Original research paper

The relationship between electrical auditory brainstem responses and perceptual thresholds in Digisonic® SP cochlear implant users

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Determining the electrical stimulation levels is often a difficult and time-consuming task because they are normally determined behaviorally – a particular challenge when dealing with pediatric patients. The evoked stapedius reflex threshold and the evoked compound action potential have already been shown to provide reasonable estimates of the C- and T-levels, although these estimates tend to overestimate the C- and T-levels. The aim of this study was to investigate whether the evoked auditory brainstem response (eABR) can also be used to reliably estimate a patient's C- and T-levels. The correlation between eABR detection thresholds and behaviorally measured perceptual thresholds was statistically significant ($r = 0.71$; $P < 0.001$). In addition, eABR Wave-V amplitude increased with increasing stimulation level for the three loudness levels tested. These results show that the eABR detection threshold can be used to estimate a patient's T-levels. In addition, Wave-V amplitude could provide a method for estimating C-levels in the future. The eABR objective measure may provide a useful cochlear implant fitting method – particularly for pediatric patients.

Keywords: Cochlear implant, eABR electrical perceptual threshold, T-level, Loudness growth

Introduction

Cochlear implant (CI) patients vary widely in the health of their remaining hearing system. Individual differences in: neural survival, neural health, and electrode placement create a situation where each patient's electrical thresholds and comfort levels must be specifically tailored for each patient by their audiologist. The main goal of this fitting procedure is to set the range of allowable electrical stimulation for each electrode to match that patient's perception: from their perceptual threshold (T-level) to their 'loudest level' that they can comfortably handle (C-level). These electrical levels are currently determined behaviorally from patient responses. And for some patients – particularly children, older or recently implanted patients – getting reliable and repeatable feedback during the fitting session is challenging. The most common example is fitting young children where a shortened attention span limits the number of thresholds that can be accurately determined within a session. The current strategy for dealing with this is to interpolate the T-levels using already measured nearby electrodes or to estimate T-levels from already determined C-levels on the same electrode. Taken together behavioral fitting methods are time-consuming; it is an art that is subject to the skill of the audiologist, and a procedure that must be done frequently in the first year (4–8 sessions are typical). It is one factor that contributes to the widely varying performance outcomes in CI patients.

Several objective measures have been proposed as tools for estimating T- and C-levels in order to assist the audiologist during CI fitting. These objective measures include: the evoked stapedius reflex threshold (eSRT), the electrically evoked compound action potential (ECAP), and the electrically evoked auditory brainstem response (eABR). The eSRT

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operates at high stimulation levels and has been shown to correlate with the C-levels (Bresnihan *et al.*, 2001; Allum *et al.*, 2002). Several studies have also noted correlations between the ECAP thresholds and behaviorally determined T-levels (Brown *et al.*, 2000; Hughes *et al.*, 2000; Smoorenburg *et al.*, 2002; Holstad *et al.*, 2009) and consequently ECAPs are often used to setup the patient's MAP (In CI, a MAP incorporates all the setting parameters, and more particularly the T- and C-levels on each of the electrodes.). ECAP thresholds are known to often overestimate T-levels (Miller *et al.*, 2008).

Although eABRs are not used to automatically fit the patient in the clinics, eABRs thresholds and the patient's T-levels have been shown to be correlated (Shallop *et al.*, 1990; Brown *et al.*, 1994, 2000; Gordon *et al.*, 2004). Similarly, Morita *et al.* (2003) observed a correlation ($r = 0.84$) between ECAP and eABR thresholds. To date, few studies have investigated the relationship between eABRs and subjective perception using CIs manufactured by Neurelec (Vallauris, France). These studies are of particular interest because the Neurelec Digisonic technology differs significantly from other manufacturers. Notably, in a Neurelec device the loudness is increased by increasing the duration of the electrical pulses delivered to the electrode while for other devices this is achieved by increasing pulse amplitude. Truy *et al.* (1998) found a strong correlation ($r = 0.98$) between eABR and T-levels in a group of seven adult patients implanted with a Digisonic® DX10, the former Neurelec CI generation. This result was further extended by Gallégo *et al.* (1999) who demonstrated the existence of a linear relationship between loudness levels and eABR response amplitude. Both studies showed eABR measures do correlate with behaviorally determined thresholds in Neurelec CI devices.

