

# Evaluation of ECAP thresholds, T and C levels in children with sequential bilateral cochlear implants

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## Abstract

**Aim:** The aim of the present study was to compare the values in threshold (T) and comfortable (C) stimulation levels as well as the neural response telemetry (NRT) measurements obtained on the first and the second cochlear implant in children with sequential bilateral cochlear implantation (CI).

**Material and Methods:** Thirty children with sequential bilateral CI between February 2007 and July 2018 were randomly selected. The mean age of the subjects was 7.0 years (age range: 3.3–15.2 years). The NRT thresholds, T levels, and C levels in the electrode (E) 22, E16, E11, E6, and E1 were retrospectively compared for the latest program on the first CI (CI1), and the second CI (CI2) in the postoperative 1st, 3rd, and 6th-month follow-up visits. The duration of daily use of the speech processor on both side was also compared.

**Results:** Twelve male and eighteen female subjects with sequential bilateral CI, were participated in the present study. The median age at CI1 was 15 months and 5 years 5 months for CI1 and CI2 respectively. There was no significant difference between the threshold NRT (tNRT) levels between two ears. The mean tNRT levels were obtained 166 CL and 179 CL in E22 and E1 respectively. The tNRT levels were found higher on the basal electrode rather than the apical electrode ( $p=0.02$ ). The changes in the T and C levels were significant in 1st, 3rd, and 6th-month follow-up visits on the CI2 side ( $p=0.000$ ). The mean daily usage time of the sound processor was found 12.05 and 9.62 hours on CI1 and CI2 respectively.

**Conclusion:** In children with sequential CI, the electrical stimulation levels were similar between ears. The present study shows the programming outcomes during the follow-up in children with sequential bilateral CI.

**Keywords:** Hearing loss; cochlear implant; sequential surgery; bilateral cochlear implantation; neural response telemetry.

## INTRODUCTION

Cochlear implantation (CI) is an effective method for the rehabilitation of hearing in pediatric and adult patients with bilateral severe or profound congenital or acquired hearing loss. Cochlear implants are provided unilaterally or bilaterally throughout the world. Due to the nature of hearing, however, bilateral cochlear implant applications are more advantageous than unilateral applications. In particular, users of the current bilateral cochlear implant technology are known to exhibit better perception of speech under noisy conditions and better sound-localization skills than unilateral implant users (1). In addition, bilateral CI is beneficial for spatial hearing, hearing quality, and speech comprehension (2).

Bilateral CI can be performed in two consecutive surgeries or a single surgery. In sequential applications, the second device is performed several months to several years after the first, while simultaneous bilateral implantation is performed in the same surgical session (3). In the case of sequential bilateral CI, the effects of parameters such as the interval between implantation surgeries, the auditory experience, and the auditory deprivation differences in CI results have been discussed in the literature. In some studies, it has been shown that users with simultaneous bilateral CI had better perceptual skills and demonstrated better auditory skills with CI (3,4).

It is still a matter of controversy, however, whether a simultaneous bilateral CI provides better results than sequential bilateral CIs. A search of the literature found

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that the results of simultaneous CI in children were better than those of sequential CI; it has also been observed that a long interval between the two implantations has either no effect on performance or a negative effect on performance (5,6).

When making decisions about second-side implantation in the pediatric group, clinicians and families should consider both the type and the extent of the expected benefit both the second implant and for bilateral performance as well as the rate of development expected after many years of unilateral CI (5).

Approximately 2–3 weeks after the surgical insertion of the cochlear implant, the speech processor must be properly programmed for the individual to experience hearing (7). The electrical parameters in the programming vary within a few months of the operation, but they stabilize within approximately the first year after the initial programming. The following psychophysical parameters are used to determine the quality of hearing: the electrical dynamic field (DR), the comfortable (C) level, and the threshold (T) level that provide the dynamic range. The C level is defined as the highest level that the patient can tolerate without experiencing discomfort, while the T level is defined as the quietest sound that the patient can perceive in all stimulation trials (8). Dynamic range is the difference between these two values and refers to the scope of the voice perceived by the patient. The psychophysical parameters are generally measured for each electrode and are reported under various regions of the electrode array. These parameters can be determined by behavioral or objective methods when programming (9).

