (Gordon et al., 2013), or the adoption of a conservative programming bias in practice for young children (Wolfe and Schafer, 2015), or some combination of these factors. On the other hand, programming of CI for older children can utilise standard audiometric procedures to provide a reliable estimate of T-levels. Nevertheless, the individual variability of the early-implanted group was similar to that in the later-implanted group (Figs 4–6). The DR at 6 months post-activation of CI was similar to that at 3 years and 5 years for the later-implanted group, but narrower than that at 3 and 5 years for the early-implanted group. This suggests that the DR took longer to be optimised for children receiving their CI before 12 months of age (despite their longer duration of using CIs by 3 years of age) as compared to those who were implanted after 12 months of age. A less conservative approach to setting T-and C-levels might be considered in early-implanted children than that adopted in current practice.

Future studies will investigate the factors influencing the programming practices of clinicians working with children who received CIs before 12 months of age in the present cohort. This is an important clinical question as current evidence from the LOCHI study clearly supports cochlear implantation for children before 12 months of age to facilitate early language development (Ching et al., 2017). A greater awareness of how programming parameters change over time in infants and young children is critical to ensure that CI parameters are optimised as early as possible to maximise outcomes from early implantation.

Proportion of non-default settings in pulse width, stimulation rate, number of active electrodes and number of maxima

For children with either auditory nerve deficiency or cochlear lesions, clinicians' settings of pulse width, stimulation rate and number of active electrodes were more likely to deviate from the manufacturer's recommended default settings than for other children. These findings are consistent with previous retrospective studies that have reported on common modifications made on MAPs for children with cochleovestibular anomalies (Coelho and Roland 2012; Dettman et al., 2011; Papsin, 2005; Vargas et al., 2013; Woolley et al., 1998), and/or hypoplastic cochlear nerve and narrow internal auditory canal (Bradley, 2008; Lee et al., 2012; Valero et al., 2012). The present data suggest that CI programming for children with auditory nerve deficiency might benefit from an initial setting of pulse width to be wider than the default setting. Typically, they also require slower stimulation rate than default settings (see Table 4 for default settings). However, a limitation to generalisation from the current study is the small number of children with auditory nerve deficiency.

The findings from this study underscore the importance of investigating the CI programming parameters for different etiological categories in children. We found no significant differences in programming parameters set for children with LVAS, ANSD, additional

disabilities, or ‘other’ (unknown, genetic factors and CMV); however, those with neural or structural lesions may require special attention to the setting of MAP parameters such at T-levels and C-levels to ensure optimisation at the earliest possible time. Further, the present study found that children who received a CI before 12 months of age did not achieve optimal settings in T-levels and C-levels at 6 months after implantation, whereas children who received an implant after 12 months of age achieved optimal settings by 6 months after activation. This suggests that an increased understanding of factors influencing CI programming practices for infants who receive CIs early may assist clinicians to optimise parameter settings earlier than is current practice to maximise the benefit of early implantation.

Conclusion

This study evaluated the programming parameter characteristics of children participating in the LOCHI study who were using CIs by 3 years of age. Children who have neural or structural lesions were found to have different programming requirements from those without these conditions. On average, CI parameters were stable by 3 years of age, and no significant changes were observed 3 year and 5-year time intervals. Further, optimal settings were achieved by 6-months post activation for those children who received a CI after 12 months of age, but took longer for those who received a CI at a younger age. Improved clinical practice should be directed towards achieving optimal settings for infants who received a CI before 12 months of age so as to capture the benefit of early implantation.

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Abbreviations

ADRO	Adaptive dynamic range optimization
ACE	Advanced combination encoder
AH	Australian Hearing

ASC	Auto-sensitivity
CI	Cochlear implant
CG	Common Ground
C-level	Comfort level
CU	Clinical units
DR	Dynamic range
HA	Hearing aid
LOCHI	Longitudinal Outcomes of Children with Hearing Impairment
μA	Microamps
μs	Microseconds
MP	Monopolar stimulation
nC	Nanocoulombs
PPS	Pulses per second
SD	Standard deviation
SPEAK	Spectral Peak processing strategy
T-level	Threshold level