Since these studies, a new generation of the Neurelec CI has been released (Digisonic® SP). This new device supports an increased stimulation rate (Digisonic® SP = 600 pulse-per-second-per-electrode; Digisonic® DX10 = 260) and has a slightly different electrical pulse shape. The change in the pulse shape was due to a change in the charge delivery method (Digisonic® SP = voltage source; Digisonic® DX10 = current source) and a change in the electronic circuit devoted to charge recovery. Although the impact of pulse shape on objective measures is a topic of debate (Macherey *et al.*, 2006; Bahmer *et al.*, 2010; Bahmer and Baumann, 2011a, 2011b; Undurraga *et al.*, 2012), it appears that stimulation strategy modifications could have a significant impact on objective measures (Eisen and Franck, 2004; McKay *et al.*, 2005; Clay and Brown, 2007).

The objective of this study was to determine the relationship between eABR-based metrics and behaviorally determined T- and C-levels using the newest generation of the Neurelec CI, the Digisonic® SP. Such metrics could provide a useful tool for assisting fitting procedures in the future.

Methods

Subjects

Data from 13 adult (6 male, 7 female; mean age = 47) CI patients from the ENT department of the University Hospital of Nancy in France and the University Hospital of Dijon in France were analyzed for the study. Only data gathered after the patients had more than 1 year of normal and consistent Digisonic® SP CI use were included. These data (eABRs and behavioral T- and C-levels) were gathered as part of the patient's regular clinical follow-up in accordance with the ethical standards described in the Helsinki Declaration of 1975, and revised in 1983. The study did not interfere either with surgical decisions, device choice or with the routine post-operative evaluation. Anonymity has been respected throughout.

Materials and stimuli

Behavioral C- and T-levels were taken directly from each patient's existing MAP file for their standard 'everyday usage' program map. These pulse widths were determined by a trained audiologist during the course of a routine fitting session using the Neurelec Digimap v4.2 fitting software.

For eABR recordings, electrical stimuli were produced by the implant (via a Neurelec Digistim USB interface) and recorded using a low noise ($<5\ \mu V$) Deltamed Centor-USB eABR recording system (sensitivity = 500 μV, bandpass filter = 1.6 Hz to 3.2 kHz, rejection criterion = 80% of the total amplitude). The only difference between the Digistim stimulation and the processor one is the stimulation rate. The first one stimulates at 47 Hz, the second one stimulates at 600 Hz. The recording system was synchronized with the stimuli via a trigger line to allow synchronous averaging. To create each response trace, 2000 sub-recordings each were acquired (sample rate, $F_s = 50$ kHz) and averaged. The recording time window was 10 ms. The first 400 μs of the eABR signal were discarded to exclude the stimulus artifact (Fig. 1). Stimulation and eABR recordings were carried out in accordance with standard protocol, as outlined in Truy *et al.* (1998). Wave identification employed general morphological criteria for ABR wave identification proposed by Picton *et al.* (1974). These criteria were adapted to the peculiarities of electrically evoked ABRs, as described in the literature: the electrically elicited response occurs ~2 ms earlier than with acoustic stimulation. We included only reproducible waves on each of two recordings. All recordings for an individual subject were made during a single session.

