J Am Acad Audiol 29:292–299 (2018)

The Value of Electrically Evoked Stapedius Reflex in Determining the Maximum Comfort Level of a Cochlear Implant

DOI: 10.3766/jaaa.16117

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Abstract

Background: One of the most important steps for good user performance with a cochlear implant (CI) is activation and programming, aimed at determining the dynamic range. In adults, current levels are determined by psychophysical measures. In babies, small children, or individuals with multiple disorders, this procedure requires techniques that may provide inconsistent responses because of auditory inexperience or the age of the child, making it a very difficult process that demands the collaboration of both the patient and the family.

Purpose: To study the relationship between the electrically evoked stapedius reflex threshold (ESRT) and maximum comfort level for stimulating electrodes (C-level) in postoperative CI users.

Research Design: Cross-sectional analytical observational case series study.

Study Sample: We assessed 24 patients of both sexes, aged between 18 and 68 yr, submitted to CI surgery.

Intervention: Otoscopy and immittance. Next, an implant speech processor connected to an Itautec® computer containing the manufacturer's software (custom sound Ep 3–2) was used, as well as an AT 235h probe inserted into the ear contralateral to the CI to capture the stapedius reflex, obtaining electrically evoked stapedius reflex thresholds.

Data Collection and Analysis: Data from the last programming, defining C-levels for each electrode studied, were extracted from the databank of each patient. The manual decay function of the AT 235h middle ear analyzer was used to observe ESRT response in a same window for a longer response capture time. Electrodes 22, 16, 11, 6, and 1 were tested when active, with the aim of using electrodes over the entire length of the CI, and ESRT was considered present when compliance was $\geq$0.05 ml. Stimuli, in current units, were always initiated at 20 cu above the C-level. The analysis of variance parametric test, Tukey's honest significant difference test, the *t*-test, Wilcoxon nonparametric test, and the Kolmogorov–Smirnov test examined whether significant relationships existed between these other factors.

Results: The results demonstrate that all the electrodes selected for the study exhibited higher mean reflex threshold values than their mean C-level counterparts. However, there was no significant difference between them, for electrodes 1, 6, 11, and 16. The data provided allow the use of ESRT to define C-level values and make it possible to stipulate a correction factor ranging between 6 and 25.6 electrical units.

Conclusion: The use of electrically evoked stapedius reflex thresholds can help the team in charge of programming CIs, making the process faster and safer, mainly for infants, small children, or individuals with multiple disorders.

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Key Words: cochlear implant; electrophysiology and middle ear; psychoacoustics/hearing science

Abbreviations: CI = cochlear implant; C-level = maximum comfort level; cu = current units; ECAP = electrically evoked compound action potential; ESRT = electrically evoked stapedius reflex threshold; HSD = honest significant difference; ISAD = individual sound amplification device

INTRODUCTION

One of the most important steps for good user performance with a cochlear implant (CI) is activation and programming, aimed at determining the dynamic range. This is the range between the amount of current that first induces an auditory sensation, that is, the threshold for electrical stimulus, and the maximum intensity of electrical stimulation without causing discomfort to the patient (C-level) (Gordon et al, 2002; Ferrari, 2003; Ferrari et al, 2004).

In adults, current levels are determined by psychophysical measures (behavioral method). In babies, small children, or individuals with multiple disorders, this procedure requires techniques that may provide inconsistent responses because of auditory inexperience or the age of the child, making it a very difficult process that demands the collaboration of both the patient and the family (Thai-Van et al, 2004).

Using only the aforementioned behavioral method to program the processor tends to prolong adaptation to the CI owing to the difficulty in establishing suitable stimulus levels (Gordon et al, 2002; Ferrari, 2003; Thai-Van et al, 2004).

To remove the behavioral factor inherent to the configuration process, some manufacturers propose to rely on telemetry capabilities of devices, where neural physiological responses induced by electrical stimulation generated from the electrodes within the cochlea can be recorded. Previous research has shown that thresholds for electrically evoked compound action potential (ECAP) (Brown et al, 1990) are correlated with threshold and C-level (Brown et al, 2000; Gordon et al, 2004; Van Den Abbeele et al, 2012), suggesting that they can be used during CI programming to predict these levels. However, not all CI manufacturers include telemetry capabilities in their products. In the absence of such capabilities, it is proposed to use evoked potential instrumentation to detect the neural activity within the cochlea and auditory nerve (Bergeron and Hotton, 2015).

