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RECOVERY FUNCTION AFTER 12 MONTHS OF COCHLEAR IMPLANT USE

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ABSTRACT

The outcomes in cochlear implants' cases depend on several factors, including the condition of and propagating of the stimulus in the auditory nerve. The auditory nerve's time constant can provide temporal information about the auditory nerve's behaviour when facing cochlear implant stimuli.We recruited cochlear implanted children with intraoperative neural response, and the recovery functionwas evaluated usingcommercially available cochlear implant software. The data were collected intraoperatively and repeated twice at 12 months after surgery.We found that relative recovery time increases over 12 months of cochlear implant use. Our results also show that the profile of ECAP-REC responses is significantly longer in the postoperative measure.The test-retest reproducibility of evoked compound action potential recordings proved to be reliable.Our study promotes the clinical use of the relative refractory period of the auditory nerve for programming the cochlear implant. It could also be a tool for audiologists while performing prognosis assessments of the changes in cochlear implants function during recovery. The response pattern after 12 months of cochlear implants use should be further studied.New studies should focus on increasing the clinical use of objective measures trustworthy to improve speech perception in cochlear implants users.

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INTRODUCTION

In recent years, there has been an increase in the number of eligible patients for cochlear implant (CI) surgery (Eshraghi et al., 2020). This insinuates the increase in the efficacy use of these implants and the method has proven to have a positive impact when it comes to treating genetic disorders if it is applied at an earlier stage. Thus, for children, CI has been proven beneficial in the end, yielding positive clinical outcomes (Eshraghi *et al*., 2020). The use of the CI does not guarantee, however, the total recovery of hearing and it is necessary in some cases, especially in children, the cognitive maturity in the collaboration to choose the programming parameters of their CI. Studies have improved and objective tests are increasingly used in CI users (Kim *et al*., 2010) because children cannot safely report certain preferences, such as rate and intensity of stimulation, problem with the rehabilitation process. When measuring the evoked compound action potential (ECAP) in children, it was found out that the percentage of electrodes with measurable ECAPs decreased as the stimulating site moved in a basal-to-apical direction (He *et al*., 2018). Similarly, in children with cochlear nerve deficiency, the stimulating site significantly affected the slope of the I/O functions and the relative refractory period. This means that in the latter, the CI's functioning depends on the length of the cochlea. Additionally, the cochlear nerve's responsiveness to the electric pulse was reduced in the children who had cochlear nerve deficiency. With these factors, it is essential to evaluate the various factors that are at play when it comes to rehabilitation from CI surgery. The electrically evoked compound action potential (ECAP) is an important objective test that reveals the auditory nerve responsiveness to electrical stimulation. ECAP recording is a direct method for evaluating ganglion cells' functional characteristics and other auditory neural structures *in vivo*. Major CI manufactures currently available allow ECAP recording through telemetry, a bidirectional communication system between the internal and external components of the CI, which stimulate and capture a response from auditory nerve fibers (Abbas *et al*., 1999; Ferrari *et al*., 2004; Cafarelli-Dees *et al*., 2005; Van Dijk *et al*., 2007; Lai *et al*., 2009). ECAP responses are important predictors of electrical stimulation levels, allowing audiologists to compose maps for testing patients' speech processors, especially children. They believed that a slow refractory period is associated with a large neural population and, consequently, greater temporal response capacity

(Brotos and Psarros, 2010). The temporal response pattern of the auditory nerve in cochlear implant users is vitalfor buildingauditory skills. The present study contributestoECAP-REC time constant (τ) research by (1) elucidating a possible temporal profile of these patients, (2) to investigate the reliability of the test ECAP-RECafter 12 months of use, (3) measuring stability after peripheral auditory stimulation for 12 months for two consecutive times.

MATERIAL AND METHODS

Participants' selection and ethic statement: The present study included nine females and two malesimplanted (n = 11)using a Nucleus 24 CI with a perimodiolar electrode array (N24 Contour Advance; Cochlear Ltd.). As two of the subjects had bilateral implants, 13 measurements were taken. The mean age of the patients was 10.61 years. Participants were recruited after their parents signed aninformed consent form. The inclusion criteria were: (1) users of multichannel Cochlear® CI24RE with perimodiolar electrode array and (2) presence of intraoperative neural responses (ECAP). The exclusion criteria were: (1) partial insertion of electrodes confirmed by imaging tests, (2) patients with multiple handicaps or auditory neuropathy and (3) absence of postoperative ECAP measurements, or (4) unable to tolerate the loudness for the postoperative ECAP-REC.
Thisprospective observational clinical study was approved by the Research Ethics Committee of the Federal University of Pará (#402.7122013) and was conducted at the Bettina Ferro de Souza University Hospital.