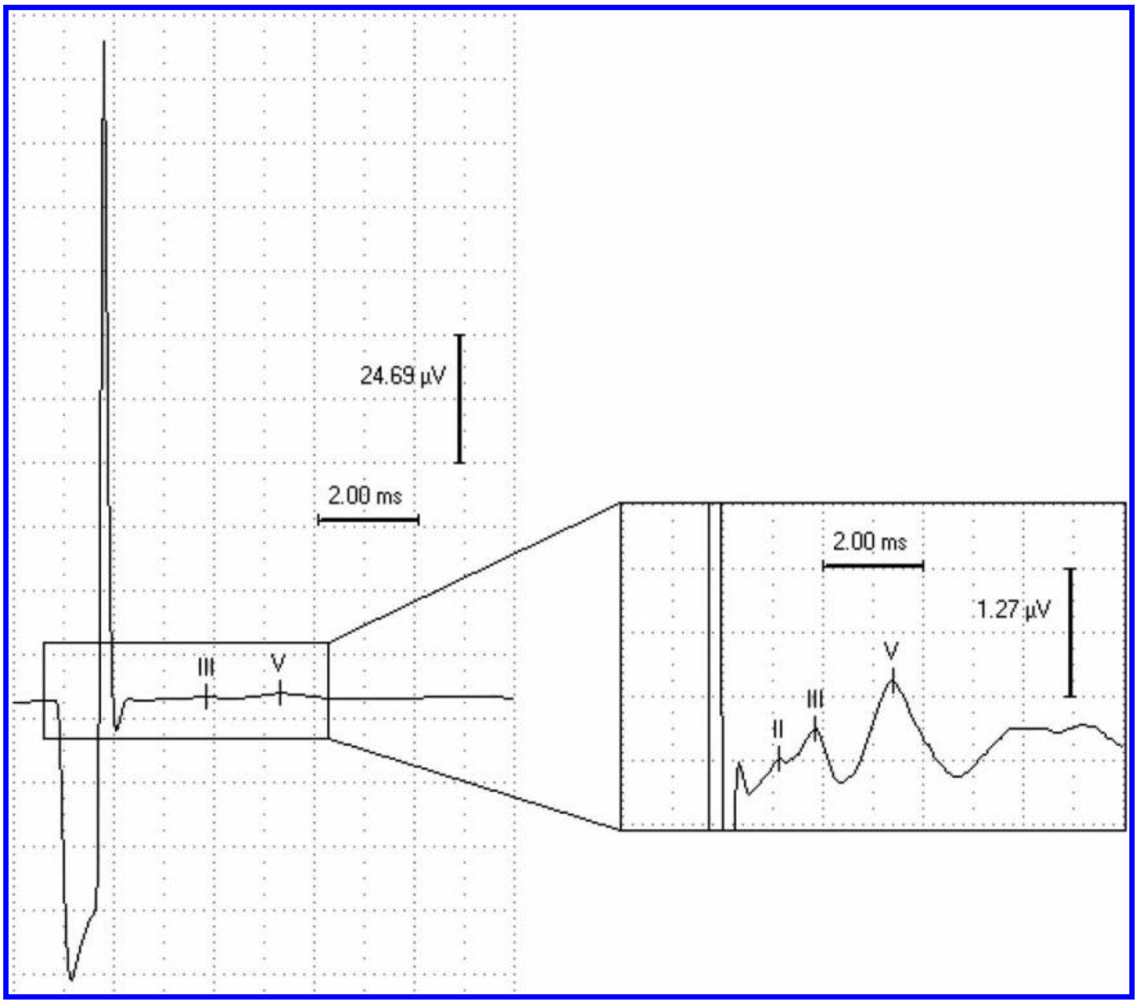

Figure 1 Example of a single electrically eABR. The first trace depicts the entire recording and mainly shows the artifact produced by the electrical stimulation (largest peak, (~150 µV)). The second trace is a magnified version revealing eABR Waves-II, III, and V.

Measurement procedure

With subjects lying comfortably on a bed, eABR surface electrodes were placed as follows: positive electrode on the vertex, negative electrode on the neck (for the eABR) or on the ipsilateral mastoid (for the integrity test), ground electrode on the chin. Electrode impedances were checked prior to performing any measurements to insure good electrical connections were made and a standard integrity test was performed in order to confirm that the implant was functioning correctly – passing this test requires observing appropriate stimuli artifacts (Fig. 1). Appropriate artifacts were observed for all subjects (at a pulse width of 20 µs and a normal amplitude level of 60 clinical units (CU)). The recording procedure described below was then carried out. This procedure was repeated using three different stimulating electrodes: (1) an apical electrode (representing 500 Hz on the subject's MAP), a middle electrode (1000 Hz), and a basal electrode (2000 Hz).