The most commonly the electrical impedance and the Electrically Compound Action Potential (ECAP) measurements are used for objective testing of the CI. With these methods, the integrity of the intracochlear electrode and the level of action potential is determined objectively. The parameters used in programming may differ for both speech processors in simultaneous or sequential bilateral cochlear implants.

In our country, bilateral CI is applied to children under 4 years of age without any conditions. On the other hand, cases of bilateral Cochlear ossification, bilaterally blindness, bilateral congestion, and corpus callosum agenesis fall within the scope of state payment for children who are older than 4 years of age. There were unilateral implant cases before bilateral cochlear implantation was initiated and with the increasing number of simultaneous or sequential cochlear implantation procedures. There is now a large number of pediatric cochlear implant users in the period between the date of their first operation and the planned second implantation. It was believed that an evaluation of the effect of the variety of surgical operation intervals on the programming parameters will contribute to the literature. The aim of the present study was to compare the values in T and C levels as well as the ECAP measurements obtained on CI1 and CI2 in children with sequential bilateral cochlear implants.

## MATERIAL and METHODS

In this study, bilateral Cochlear implants were applied in Department of Otorhinolaryngology at Hacettepe University. The programming visits of all subjects were followed by the Department of Audiology at Hacettepe University. Ethical approval was obtained from the Hacettepe University Non-Interventional Clinical Researches Ethics Board for the retrospective analysis of the data (GO 18/411-26).

### Inclusion Criteria

1. Patients with bilateral CI sequentially
2. Patients who had an etiology of idiopathic hearing loss
3. Exhibiting no evidence of auditory neuropathy, cochlear nerve hypoplasia, or cochleovestibular malformation
4. Normal preoperative radiological evaluation of the cochlear structures and the cochlear nerve
5. Full insertion of the electrode array in the surgery
6. Using the default pulse width values on the both side
7. At least six months of usage on the CI2
8. Regular use of both speech processors

Thirty children with sequential bilateral CI between February 2007 and July 2018 were randomly selected. The mean age of the subjects was 7.0 years (age range: 3.3–15.2 years). The demographic characteristics of the subjects included in the study are shown in Table 1.

### Neural Response Telemetry (NRT) Measurements and Postoperative Programming Parameters

The data in five distinct electrode (E) regions (E22, E16, E11, E6, and E1), grouped with electrodes for T levels, C levels, and Neural Response Telemetry (NRT) thresholds, were included in the analysis. The NRT thresholds were measured with AutoNRT module. The programming parameters were analyzed using Custom Sound™ 5.1 software, which was used routinely in the audiological follow-up after cochlear implantation. First, the NRT thresholds, T levels, and C levels were determined for the latest program applied to the first CI (CI1), and then the second CI (CI2) was compared with the changes in the postoperative 1st-, 3rd-, and 6th-month controls of the CI2. The NRT thresholds could not be determined while the child was crying or disturbed during the programming session. Non-definable programming sessions with NRT thresholds were not included in the analysis.

In the programming the default programming parameters (such as Advanced combined encoder strategy, maxima of eight, monopolar 1+2 stimulation mode) were selected in all subjects. The data of the adjacent electrode were evaluated if the specified electrodes were switched off due to a short circuit, open circuit, or high impedance. In order to prevent individual differences, the T and C levels were adjusted by two experienced pediatric audiologists using a behavioral method by considering the NRT thresholds in programming. At the same time, the duration of daily use of the speech processor in both ears was compared, and the relationship to the interval between the two CIs was evaluated.