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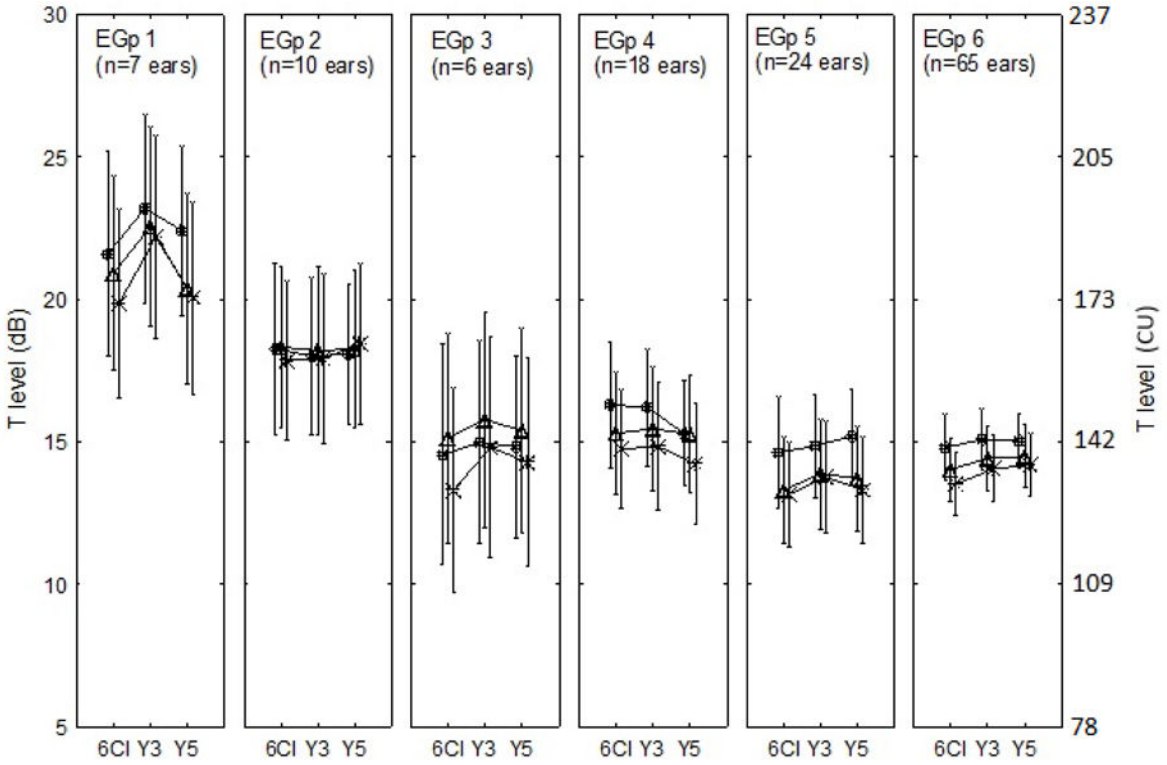

Figure 1.

T-levels averaged across electrodes at basal (filled circles), medial (open triangles), and apical (asterisks) regions in CIs used by children at 6-months post-activation (6CI), and at chronological ages of 3 (Y3) and 5 years (Y5). The values for 6 etiology groups (EGp) are shown in separate panels. The 6 groups are: 1) auditory nerve deficiency; 2) cochlear lesions, 3) enlarged vestibular aqueduct; 4) auditory neuropathy spectrum disorder; 5) additional disabilities; and 6) Other (unknown etiology, genetic factors, and cytomegalovirus infection). T-levels are denoted in charge in dB units (re:1nC) on the left y-axis and in clinical units CU (re:CIC4 implant and 25 μs pulse width) on the right y-axis of the graph. Vertical bars denote 95% confidence intervals.