Internal component developed by Neurelec is Digisonic® SP. The standard array is composed of 20 active electrodes and has a notched surface. The electrode beam active is 25 mm length and allows an insertion angle of 423.6° ± 125.52° (263°–519°). Frequencies 500, 1000, and 2000 Hz are, respectively, programmed on the electrodes 18, 14, and 9.

During the eABR recording protocol, the stimulation *amplitude* (pulse height) for the stimulating electrode was set at the subject's standard level as defined in their standard MAP (mean across subjects = 68 CU, standard deviation = ±8, range 60–100). The stimulation pulse is a charge-balanced biphasic pulse starting by an anodic phase. A common ground stimulation mode was used since all subjects' MAP is obtained under this stimulation mode. Subsequently, the pulse duration was set midway between the subject C- and T-levels and increased until the subject reported a 'comfortable but loud' sensation. EABR peaks were selected using a visual criterion and the amplitude and latency were obtained from the selection. At this point, a minimum of three usable eABR recordings were made – recordings were considered usable if they clearly showed Waves-III and V (under this condition, all subjects produced usable eABRs; in addition, Wave-II was visible for 7 of

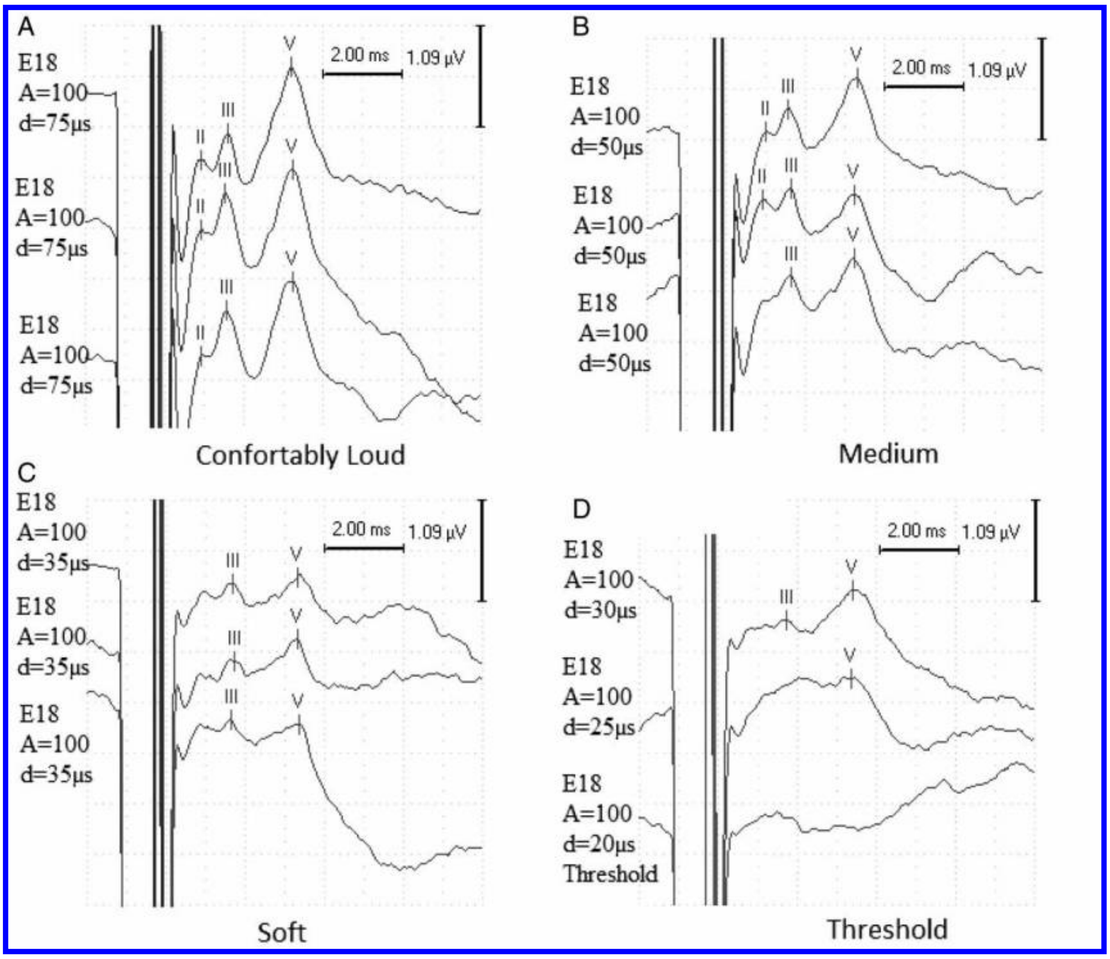

Figure 2 Example of a typical eABR recording set. This one was with stimulation on electrode 18 of patient A. Three traces are shown from repeated measurements (vertically offset for readability) at each loudness level: comfortably loud (stimulus amplitude = 100, duration = 75 μs; Panel (A)) Medium loud (stimulus amplitude = 100, duration = 50 μs; Panel (B)), and Soft (stimulus amplitude = 100, duration = 35 μs; Panel (C)). Traces are labeled to show eABR Waves-II, III, and V and demonstrate good repeatability.

13 subjects) (Fig. 2). Similar recordings were made at stimulation levels reported to be 'medium' and 'soft'.