Table 1. Demographic Characteristics of Individuals

ID	Age (years)			CI1		CI2			
		Age at CI	Duration of CI use	Type of implant	Type of SP	Age at CI	Duration of CI use	Type of implant	Type of SP
1	4.6	1.2	3.4	CI422	CP910	3	1.6	CI422	Kanso
2	5.1	1.9	3.2	CI422	Kanso	3.7	1.4	CI422	CP910
3	6.3	1.7	4.6	CI422	CP910	4.8	1.5	CI422	Kanso
4	5.7	1	4.7	CI24RE(CA)	CP910	3.6	2.1	CI422	CP910
5	10.3	1.5	8.8	CI512	Kanso	6.5	3.8	CI422	CP910
6	6	1	5	CI422	CP910	3.9	2.1	CI422	Kanso
7	12.6	2.4	10.2	CI24RE(CA)	CP910	12.0	0.6	CI422	CP910
8	10.8	3.7	7.1	CI24RE(CA)	CP810	9.9	0.9	CI422	Kanso
9	15.2	12.1	3.1	CI422	CP910	14.2	1	CI422	Kanso
10	5.4	2.6	2.8	CI422	CP810	3.5	1.9	CI422	CP810
11	9.6	1.2	8.4	CI512	Kanso	8.3	1.3	CI422	Kanso
12	3.3	0.9	2.4	CI422	CP910	1.6	1.7	CI422	CP910
13	3.3	0.9	2.4	CI422	CP810	2.6	0.7	CI422	Kanso
14	4.1	1.1	3	CI422	CP910	2.3	1.8	CI422	CP910
15	4.1	1.9	2.2	CI422	CP910	2.8	1.3	CI422	CP910
16	4.1	1.1	3	CI422	CP910	2.3	1.8	CI422	Kanso
17	6.6	1.4	5.2	CI422	CP910	4.8	1.8	CI422	CP910
18	7.7	1	6.7	CI422	CP810	6.6	1.1	CI422	Kanso
19	10.3	1.4	8.9	CI512	CP810	9.3	1	CI422	Kanso
20	4.9	2.4	2.5	CI422	CP910	3.8	1.1	CI422	Kanso
21	4.3	1	3.3	CI422	CP910	3.4	0.9	CI422	CP910
22	5.9	3.5	2.4	CI422	CP910	4.8	1.1	CI422	Kanso
23	3.7	1.1	2.6	CI422	CP910	1.7	2	CI422	Kanso
24	4.3	1	3.3	CI422	CP910	2.7	1.6	CI422	Kanso
25	7.1	2	5.1	CI24RE(CA)	CP910	6.1	1	CI422	CP910
26	4.1	1.2	2.9	CI422	CP910	2.5	1.6	CI422	CP910
27	13.5	1.2	12.3	CI24RE(CA)	CP910	11.1	2.4	CI422	Kanso
28	7.8	4.1	3.7	CI422	CP910	6.7	1.1	CI422	Kanso
29	4.7	1.1	3.6	CI422	CP910	2.9	1.8	CI422	CP910
30	13.8	1.7	12.1	CI24RE(CA)	CP910	11.3	2.5	CI422	CP910

CI: Cochlear implantation. CI1: First performed CI; CI2: Second performed CI; SP: Sound processor

### Daily usage time of the sound processor

The daily usage time of the sound processor was recorded in subjects with CP910 and Kanso sound processors from the most recent programming session in the Custom Sound 5.1 software. In the CI1 side, data were collected for 24 subjects and in the CI2 for 28 subjects.

### Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics 18.0 for Windows. The mean, median and standard deviation values were used for numerical variables and the frequency distribution was used for ordinal variables for the analysis of the data with descriptive statistical methods. As the evaluated

parameters did not show normal distribution, independent t-test was used in the comparisons between the groups. Statistical significance was determined as  $p < 0.05$ .