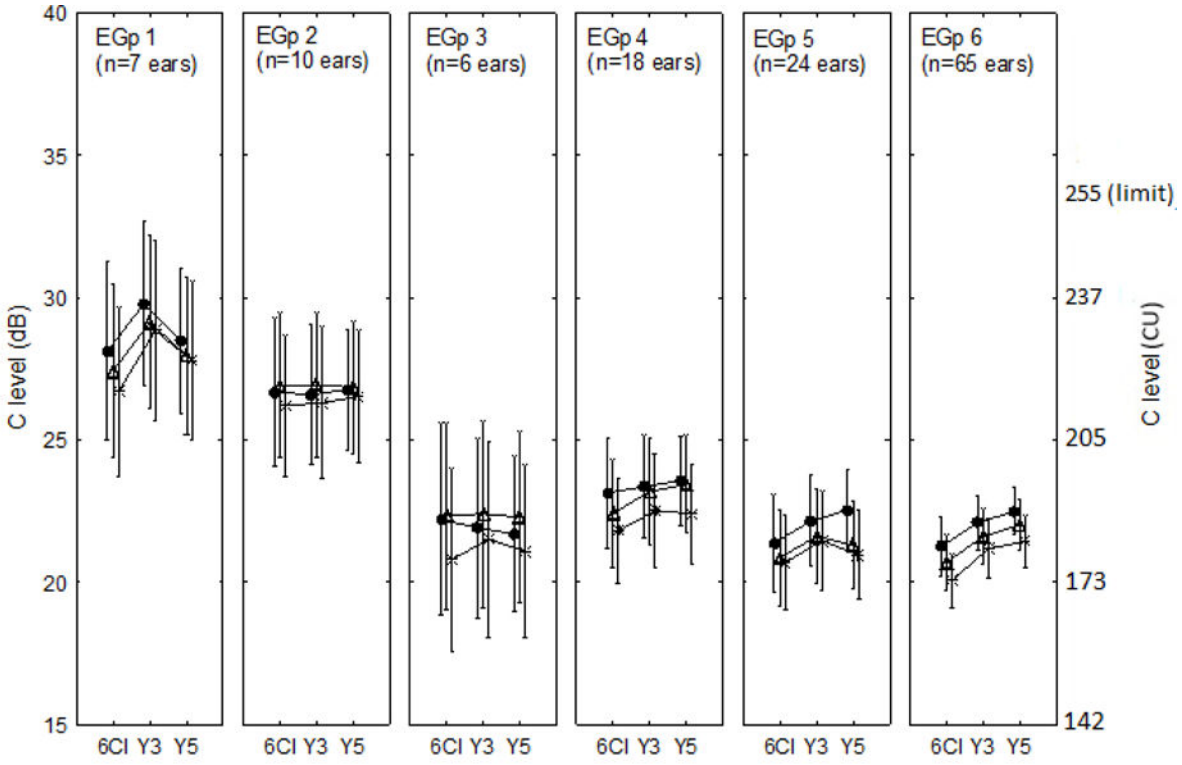

Figure 2.

C-levels averaged across electrodes at basal (filled circles), medial (open triangles), and apical (asterisks) regions in CIs used by children at 6-months post-activation (6CI), and at chronological ages of 3 (Y3) and 5 years (Y5). The values for 6 etiology groups (EGp) are shown in separate panels. The 6 groups are: 1) auditory nerve deficiency; 2) cochlear lesions, 3) enlarged vestibular aqueduct; 4) auditory neuropathy spectrum disorder; 5) additional disabilities; and 6) Other (unknown etiology, genetic factors, and cytomegalovirus infection). C-levels are denoted in charge in dB units (re:1nC) on the left y-axis and in clinical units CU (re:CIC4 implant and 25 μs pulse width) on the right y-axis of the graph. Vertical bars denote 95% confidence intervals.

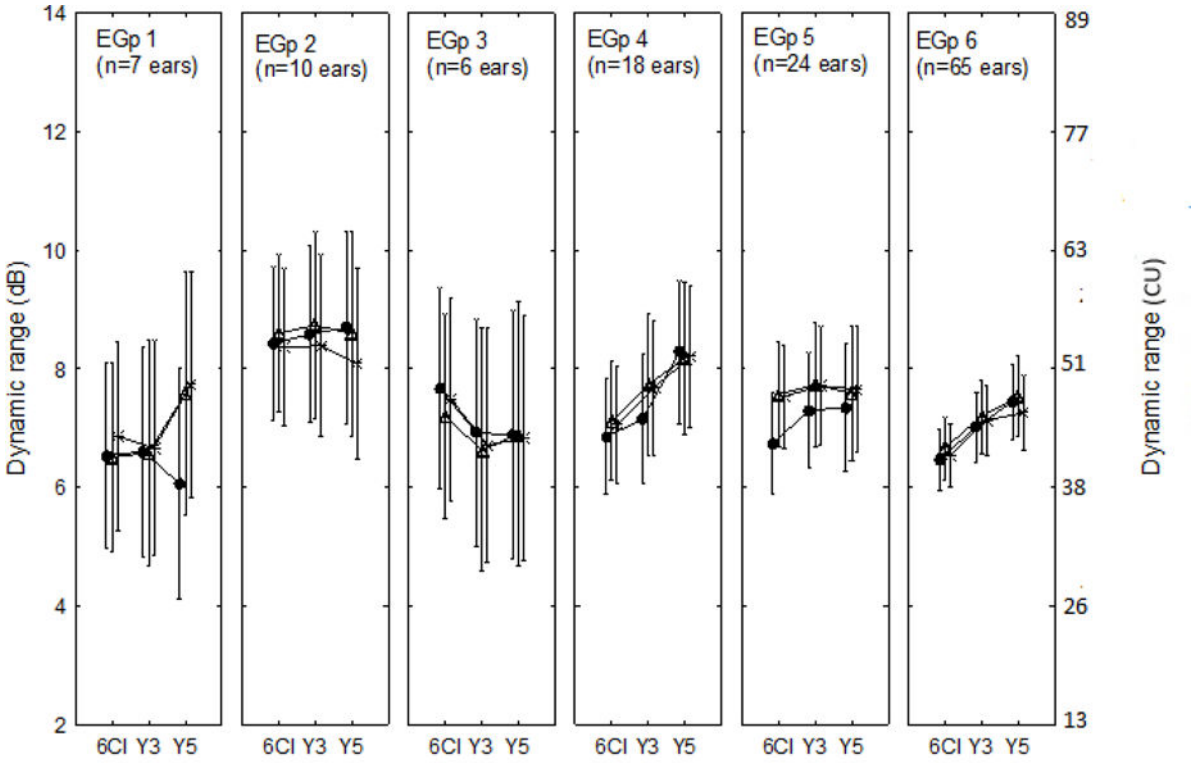

Figure 3.