Procedure and data acquisition: The measurement parameters of nerve action potentials were determined by the software(Nucleus Custom Sound™; E.P.), according to themethods described by Miller *et al*. (2000), who used advanced modified forward masking techniques. The software automatically measured the recovery function usingthe exponential function, as follows (Müller-Deile *et al*., 2003):

$$ECAP = A\left(1 - e^{\left(-\frac{1}{\tau}\right)(MPI-T0)}\right)$$

A programming interface (POD™) was connected to aspeech processor (Freedom, Cochlear Co.) as a stimulator and a transmission antenna to allow intraoperative measurement. In the postoperative measurement, the stimulator was the patient's speech processor and implant, and the data wereregistered in the software. The medial electrode 11 was usedfrom the array of 22 electrodes to evaluate ECAP-REC. Whenever possible, ten current levels above the ECAP thresholdwere usedintraoperatively. The default parameters were kept for the data collection and recordingsuch as 80 Hz of stimulation rate, with pulse widths of 25 μs, gain (50 dB) and delay (122ms). When no responsewas recorded, the current was increased bytencurrent levels.Intraoperatively, the examination time was approximately 5 min, while postoperativelystimulation levels were increased according to the subjects' loudness comfort, and data were collected twice to evaluate test-retest reliability.Thus,the session lasted approximately 30 min. The three parameters available from the CS EP software werecollected; the absolute refractory period (t0); τ and the amplitude at the saturation level (A). The variable τwas chosen because it is the parameter that represents a possible temporal pattern of the auditory nerve.The data were collected intraoperatively and repeated twice at 12 months after surgeryto analyze the measured stability reliability.

Statistical analyses: Data distribution was Gaussian (D´Agostino Test = 0.2307). The paired t test was used to compare data of intraoperative and postoperative moments. We used arepeated measure Anova and a Tukey post hoc test. Analyses were performed using GraphPad Prism (GraphPad Software Inc).Statistical significance threshold was set at $p<.05$.

RESULTS

ECAP-REC test must be performed through electrical current stimulation. For this reason, we put below in Figure 1 the level of electric current in microvolts used in the intraoperative and in the postoperative moment. The mean of ECAP intraoperative was 187.46 ±16.09 (SD) and postoperative 172.92 ± 10.21 (SD). The mean of ECAP-REC in intraopetative time was 195.41 ± 15.63 (SD) and postoperative 183.44 ± 9.16 (SD).

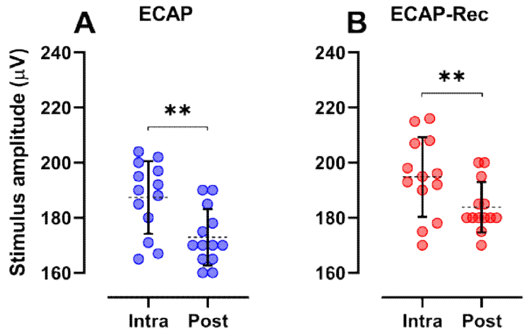

Figure 1. Comparison between electrical current levels used to obtain intraoperative ECAP at the time of surgery (Intra) and after 12 months (Post). The statistically difference (*p*<0.001, t=4.421,df=12) between the intraoperative and postoperative current levels reveals that, at the time of surgery, a higher level of electrical current was needed than after 12 months of use. The dashed lines represent the mean and the bars in format I, the second and third quartiles

The auditory nerve recovery function measured after 12 months of CI use revealed an increase in the temporal response pattern of the τ.The repeated measure Anovaindicateda statistically significant difference in τ between the intraoperative and postoperative measures (F (2.24) = 5.375, $p = 0.01$), between Post and Retest there were no differences (Tukey's test, $p = 0.534$) as shown in Figures 2 and 3. The mean of τ measurements intraoperative was 830.34 ± 456.34 (SD) and postoperative 1196.75 ± 369.21 (SD).

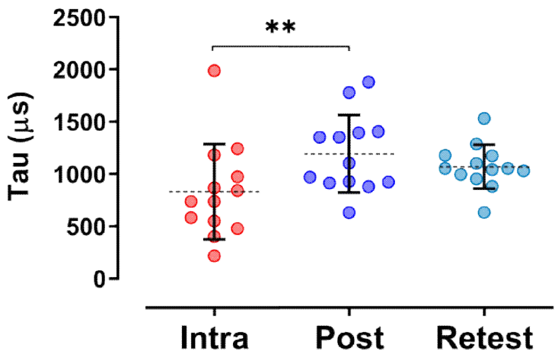

Figure 2. The average of the τ in the intraoperative, postoperative, and testing-retesting data. Statistically, a significant difference was observed between intraoperative and postoperative measures. It also shows the test-retest measuresstability. The profile of ECAP-REC responses is significantly longer in the postoperative measure