## RESULTS

### Demographic Features

Twelve male and eighteen female subjects with sequential bilateral CI, were participated in the present study. Only four patients were implanted on the left ear in CI1, and remaining were implanted on the right side. The median age at CI1 was 15 months (12 mo – 12 y 2 mo) and mean duration of CI1 use was 5 years (25 mo – 12 y 3 mo). The median age at CI2 was 5 years 5 months (20 mo – 14 y 3

mo) and mean duration of CI2 use was 18 months (7 mo – 3 y 8 mo). The mean time between two CI was determined 3 years 5 months (10 mo – 9 y 7 mo). The types of the implants were CI422 (n=21), Freedom CI24RE (CA) (n = 6), and CI512 (n= 3) in the first ear. All subjects were implanted with CI422 (n=30) in the CI2.

**Threshold NRT (tNRT) Measurements**

The tNRT levels were obtained in at least one measurement for all subjects. Mann Whitney U test was performed to compare the tNRT levels of CI1 in the most recent programming session and CI2 in sixth month follow-up. There was no significant difference between the tNRT levels of the E22 (p = 0.34), E16 (p = 0.76), E11 (p = 0.21), E6 (p=0.11), and E1 (p = 0.40) between two ears. The tNRT levels of both ears are shown graphically in Figure 1. The changes in the NRT thresholds were not statistically significant in 1st, 3rd, and 6th-month follow-up visits on the CI2 side (p>0.05).

The mean tNRT levels were obtained 166 CL and 179 CL in E22 and E1 respectively. The tNRT levels were found higher on the basal electrode rather than the apical electrode (p=0.02).

The changes in the tNRT levels were not significant in 1st, 3rd, and 6th-month follow-up visits on the CI2 side (p>0.05). No statistical significance was observed between the tNRT thresholds of two ears with a different type of implant electrode in nine cases (p>0.05).

**Postoperative Programming Parameters**

During regular follow-up visits, the programmes of all subjects were analyzed via Cochlear™ Custom Sound 5.2 software retrospectively. The Advanced Combination Encoder (ACE) strategy was used in all subjects. The same pulse width values with the CI1 were selected for the programming of the CI2 side. The default pulse width value differs according to the type of the internal implant. The pulse width was selected automatically from the software as default 37µsec for CI422 implants and 25 µsec for CI24RE(CA) and CI512. There was no change in the pulse width during the follow-up visits in none of the children.

**Evaluation of the T levels**

The mean T levels were given in Figure 2 for the CI1 in the most recent programming session and CI2 in 6th-month follow-up visit. There was no significant difference between the T levels of the E22 (p = 0.63), E16 (p=0.27), E11 (p=0.57), E6 (p=0.54), and E1 (p=0.44) between two ears. The changes in the T levels were significant in 1st, 3rd, and 6th-month follow-up visits on the CI2 side (p=0.000) (Figure 3).

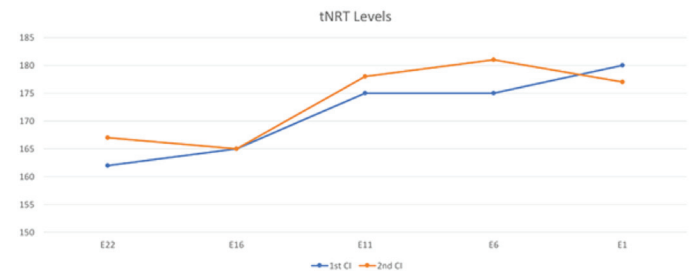
**Evaluation of the C levels**

The mean C levels were given in Figure 4 for the CI1 in the most recent programming session and CI2 in the 6th-month follow-up visit. There was no significant difference between the C levels of the E22 (p=0.32), E16 (p=0.12), E11 (p = 0.37), E6 (p=0.40), and E1 (p = 0.26) between two ears. The changes in the C levels were significant in 1st, 3rd,

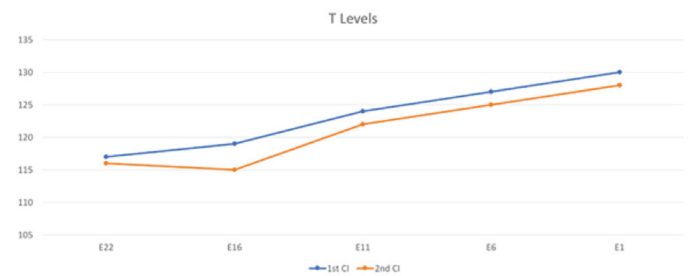
and 6th-month follow-up visits on the CI2 side (p=0.000) (Figure 5).