Dynamic range averaged across electrodes at basal (filled circles), medial (open triangles), and apical (asterisks) regions in CIs used by children at 6-months post-activation (6CI), and at chronological ages of 3 (Y3) and 5 years (Y5). The values for 6 etiology groups (EGp) are shown in separate panels. The 6 groups are: 1) auditory nerve deficiency; 2) cochlear lesions, 3) enlarged vestibular aqueduct; 4) auditory neuropathy spectrum disorder; 5) additional disabilities; and 6) Other (unknown etiology, genetic factors, and cytomegalovirus infection). DRs are denoted in charge in dB units (re:1nC) on the left y-axis and in clinical units CU (re:CIC4 implant and 25 μs pulse width) on the right y-axis of the graph. Vertical bars denote 95% confidence intervals.

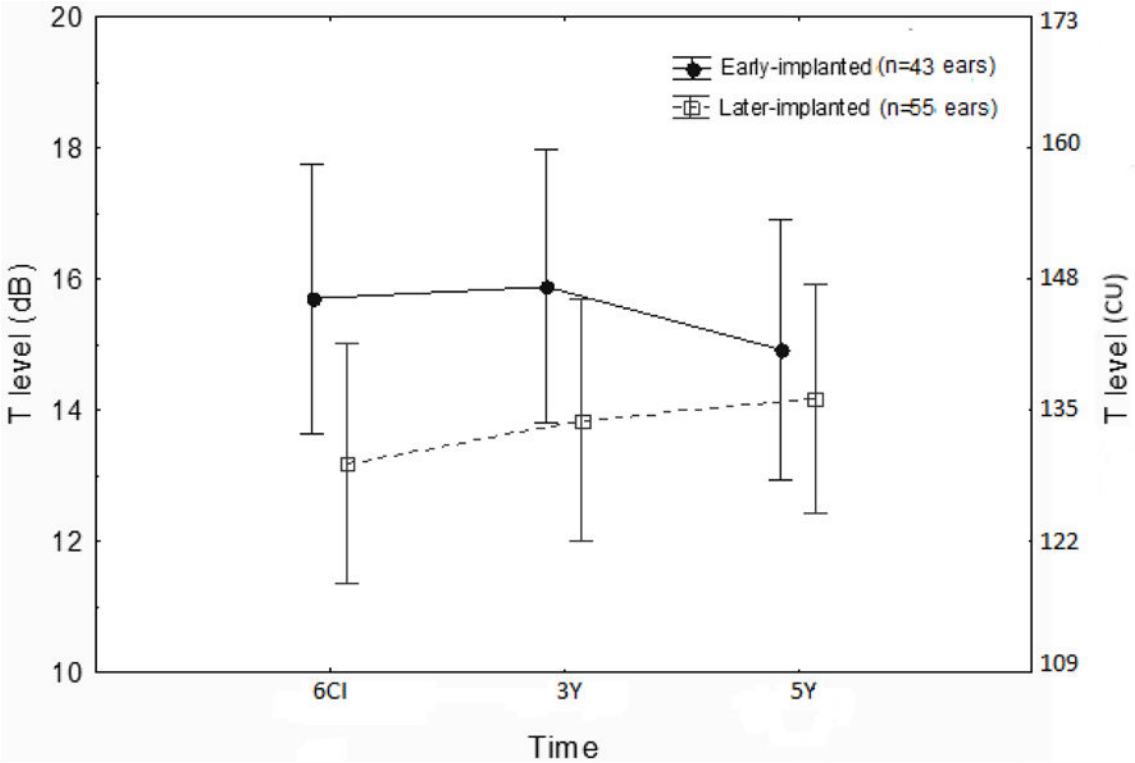

Figure 4.

T-levels for children who received their first cochlear implant at or before 12 months of age (early-implanted, depicted by filled circles) and children who received their first cochlear implant after 12 months of age (later-implanted, depicted by open squares). Data are shown for device settings at 6 months post-activation (6CI), and at chronological ages of 3 (Y3) and 5 years (Y5). T-levels are denoted in charge in dB units (re:1nC) on the left y-axis and in clinical units CU (re:CIC4 implant and 25 μs pulse width) on the right y-axis of the graph. Vertical bars denote 95% confidence intervals.