The use of objective measures in the CI adaptation process has contributed to defining the dynamic range because they provide specific values that serve as the basis for initiating the electrode mapping process, especially in infants and young children. There are a number of ways to obtain objective measures from the auditory nerve in CI users using electrical stimulation. One of these is by measuring the stapedius reflex (Gantz et al, 1994; Brown et al, 2000), a simple and rapid procedure that involves inserting a probe into the ear contralateral to the CI.

The correlation between the values obtained objectively and those obtained by the behavioral method has been widely studied. However, in clinical practice, there is no consensus or standardization as to the use of these measures for the treatment of CI users. Electrically evoked stapedius reflex thresholds (ESRT) are promising, given that the research has shown a relationship between these thresholds and the maximum comfort level in adults and children with CI (Stephan and Welzl-Müller, 2000). The ESRT can be obtained easily in the clinic, using standard immittance measurement instrumentation, or intraoperatively, via direct observation or immittance measurements (Pau et al, 2011). It can be recorded for a majority of patients (Hodges et al, 1999; Gordon et al, 2004; Van Den Abbeele et al, 2012) and generally lies around the comfort level, thus below the uncomfortable level (Jerger et al, 1988; Hodges et al, 1997). However, reports on applying the method in children are scarce (Bresnihan et al, 2001).

As such, and given the need for more studies that use objective data to program the speech processor, primarily in children, the aim of this study was to assess the relationship between ESRT and maximum comfort levels in postoperative electrical stimulation of electrodes in users of CIs who could safely and definitively define maximum comfort levels in postoperative electrical stimulation of the electrodes.

METHODS

This is a cross-sectional, observational, and analytical case series study conducted with patients of both sexes, treated at the CI program of two hospitals specialized in CIs in Pernambuco state, Brazil. The sample was composed of 24 volunteers, 14 (58%) men and 10 (42%) women. Two volunteers exhibited bilateral CI, and testing was carried out individually in both ears, resulting in the study of 26 ears, with 18 (69%) devices implanted in the right ears and eight (31%) in the left. The participants were aged between 13 and 68 yr (mean = 39 yr, Med = 39 yr, Mod = 41 yr, $\sigma = 16.51$). All the individuals were submitted to CI surgery (Cochlear®) from 2007 to 2013. All the electrodes were Contour® Advanced models, manufactured by the Cochlear Corporation®. Only one participant had a deactivated electrode (electrode 1), which therefore was not submitted to the reflex test.

Participants exhibited the following auditory loss etiologies: meningitis, ototoxic, idiopathic congenital factors, gestational rubella, acquired idiopathic, otitis, acoustic trauma, traumatic brain injury, neurotoxoplasmosis, and neurofibromatosis. With respect to duration of hearing loss, 10 participants showed prelingual hearing impairment (41.6%), and 14 participants showed postlingual loss (58.4%). The mean auditory privation time was 9.86 yr (σ = 12.22). Mean individual sound amplification device (ISAD) use was 9.10 yr (σ = 11.22). Mean CI use time was 2.16 yr (σ = 1.34).

The following inclusion criteria were adopted: patients submitted to CI surgery at the two reference hospitals in Pernambuco who could safely and definitively define maximum comfort levels in postoperative electrical stimulation of the electrodes; patients with "type A" tympanogram curve in the ear contralateral to the CI; patients with no diagnosis of osteosclerosis, auditory neuropathy spectrum disorder, or cochlear malformations; and individuals with Cochlear® CIs.

The exclusion criteria were patients with altered otoscopy and/or tympanometry that indicated changes in the outer ear and/or malfunctioning of the middle ear contralateral to the CI, and those with an altered or damaged outer and/or inner CI unit.

Data collection was performed at two hospitals specialized in CI in Pernambuco state, one private and the other public. This study was approved by the Human Research Ethics Committee of the Health Sciences Center of Universidade Federal de Pernambuco (CEP/CCS-UFPE) (protocol number 165.894/2012). All the participants gave their informed consent.

Data Collection Methods

Medical records were analyzed to screen participants to collect the relevant study variable data.

In the next step, the following procedures were carried out:

- Otoscopy—performed by an otorhinolaryngologist to assess the external auditory canal and the tympanic membrane, using a Heine® k100 otoscope.
- Immittance—tympanometry was conducted with an Interacoustics® automatic AT 235h middle ear analyzer to select participants with a "type A" tympanogram curve in the ear contralateral to the CI. Next, an implant speech processor connected to an Itautec® computer containing the manufacturer's software (custom sound Ep 3–2) was used, as well as an AT 235h probe inserted into the ear contralateral to the CI to capture the stapedius reflex, obtaining ESRT. The electrical stimuli were sent via CI, and the reflex was captured by the AT 235h probe. The aim was to obtain the lowest electrical stimulus in which the reflex is captured.