**Daily usage time of the sound processor**

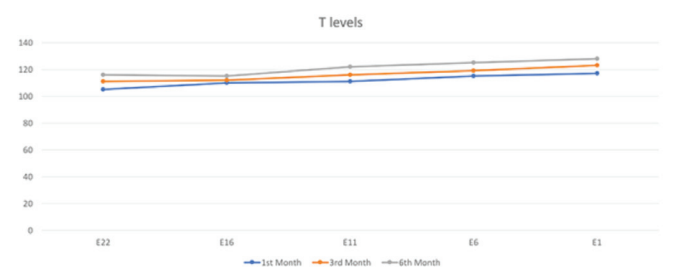
The mean daily usage time of the sound processor was found 12.05 and 9.62 hours on CI1 and CI2 respectively. Although the daily usage of the sound processor was higher on the first ear, it was not observed a significant difference between the ears (p>0.05).



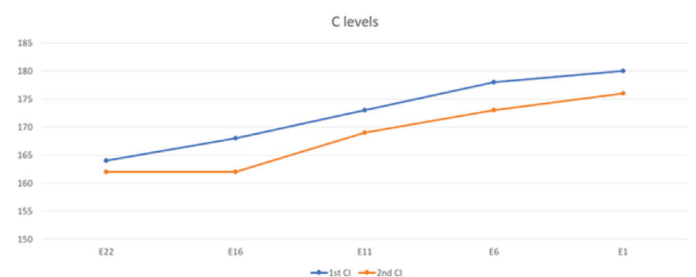
**Figure 1.** The tNRT levels of first and second cochlear implant side



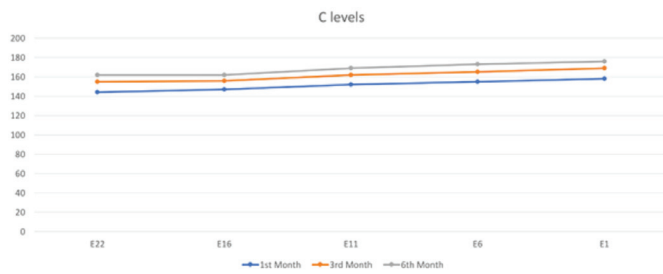
**Figure 2.** The mean T levels for the CI1 in the most recent programming session and CI2 in 6th-month follow-up visit



**Figure 3.** The changes of the T levels in 1st, 3rd, and 6th-month follow-up visits on the CI2 side



**Figure 4.** The mean C levels for the CI1 in the most recent programming session and CI2 in the 6th-month follow-up visit



**Figure 5.** The changes of the C levels in 1st, 3rd, and 6th-month follow-up visits on the CI2 side

## DISCUSSION

This study was performed to investigate the changes in T levels, C levels, and, ECAP thresholds between CI1 and CI2 in children with sequential bilateral CI. Results of the present study revealed that T levels, C levels and ECAP thresholds are similar on both ears in children with sequential bilateral CI.

The stimulation levels can be set with objective measures and also with the behavioral judgement of the loudness during the programming session (10). The ECAP levels can be used for setting the T and C levels during the programming in children with CI (11). Gordon et al. stated that ECAP thresholds recorded on the same day should be used for setting the MAP levels with the method of ECAP in the CI users (12). In the current study, the ECAP based fitting was performed together with the behavioral responses in all children. The T-levels and C-levels were set using the ECAP thresholds recorded at the same fitting session. Due to the similar ECAP thresholds and C levels, no statistically significant difference was observed between the two ears.