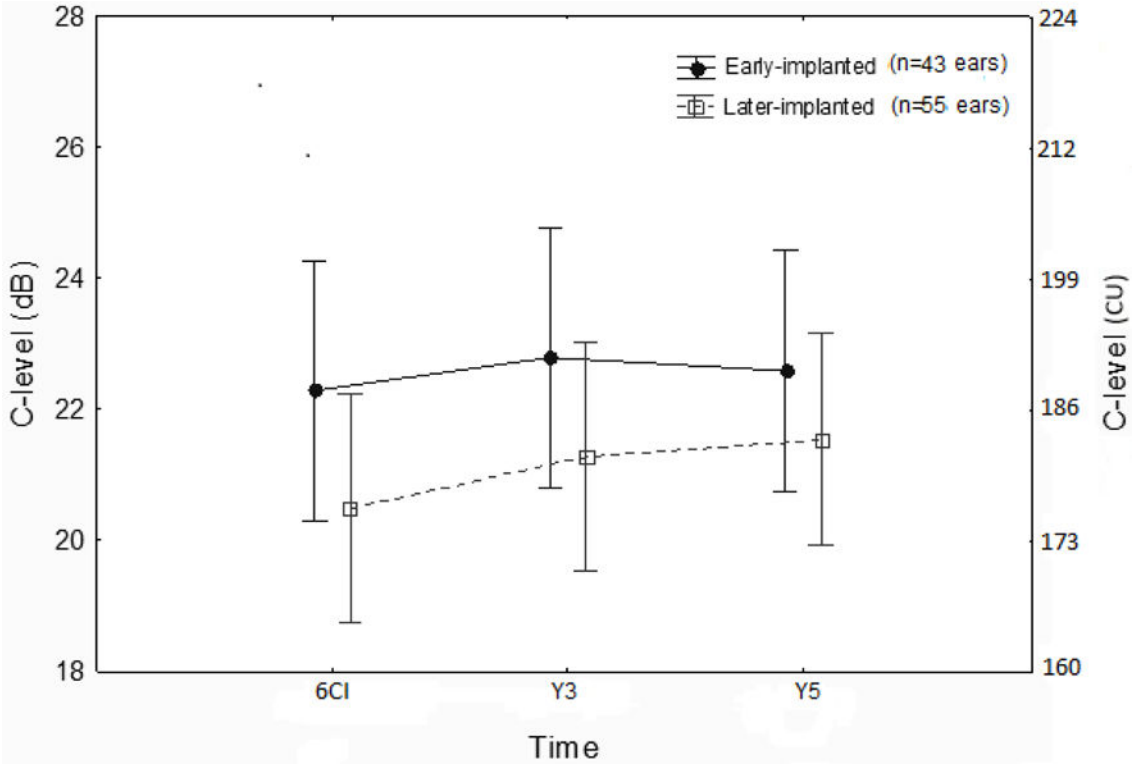

Figure 5.

C-levels for children who received their first cochlear implant at or before 12 months of age (early-implanted, depicted by filled circles) and children who received their first cochlear implant after 12 months of age (later-implanted, depicted by open squares). Data are shown for device settings at 6 months post-activation (6CI), and at chronological ages of 3 (Y3) and 5 years (Y5). C-levels are denoted in charge in dB units (re:1nC) on the left y-axis and in clinical units CU (re:CIC4 implant and 25 μs pulse width) on the right y-axis of the graph. Vertical bars denote 95% confidence intervals.

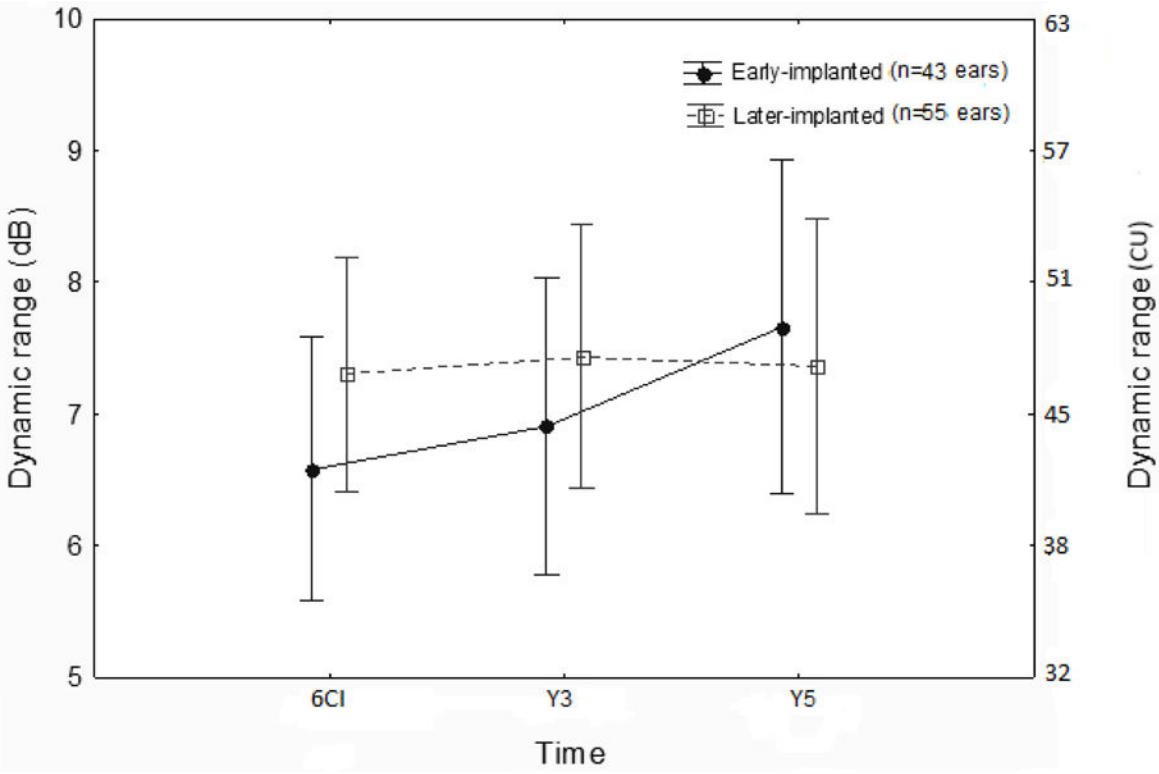

Figure 6.