Data from the last programming, defining C-levels for each electrode studied, were extracted from the databank of each patient.

The manual decay function of the AT 235h middle ear analyzer was used to observe ESRT response in the same window for a longer response capture time. Electrodes 22, 16, 11, 6, and 1 were tested when active, with the aim of using electrodes over the entire length of the CI (basal, medial, and apical), and ESRT was considered present when compliance was $\geq$0.05 ml. When inactive, the electrode could not be used to obtain the reflex.

Stimuli, in current units (cu), were always initiated at 20 cu above the C-level. For the study of ESRT, the values declined every 10 cu and increased every 5 cu. This process was repeated several times until ESRT was observed.

Statistical Method

Statistical analysis was conducted using the Statistical Package for the Social Sciences (SPSS), version 20.0. The analysis of variance parametric test was used to assess interelectrode differences in ESRT and C-level. Tukey's honest significant difference (HSD) test was applied to determine homogeneity between electrode pairs for each group.

The *t*-test was used to determine whether there were statistically significant differences between ESRT and C-level values, when observed independently from the electrodes. ESRT and C-level values were then compared by electrode using the Wilcoxon nonparametric test.

The Kolmogorov–Smirnov test was carried out considering electrodes 1, 6, 11, and 16 to assess interelectrode differences in ESRT and C-levels.

Correction factors of ESRT in relation to C-levels were obtained by dividing mean ESRT values by mean C-level values, for each electrode.

Multivariate analysis was used to analyze the relationship between the presence/absence of a reflex and the qualitative variables (age group, gender, and etiology), and a correlation test was conducted between the mean ESRT value and the continuous variables (duration of ISAD, auditory privation, and CI use).

The test results were assessed from two perspectives. In the first, a reflex was considered present when at least one of the electrodes exhibited a response and absent when none showed a response. In the second, the cu value of the reflex was determined in each electrode in which it was present. In the first case, comparative analysis between presence/absence and qualitative variables (age group, gender, and etiology) was used. In the second, the individual reflex values were subtracted from the individual C-level values for each electrode to determine a correction factor, that is, a factor used to correct ESRT values in relation to the C-level. This correction factor was calculated by subtracting the mean reflex values from the mean C-level values, per electrode. This was made possible by defining mean reflex and C-level values for each electrode.

The means, standard deviations, and p-values were expressed in tabular form. Differences were considered significant for p and alpha values <0.05.

RESULTS

Of the patients assessed, 73% had reflexes in at least one of the electrodes and 27% showed no reflexes. Table 1 shows the reflex behavior in each electrode, by ear. Figure 1 shows the mean ESRT and C-level values for different electrodes. Figure 2 shows the variability in ESRT and C-levels, per electrode.

The study sample fits a normal distribution. As such, to assess the differences between ESRT and C-level, and interelectrodes and interarrays, that is, considering each electrode individually, the parametric analysis of variance test was applied. The results demonstrated no statistically significant differences, with p-values of 0.748 and 0.359 for ESRT and C-level, respectively.

Furthermore, analysis of the responses for the arrays of basal, medial, and apical electrodes, according to Tukey's HSD test, showed a statistically significant difference for both the ESRT and C-level group, in all the cases in which the array of apical electrodes was studied. Tukey's HSD test was used to determine homogeneity between the electrode pairs for each of the groups. p-values were 0.814 and 0.378 for the ESRT and C-level group, respectively.

The values for ESRT and C-levels, irrespective of electrodes, exhibited statistically significant differences ($p = 0.006$). However, analysis by electrode revealed that only electrode 22 showed a statistically significant difference ($p = 0.007$).

Given these results, the Kolmogorov–Sminorv test was applied, considering electrodes 1, 6, 11, and 16. The p-values for the ESRT and C-level groups were 0.057 and 0.2, respectively, demonstrating normal distribution. The t-test was once again used to compare the two groups, irrespective of electrodes, and no statistically significant differences were observed between ESRT and C-level values ($p = 0.137$). The correction factors measured from the mean ESRT and C-level values, by electrode, ranged from 6 to 25.6 cu, representing 13.89–18.12%, as shown in Table 2. Multivariate analysis demonstrated that the correlation between qualitative variables (age group, gender, and etiology) and the presence/absence of ESRT were not statistically significant.