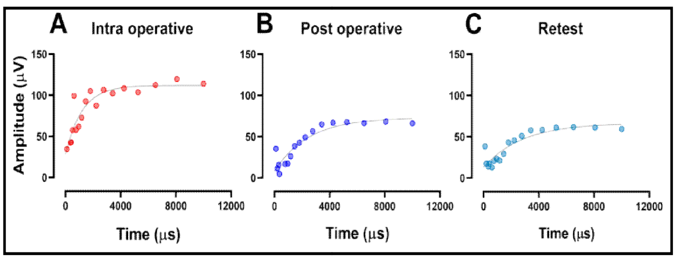

Figure 3. ECAP-RECfunctions exponential growth.(A) represents ECAP-REC τ data, obtained during the intraoperative period.(B) shows ECAP-REC τ data obtained after 12 months of using the cochlear implant. (C) revealsthe measured stability's reliability comparing two subsequent recovery functions after 12 months using the CI device

Regarding the stability of the ECAP-REC test after 12 months of use. The subsequent measurement of the above variables is stable and reliable. All the means of the variables A (μV), t0 (μs) and τ (tau-μs) were not statistically significant between the subsequent measures as defined in Figure 2 (Post and Retest) and Figure 3 (B and C).

DISCUSSION

This study's initial objective of creating the patients' profile of τ responses was aimed at subsequently creating a pattern of standard τ responses.The temporal pattern of auditory nerve responses should be determined first, and then to compare with other auditory tests. The postoperative τwasmeasured after 12 months of continuous CI use and subsequently repeated showed the evaluation of these parameters using the Custom Sound software was safe and reliable. The present study results, combined with previous studies, show that the test's functionality is still limited. Many studies have tried to correlate τ responses and CI stimulation rate (Hughes, Baudhuin, &Goehring, 2014; Shpak *et al*., 2004; He *et al*., 2018) with speech perception tests (Blake, 1997; Brown *et al*., 2000; Kiefer *et al*., 2001). However, a test that evaluates the peripheral auditory system - τ responses - found no strong correlation between speech perception tests and stimulation rates (Lee *et al*., 2012). Our study showed that theτisfaster after 12 months (Figure 2 and 3) of CI use, corroborating Botros and Psarros (2010) study. These results indicate that CI stimulation can prolong theτ response since there may be greater recruitment of nerve fibers after a CI continuous stimulation. Turner *et al*. (2002) stated that"understanding the effects of stimulus level on auditory nerve responses can provide more information on improving the use of objective measures to optimize speech processing strategies potentially." Thus, several factors need to be considered in determining the response that the current study vaguely considered. For instance, a study on the recovery indicated that children who have had cochlear nerve deficiency have a lower response rate when it comes to their CI than those who do not (He *et al*., 2018). Additionally, the same study showed that the cochlea's length also influences the same responsiveness, affecting recovery time. Nevertheless, Da Silva *et al*., (2020) found no correlation between the spread of the current and the recovery period in any electrode array at the electrode 11 site, suggesting that the cochlea's physical aspects have less influence on the refractory time constants. The study shows that most patients responses related to recovery function were a shorter τin the intraoperative period, probably due to higher current levels. However, this is not definite considering that several factors are considered when measuring the CI's responsiveness. Assuming that there was no interference in recovery resulting from the surgery, the time taken for the full recovery was found to be variant. The auditory nerve recovery time after 12 months of stimulation became longer due to lower current levels or better nerve recruitment.Tanamati*et al*. (2009) observed an increased amplitude in neural response after 12 months of CI use (Figure 1). The present study implies that searching for reliable and objective clinical measures improves speech perception in CI users. According to Caldwell, Jiam, and Limb (2017), there are challenges that people with CI face when identifying sounds, especially in a noisy environment. This was similarly echoed by Arenberget*et al*. (2018)in their research, insinuating the need to develop comprehensive research relating to how CI users perceive sound.New studies should focus on increasing the clinical use of objective measures trustworthy. Together, these results show that the expected response pattern τ, ECAP-REC, is shorter in the intraoperative period. These responses tend to increase the auditory nerve recovery time after 12 months of CI use, as there are neural stimulation and possibly greater recruitment of nerve fibers. As such, the response pattern after 12 months of CI use should be further studied. Considering the various profiles and factors that influence nerve recovery, our study promotes the clinical use of the relative refractory period of the auditory nerve for programming the cochlear implant as well ascould be a tool foraudiologists while performing prognosis assessments of the changes in CI function during recovery. A study with a much larger number of subjects may reveal the auditory nerve's temporal pattern. It could be used to validate examinations of brainstem evoked potentials and potentially contributeto study hearing loss in the elderly and other auditory neuropathy occurrences.

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