Dynamic range in dB for children who received their first cochlear implant at or before 12 months of age (early-implanted, depicted by filled circles) and children who received their first cochlear implant after 12 months of age (later-implanted, depicted by open squares). Data are shown for device settings at 6 months post-activation (6CI), and at chronological ages of 3 (Y3) and 5 years (Y5). DRs are denoted in charge in dB units (re:1nC) on the left y-axis and in clinical units CU (re:CIC4 implant and 25 μs pulse width) on the right y-axis of the graph. Vertical bars denote 95% confidence intervals.

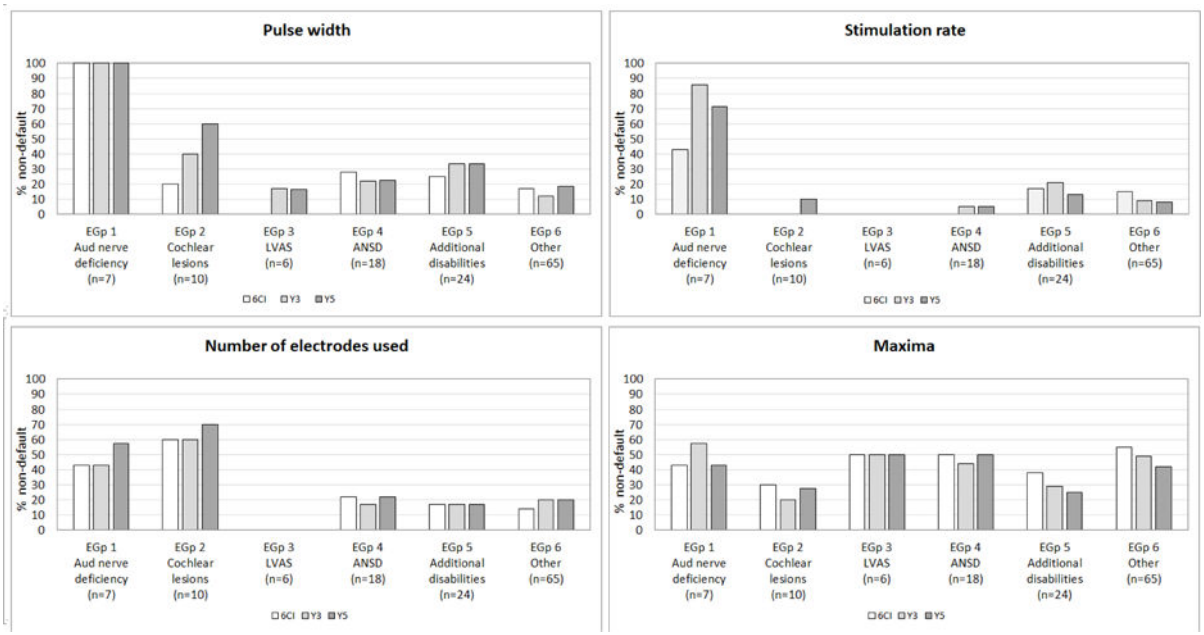

Figure 7.

Percentage (%) of device programming parameter settings with non-default values . Four parameters, including pulse width, stimulation rate, number of active channels, and number of maxima are shown for each of the six etiology groups (EGp). The 6 groups are: 1) auditory nerve deficiency; 2) cochlear lesions, 3) enlarged vestibular aqueduct; 4) auditory neuropathy spectrum disorder; 5) additional disabilities; and 6) Other (unknown etiology, genetic factors, and cytomegalovirus infection) Data are shown for device settings at 6-months post-activation (white bars), and chronological ages of 3 (light grey bars) and 5 years (dark grey bars) for 88 children (n=98 ears).