After the initial activation of the CI2, the electrical stimulation levels of the CI1 were not changed for a while during the follow-up of the children with sequential bilateral CI in our clinical routine. In the adaptation period prior to the CI2, we recommend performing auditory perception activities only with CI2 condition for 1-2 hours daily.

Caldes et al., evaluated the NRT thresholds in six children with bilateral cochlear implant with simultaneous surgery. They reported no significant difference in NRT thresholds between the ears and mentioned that simultaneous CI surgery is efficient for bilateral synchronized neural stimulation (13). Similar to this finding, the ECAP thresholds of the children with sequential bilateral CI were not significantly different between the ears in the present study.

These findings were in agreement with previous studies who analyzed postoperative ECAP measurements (11). Telmesani et al., compared the intraoperative and postoperative ECAP thresholds and found no statistically significant differences in ECAP thresholds at the different follow-up visits. They defined that mean ECAP thresholds measured at 3, 6 and 12 months remained similar to initial

stimulation (11). During the follow-up visits, it is important to determine tNRT levels for effective mapping especially in children.

In our series, there was a significant difference between the ECAP thresholds in the basal (E1) and the apical (E22) electrodes. The ECAP thresholds were significantly higher in the basal portion of the cochlea. Caldes et al. showed that the mean NRT thresholds in E1 were significantly higher than E22 and E16 (13). These findings suggest that apical portion of the cochlea was stimulated with hearing aids preoperatively and neuronal synchronization was better at apical electrodes.

The location of the electrode is a crucial issue in cochlear implantation. In the literature, many papers show the electrical stimulation levels of the differently located electrode arrays (14,15). In the study of Saunder et al. it was found that the electrodes closer to the modiolus can be stimulated at a reduced current level due to the higher spread of excitation (15). Park et al., investigated the electrical stimulation levels in fourteen children with sequential bilateral CI who were implanted with a perimodiolar array in one ear and a slim straight in the other ear (14). Although T and C levels was found similar in the lateral wall and perimodiolar electrodes, ECAP levels were higher in lateral wall electrodes. In the present study, six children were implanted with Freedom Contour Advance electrode on CI1 and CI422 on the CI2. No significant difference was found in ECAP levels between the ears with the different electrode array.

Considering the literature findings correlated to the present study, Sparreboom et al. evaluated the effect of sequential bilateral cochlear implantation in children and measured the device use on a Likert scale subjectively (16). They defined the percentage of the device use as full-time in 95% on the CI1 and 68% on the CI2. It was recommended to evaluate the objective device use indicated by data logging. In the present study, the mean daily use of the sound processor was found lower on the CI2 when compared with CI1. This may be due to the limited experience on the CI2. Children with sequential bilateral CI expect similar sound quality and auditory perception with CI1 on the CI2.

A recent article published by Galvin et al., compared the electrical stimulation levels between the CI1 and CI2 and examined the changes in the levels during the follow-up in fifty-seven CI users (17). They evaluated the T and C levels at the initial activation, the second year and the fifth year follow-up visits retrospectively. They excluded the data in the second and third fitting session because of the beginning of the behavioral measurements of C-levels start after the third or the fourth session. It was found out that T levels are similar between the ears whereas C levels are lower in CI2 when compared with CI1. In our series, we could not observe any difference between the two ears in both T and C levels. The reasons for this finding can be the younger age of the children and collected data from

the early programming sessions. Young children cannot respond to the sound or electrical stimulation accurately and give suprathreshold levels for T levels. It is also difficult to evaluate the C levels in appropriate way using loudness scales. Our study presented the early changes in the electrical current levels of children with sequential bilateral CI. In the future studies, it was recommended that long term analysis of the stimulation levels can be investigated in larger cohorts. This is the first study from our country that evaluated and compared the stimulation levels in children with sequential bilateral CI.

## CONCLUSION

In children with sequential CI, the electrical stimulation levels were similar between ears. The T and C levels increased in follow-up visits 6 months after the CI. The daily usage time of the CI was higher on the CI1. The present study shows the programming outcomes during the follow-up in children with sequential bilateral CI.

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