From the 'soft' loudness level, the stimulation duration was further reduced in 5 μs increments and an eABR recording was taken at each new level until no visibly discernible Wave-V remained. This final stimulation level was considered the eABR detection threshold and was noted for comparison with behaviorally measured T-levels. Fig. 2D shows the eABR recording traces from a typical search for the eABR detection threshold in one subject for one electrode location. Here, the eABR threshold is 20 μs.

Statistical analysis

Correlation between the subjects' behaviorally measured thresholds (T-levels) and their objective eABR detection thresholds was computed using Pearson's product-moment correlation coefficient (r). The correlation was considered significant at the $P <$ 0.05 level. Error bars represent 95% confidence intervals. To determine whether eABR Wave-V amplitudes differed significantly across the three loudness levels, data from the three stimulation sites (basal, middle, and apical) were pooled and a one-way analysis of variance (ANOVA) was performed across the loudness levels.

Appropriate conditions for normality and homogeneity of variance were verified using Lilliefors test and Bartlett's test, respectively, prior to computing the ANOVA or the correlation coefficient. All statistical analysis was performed using Statistica 9 (Stat. Soft. Inc., Tulsa, Oklahoma, USA).

Results

eABR detection thresholds vs. T-levels

Mean C-levels (mean = 51 μs; SD = ±17 μs) from all 13 patients and over all 3 electrode locations were 1.82 times higher than mean T-levels (mean = 28 μs; SD = ±8 μs) and had a higher variability (Table 1). T-levels (from all subjects and all electrodes) were significantly correlated with their associated eABR detection thresholds ($r = 0.71$; $P < 0.001$; Fig. 3) (Table 1). This correlation was nearly as strong as the one observed between C- and T-levels in this same subject group ($r = 0.77$; $P < 0.001$). Linear regression analysis (solid line, Fig. 3) showed a slope