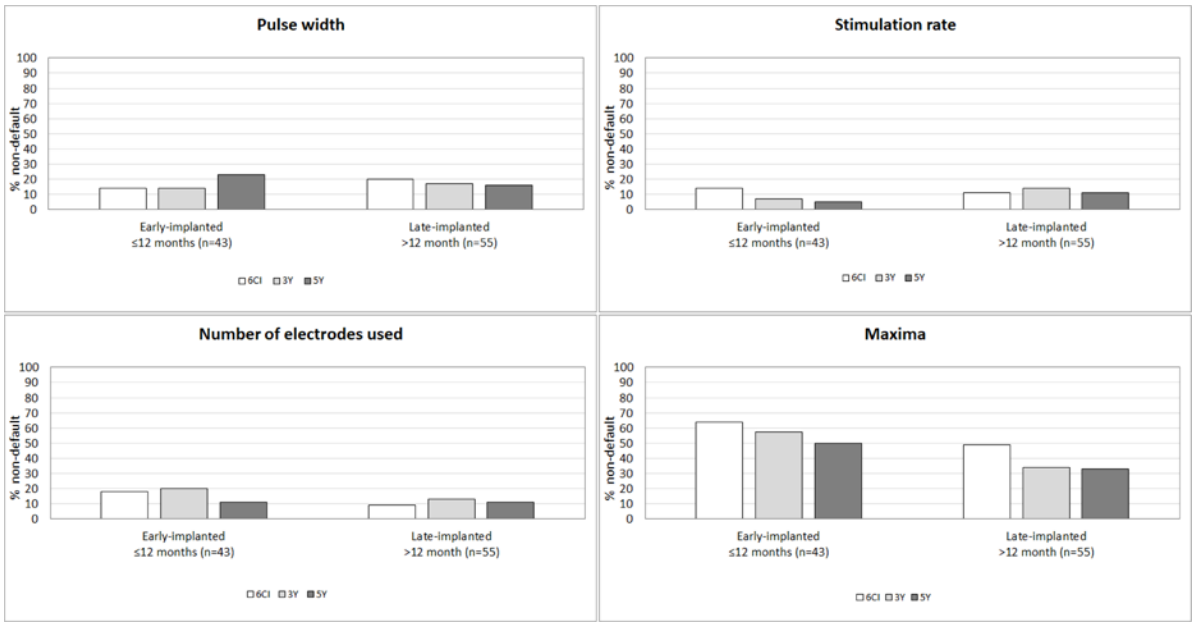

Figure 8.

Percentage (%) of device programming parameter settings with non-default value. Four parameters, including pulse width, stimulation rate, number of channels, and number of maxima are shown for children who received their first CI at or before 12 months of age and for children who received their first CI after 12 months of age. Data are shown for device settings at 6-months post-activation (white bars), and chronological ages of 3 (light grey bars) and 5 years (dark grey bars) for 88 children (n=98 ears).

Table 1

Conversion of Clinical units (CU) to Charge in dB (re:1nC). For a current level of 200 clinical units (CU) and a pulse width of 25 μs, the current in microAmps (μA), charge in nanoCoulombs (nC) in dB re 1nC varied between implant types.

	Example 1: CI24RE (CIC4 chip)		**Example 2: CI24M and CI24R (CIC3 chip)**	
Current in microamps (μA)	$\mu A = 17.5 * 100^{(CU/255)}$	648.14	$\mu A = 10 * 175^{(CU/255)}$	574.44
Charge in nanocoulombs (nC)	$(\mu A*10^{-6})* (\mu s*10^{-6})* 10^{-9}$	16.20	$(\mu A*10^{-6})* (\mu s*10^{-6})* 10^{-9}$	14.36
Charge in dB, re: 1nC	20 × log (nC)	24.19	20 × log (nC)	23.14

Table 2

Demographic characteristics of participants at 5 years of age.

Characters	Number children (percentage)
Gender:	
Male	84 (52.2%)
Female	77 (47.8%)
Age at diagnosis:	
within 6 months	124 (77.0%)
7 to 12 months	14 (8.7%)
13 to 24 months	14 (8.7%)
25 to 36 months	6 (3.7%)
No information available *	3 (1.9%)
Device Configuration:	
Unilateral CI	15 (9.3%)
CI + HA	53 (32.9%)
Bilateral CI	93 (57.8%)
Age at first CI activation:	
within 12 months	55 (34.2%)
13 to 24 months	49 (30.4%)
25 to 60 months	57 (35.4%)
Ear first implanted:	
Right (unilateral)	75 (46.6%)
Left (unilateral)	74 (46%)
Both Ears (simultaneously)	12 (7.4%)
Bilateral:	
Simultaneous CIs	12 (13%)
Sequential CIs	81 (87%)
Time between first and second implants for sequential CI:	
within 12 months	39 (48.1%)
13 to 24 months	25 (30.8%)
25 to 60 months	17 (21.1%)

Abbreviations: CI = cochlear implant, HA = hearing aid

* 3 children diagnosed overseas and no information available.

Table 3

Mean and standard deviation (SD) of T- and C-levels in charge dB (re:1 nC) for six etiology groups at 5 years of age (n=161 children, 252 ears).