Furthermore, the correlation between mean ESRT and the continuous variables was not statistically significant, with a correlation index close to zero, denoting the absence of a relationship between the values studied (duration of CI use: $r = -0.179$ and $p = 0.462$; duration of ISAD use: $r = 0.097$ and $p = 0.692$; and auditory privation time: $r = 0.032$ and $p = 0.898$).

Table 1. The Reflex Behavior in Each Electrode

Electrode	ESRT Present (Number of Ears)	%	N
1	10	38.5	25*
6	9	34.6	26
11	12	46.1	26
16	12	46.1	26
22	16	61.5	26

Note: *One of the survey participants presented the first disabled electrode.

DISCUSSION

In the present study, 73% of the participants showed the presence of ESRT. Similarly, other studies that also assessed ESRT obtained equivalent results. Spivak and Chute (1994) evaluated 35 CI users, including adults and children aged between 5 and 70 yr, obtaining reflex responses in 69% of the individuals. Battmer et al (1990) studied 25 CI users aged between 19 and 68 yr, observing no reflex in 24% of the individuals. One of the possible explanations for this finding is that, to avoid discomfort, the intensity of the maximum electrical stimulus was limited to the C-levels of each patient. Thus, the electrical stimulus may have not been sufficient to trigger the stapedius reflex. A second explanation may be related to physiological factors, such as a lower number of surviving fibers in the auditory nerve in cases where there is no reflex.

Hodges et al (1997) observed that reflexes were present in 68% of the patients and were obtained separately for each of the electrodes tested (basal, medial, and apical), which demonstrated a weak correlation between ESRT and behavioral thresholds and a strong correlation between ESRT and discomfort thresholds as well as between ESRT and C-levels. Although ESRT occurred slightly above the C-level, in no case did ESRT exceed the discomfort level.

Cohen et al (1989), during a study of ESRT in basal electrodes, specifically electrodes 1 and 6, showed that 12% of the CI users reported discomfort or even pain in the throat and eyes. This sensation was directly proportional to the increase in cu applied, possibly due to facial nerve stimulation from the electrodes themselves.

Individual assessment of the electrodes showed an absence of reflex in most of those studied, except electrode 22, where the reflex was present in 61.5% of the ears (Table 1). Basal electrodes (1 and 6), as well as those in the study by Battmer et al (1990), exhibited the lowest number of reflexes. This finding may be due

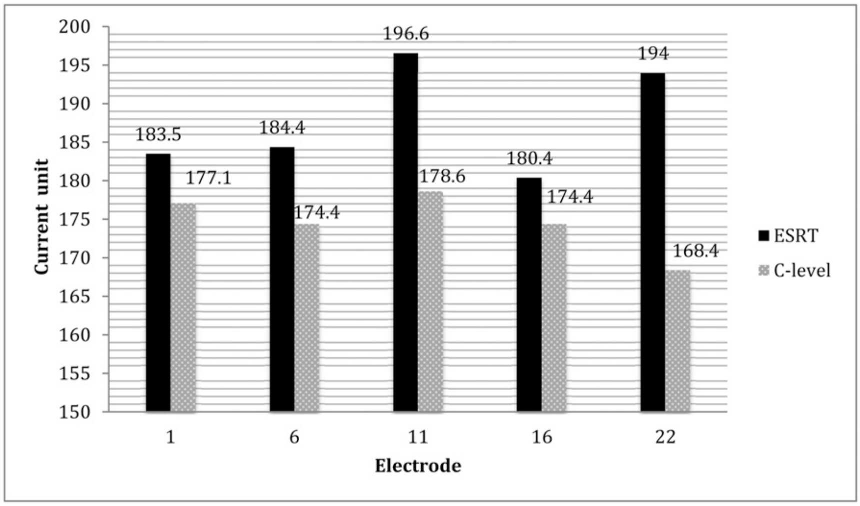

Figure 1. Mean ESRT and C-level values for the different electrodes.

to damage or incomplete insertion of one or more electrodes during surgery. In general, electrode 22, in contrast to electrode 1, routinely exhibits the best insertion in the cochlea because of its most apical position.