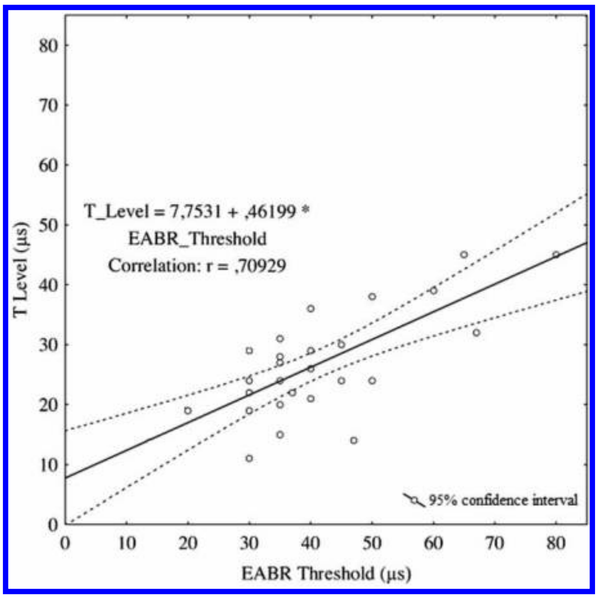

Figure 3 Scatter plot and linear regression showing the relationship between the eABR thresholds and Digimap thresholds (*T*) in µs. The correlation is statistically significant (*N* = 31; *P* < 0.001).

relationship that was slightly lower than the C- to T-level slope (slope = 0.432 vs. 0.6317, respectively).

Amplitude of Wave-V vs. loudness

Amplitude of eABR waves reduced monotonically with decreasing loudness. For instance, at a comfortably loud level, three peaks are identifiable in Fig. 2A (Waves-II, III at 1.1 ms and Wave-V at 2.75 ms). The amplitude of these peaks decreased monotonically as the pulse width of stimulation was reduced from 75 to 50 µs, with Wave-II only visible in two out of three cases (Fig. 2B). At the softest level (pulse duration = 35 µs; Fig. 2C), Wave-II was not visible anymore.

Fig. 4 shows the mean of the amplitude of Wave-V at each of the three loudness levels (soft, medium, and comfortably loud) across all subjects and electrodes tested. Error bars represent a 95% confidence interval. It can be noted that the confidence intervals are similar for each level. To test whether these differences where statistically significant, a one-way ANOVA was performed. The test showed that the amplitude of Wave-V was statistically significantly different between the levels and these results held for all of the three groups of tested electrodes (500 Hz: $F = 10.1$, $P < 0.001$; 1000 Hz: $F = 12.9$, $P < 0.0001$; 2000 Hz: $F = 18$, $P < 0.0001$).

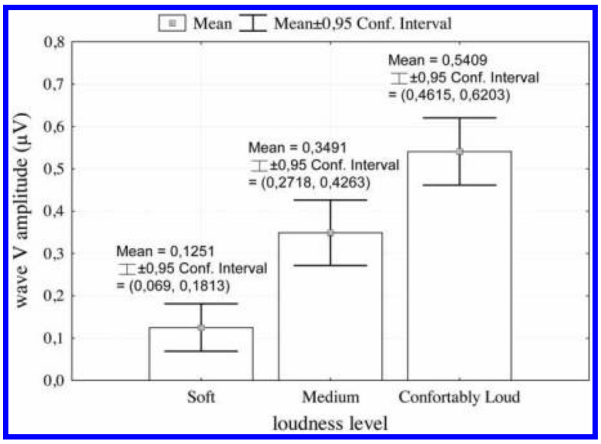

Figure 4 Averages values of Wave-V amplitudes (µV) recorded at three loudness sensation levels in 13 patients on all three electrodes. The 95% confidence interval around the mean is displayed on each bar. The difference between low and medium, medium and comfort, and low and comfort are all significant (see the Results section). This is the case at each electrode location.

Discussion

This study showed a significant correlation ($r = 0.71$, $P < 0.001$) exists between T-levels, and eABR detection thresholds and that the amplitude of Wave-V grows significantly ($F > 10$, $P < 0.001$) with perceived loudness. Our results showed firstly an important correlation between T-levels and eABR detection thresholds with the new generation of implant, the Digisonic® SP. This comparison of eABRs and T-levels is consistent with previous results by Truy *et al.* (1998) on the Digisonic® DX10 implant where a strong correlation ($r = 0.98$, $P < 0.001$) was also found. Truy *et al.* further found that eABR detection thresholds tend to overestimate T-levels. Our study results showed the same tendency (see Fig. 3, where all points are below the unit line $y = x$).