	T-level			C-level		
Etiology	**All electrode arrays: (Perimodiolar and straight)**	**Perimodiolar electrode array**	**Straight electrode array**	**All electrode arrays: (Perimodiolar and straight)**	**Perimodiolar electrode array**	**Straight electrode array**
1) Auditory nerve deficiency						
Mean ± SD n=ears	21.3 ± 5.7 (n=12)	19.1 ± 8.9 (n=3)	22.1 ± 4.3 (n=9)	28.8 ± 4.6 (n= 12)	27.0 ± 10.9 (n=3)	29.0 ± 2.9 (n=9)
2) Cochlear lesions						
Mean ± SD n=ears	17.6 ± 4.9 (n=27)	16.2 ± 3.8 (n=12)	18.6 ± 5.6 (n=15)	25.1 ± 4.6 (n=27)	24.1 ± 4.1 (n=12)	26.0 ± 4.9 (n=15)
3) LVAS						
Mean ± SD n=ears	14.2 ± 3.4 (n=19)	13.7 ± 3.4 (n=9)	14.7 ± 3.5 (n=10)	21.5 ± 2.6 (n=19)	21.1 ± 2.0 (n=12)	21.9 ± 3.2 (n=12)
4) ANSD						
Mean ± SD n=ears	14.8 ± 4.7 (n=29)	14.2 ± 5.4 (n=13)	15.2 ± 4.1 (n=16)	22.4 ± 4.0 (n=29)	22.9 ± 4.0 (n=13)	22.0 ± 4.0 (n=16)
5) Additional disabilities						
Mean ± SD n=ears	14.0 ± 4.0 (n=38)	13.3 ± 3.8 (n=26)	15.6 ± 4.4 (n=12)	21.4 ± 4.8 (n=38)	20.3 ± 4.7 (n=26)	24.0 ± 4.2 (n=12)
6) Other Mean ± SD n=ears	14.2 ± 3.5 (n=127)	13.4 ± 3.1 (n=77)	15.4 ± 3.8 (n=50)	21.5 ± 3.4 (n=127)	20.6 ± 3.4 (n=70)	22.9 ± 2.8 (n=50)

Abbreviations: ANSD = auditory neuropathy spectrum disorder, LVAS = large vestibular aqueduct syndrome, n = number of ears.

Table 4

Cochlear implant type, sound processor model and MAP parameters for all children (n=161 children, 254 ears) at 5 years of age.

	Number of ears (percentage)
Implant type:	
CI512/13	21 (8.3%)
CI24RE	202 (79.5%)
CI24R	31 (12.2%)
Electrode array:	
Straight: (CI24R(ST), CI24RE(ST), CI512/13)	113 (55.5%)
Perimodiolar: CI24R(CS), CI24RE(CA)	141 (44.5%)
Sound Processor:	
CP810	84 (33.1%)
Freedom	168 (66.1%)
ESPrit 3G	2 (0.8%)
Sound Coding strategy:	
ACE *	252 (99.2%)
SPEAK	2 (0.8%)
Input processing:	
ADRO and ASC	69 (27.2%)
ADRO	173 (68.1%)
Nil	12 (4.7%)
Stimulation mode:	
MP1+2 *	246 (96.8%)
MP1	4 (1.6%)
MP2	3 (1.2%)
CG	1 (0.4%)
Pulse width:	
25 μs *	190 (74.8%)
<25 μs	2 (0.8%)
>25 μs	52 (20.5%)
Variable	10 (3.9%)
Maxima:	
= 8 *	171 (67.3%)
< 8	9 (3.6%)
> 8	74 (29.1%)
Rate:	

	Number of ears (percentage)
= 900 pps *	217 (85.4%)
< 900 pps	20 (7.9%)
> 900 pps	17 (6.7%)
Number electrodes used:	
22 *	213 (83.86%)
21	7 (2.76%)
20	20 (7.87%)
19	5 (1.97%)
18	5 (1.97%)
17	2 (0.79%)
15	1 (0.39%)
11	1 (0.39%)

Abbreviations: ACE = Advanced Combination Encoder, MP = Monopolar; stimulation mode; μs = microseconds, pps = pulses per second per channel, SPEAK = Spectral Peak

* indicates the default parameter settings recommended in Cochlear Limited's clinical programming software for Nucleus® Freedom™ and Nucleus® CP810 sound processors.

Table 5

Mean and standard deviation (SD) of dynamic range in charge dB (re:1 nC) for six etiology groups at 6-months post-activation (6CI), and at chronological ages of 3 (Y3) and 5 years (Y5).

	Dynamic range in charge dB (re:1 nC)		
Etiology	**6CI**	**Y3**	**Y5**
1) Auditory nerve deficiency (n= 7)			
Mean ±SD	6.6 ± 1.2	6.6 ± 1.3	7.1 ± 2.8
Range	4.4–8.0	4.2–8.1	3.9–12.3
2) Cochlear lesions (n=10)			
Mean ±SD	8.5 ± 3.1	8.6 ± 4.0	8.5 ± 3.0
Range	3.3–13.7	4.2–18.6	4.2–14.7
3) LVAS (n=6)			
Mean ±SD	7.5 ± 2.7	6.8 ± 2.0	6.9 ± 2.5
Range	4.2–11.3	4.7–9.6	4.9–11.6
4) ANSD (n=18)			
Mean ±SD	7.0 ± 2.4	7.5 ± 2.5	8.2 ±2.5
Range	3.7–10.4	2.9–11.2	3.7–13.4
5) Additional disabilities (n=24)			
Mean ±SD	7.7 ± 1.5	7.9 ± 2.3	7.1 ± 2.7
Range	5.6–11.5	2.8–12.0	5.6–14.1
6) Other (n=65)			
Mean ±SD	6.6 ± 1.8	7.1 ± 2.2	7.4 ± 2.3
Range	2.7–11.9	3.0–13.7	2.7–12.9

Abbreviations: ANSD = auditory neuropathy spectrum disorder, LVAS = large vestibular aqueduct syndrome, ‘Other’ include XXXXXXX, n = number.