However, even though electrode 22 obtained the best quantitative result, there is greater discrepancy between mean ESRT and mean C-level values, with a difference of 25.6 cu, whereas electrode 11 showed the second highest discrepancy, with 12 cu, as depicted

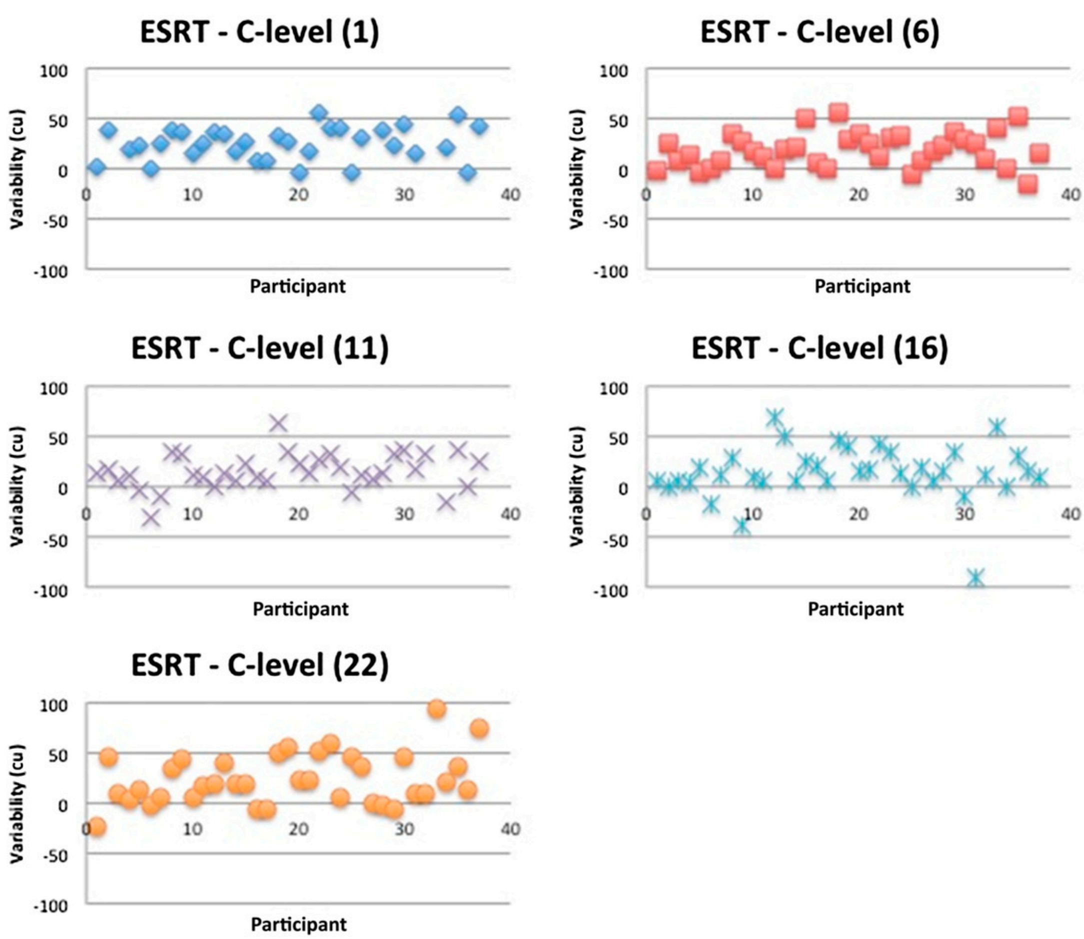

Figure 2. The variability in ESRT and C-levels. (This figure appears in color in the online version of this article.)

Table 2. Correction Factors, in cu and Percentage, for Each Electrode to be Programmed and Measured from the Mean ESRT and C-Level Values

Electrodes	1	6	11	16	22
Correction factor (cu)	6.4	10	12	6	25.6
Correction factor (%)	18.12	17.11	13.89	15.77	14.89

in Figure 1. Vallés et al (2009) also found the largest difference between the two thresholds for electrode 22. This result may be attributed to the greater anatomical distance between the most distal electrode and the stimulation zone of the cochlea.

Mean ESRT values were higher than mean C-level values (Figure 1). This is explained by the fact that ESRT is closer to the discomfort threshold, in contrast to C-level, which is measured using behavioral methods to determine patient comfort levels. This result partially corroborates another study, where ESRT was observed largely above the dynamic range of electrical stimulation of electrodes. However, the study also reinforces the hypothesis that ESRT may be used in the programming of C-levels in patients with inconsistent responses (Stephan et al, 1988).

Electrodes 1, 6, 11, and 16 excluding electrode 22 because it was the only one to show a significant difference when all five electrodes were analyzed together, demonstrated that ESRT and C-level values were not significantly different, which confirms their relevance in clinical use. According to other authors, ESRT can be used for initial programming of C-levels in CI speech processors and provide valuable data for future programming of the device (Battmer et al, 1990; Bresnihan et al, 2001; Lorens et al, 2003; Mason, 2004). Walkowiak et al (2010), in a study with 30 CI users, found no statistically significant differences between mean ESRT and mean C-level values, in adults or children.

Vallés et al (2009) compared intraoperative ESRT and C-levels in the first and second trimester after CI activation in 22 children and also observed that mean ESRT values were higher than mean C-level values in all the electrodes. This same study also demonstrated that, by determining intraoperative ESRT, it was possible to predict approximate C-level values during CI surgery for each of the electrodes studied six months after CI activation.

Table 3. Correction Factors, in cu and Percentage, for Each Electrode to be Programmed and Measured from the Mean ESRT and C-Level Values

Electrodes	1	6	11	16	22
Correction factor (cu)	6.4	10	12	6	25.6
Correction factor (%)	18.12	17.11	13.89	15.77	14.89

Using ESRT, neural response telemetry, and behavioral measures in 16 CI users, Caner et al (2007) reported that the data of these two objective measures, along with behavioral responses, should be included in CI programming to avoid very high C-levels. Walkowiak et al (2011), in a study with the same number of CI users, concluded that both ESRT and ECAP are useful in the creation of CI maps for children.

The present study made it possible to measure correction factors, in cu and percentage, for each electrode to be programmed (Table 2). These correction factors will help the team responsible for programming CI electrodes to determine the C-level objectively, given that the values obtained will serve as the basis for mapping CI electrodes. A number of studies, however, suggest the use of ESRT as C-level in the programming software without applying any correction factor. Polak et al (2005), in a study aimed at comparing the behavioral judgment of C-level and behavioral thresholds for straight and Contour electrode arrays with two objective thresholds, ESRT and ECAP, in experienced adult CI users, in addition to assessing the predictive value of objective measures for the straight and Contour electrode arrays, respectively, concluded that both ESRT and ECAP thresholds can be used equally to estimate subjective levels for either straight electrode or Contour electrode arrays. However, other studies such as that conducted by Hodges et al (1997) report that the stapedius reflex became a routine procedure with adults at their study center and recommend that C-levels can be below 15% of ESRT at the start of CI electrode mapping. This value is close to those estimated in the present study, which ranged from 13.89% to 18.12%, depending on the electrode studied. According to the authors, in the ensuing programming sessions, C-levels should be changed according to the sound experience of each patient. A significant advantage of using correction factors, especially per electrode, is to avoid causing any feeling of discomfort in the patient, given that ESRT, as previously mentioned, is close to the discomfort threshold.

Despite the thought-provoking and positive responses in relation to the use of ESRT in the clinical routine of rehabilitating CI users, it is important to underscore the need to increase sample size in future investigations. The p-value obtained for electrode 22, for example, when ESRT and C-level values are compared, was higher than the confidence interval (0.05). If the sample was larger, the p-value for this electrode might be statistically equal like the other electrodes assessed.

A limitation to the use of ESRT in children is the high prevalence of middle ear changes, which could compromise reflex capture. Moreover, although the procedures described in this study are rapid (~10–15 min to obtain reflexes in five electrodes), this time it may be beyond the capacity of 2-yr-old children to remain calm and motionless. However, this problem can be easily overcome by using entertaining visual resources.

For infants, measures can be obtained during sleep, either spontaneously or induced. Another possibility for the child population would be visual intraoperative assessment of the stapedius reflex, a simple, fast, and objective procedure. Even though intraoperative ESRT was higher than postoperative values, possibly due to the action of anesthetic agents that can weaken the stapedius reflex muscle during surgery (Ruth et al, 1982; Gnadeberg et al, 1994; Pau et al, 2011), this procedure provides important information both at the time of surgery and postoperative activation of the CI (Baysal et al, 2012).

CONCLUSIONS

The electrically evoked reflex stapedius threshold is an objective measure capable of helping in the programming and mapping of the CI because data obtained from this test show good correlation with postoperative C-levels and may provide adequate assistance in adjusting the speech processor of the device.

The correction factors obtained from mean ESRT and C-level values can be used to estimate C-levels.

The use of data from objective tests, which is the case of ESRT, makes the programming and mapping of CI electrodes faster and safer. This is a reliable and objective process and therefore a valuable programming tool.

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