Differences between eABR thresholds and T-levels were expected because the eABR recordings are performed at a stimulation rate (47 Hz Digistim), which differs from the stimulation rate used for estimating the patient T-levels (typically 600 Hz in Digimap). This is because the eABR signal extends over a few milliseconds and requires synchronous neural discharges to be recorded. Faster rates of stimulation are thought to decrease neural synchronization (Rubinstein *et al.*, 1999; Litvak *et al.*, 2003) and have an effect on thresholds obtained from objective measures. For instance, ECAP thresholds are known to increase with increased stimulation rates (McKay

Table 1 Mean and standard deviation of T- and C-levels across subjects

Behaviorally measured T- and C-levels					
	Cochlear area	Apical 500 Hz	Medial 1000 Hz	Basal 2000 Hz	Combined
T (µs)	Average (standard deviation)	23 (6)	29 (8)	32 (7)	28 (8)
C (µs)	Average (standard deviation)	43 (11)	56 (20)	54 (15)	51 (17)

et al., 2005; Clay and Brown, 2007; Botros and Psarros, 2010). Moreover, it has been observed that fast-rate high-resolution stimulation strategy produces lower correlation between T-levels and ECAP thresholds (R^2 ranges 0.66–0.74) than with slower stimulation strategy ($R^2 = 0.9$ with SPEAK at 250 Hz – see (Eisen and Franck, 2004)). Therefore, stimulation rate can have a perceptual effect on both T-levels and objectively measured thresholds.

The second important result of the present study is the statistically significant difference in Wave-V amplitude as a function of perceived loudness level (soft, medium, or loud). ANOVA scores calculated at all electrode locations demonstrate a statistically significant difference between the means for each group (and thus a positive correlation across the groups). The change in Wave-V amplitude between each loudness level was larger than the inter-subject variability. This demonstrates that eABR Wave-V amplitude can be used to objectively evaluate loudness growth as a function of the stimulation intensity with Digisonic® SP CIs. In principle, this means the Wave-V amplitude could be used to estimate a patient's C-level if a baseline can be determined.

This result is consistent with previous studies showing that eABR waves amplitude increase with perceived loudness (Abbas and Brown, 1991; Gallégo *et al.*, 1999; Kirby *et al.*, 2012). However, it should be noted that Kirby *et al.* (2012) found a larger variability between perceived sound level and eABR Wave-V amplitude. Methodological differences both in the assessment of perceived loudness and in the stimulation procedure could explain this divergence of results. While Kirby *et al.* used a fixed set of stimulus amplitude and ask the patient to rate them on an arbitrary scale, in our study stimulus intensity was iteratively varied until the patient reported 'soft', 'medium', or 'comfortable' loudness. Furthermore, the coding of stimulus intensity using pulse duration vs. pulse amplitude could produces less variable results. Our result is consistent with Gallégo *et al.* (1999) who found that Digisonic® DX10 patient had a linear relationship between their Wave-V amplitude and perceived loudness as coded by pulse width.

It has to be noted that in the present study, the impulses were generated by current sources and so differed from those of Gallégo *et al.* (1999) generated by voltage source. Electrical pulses generated by different types of sources will generally not have the same shape. It is known that the shape of the stimulation pulse can modify the results obtained from objective measures (Macherey *et al.*, 2006; Bahmer and Baumann, 2011a; Undurraga *et al.*, 2012). However, the significant relationship between loudness and wave amplitude observed both here and in Gallégo *et al.* (1999) suggests that generating impulses from current or voltage sources does not fundamentally impact the measurement. In the future, it could be interesting to test a larger set of loudness perception to see whether the eABR can accurately predict them as well.

Finally, these results were obtained in adult CI users with at least 1 year of implant experience, and can be extended to per-operative eABR measures in order to facilitate first CI fitting. Differences between per-operative measures and measures performed 1 year onward are to be expected for at least two reasons. First, it is known that both impedances and thresholds vary in relation with the delay after implantation (Pfingst, 1990; Dorman *et al.*, 1992; Hughes *et al.*, 2001). Changes in threshold can reflect both changes in impedance and changes in the patient's ability to detect a sound. This plasticity of a patient's central nervous system is known to affect the recorded eABR waves (Gordon *et al.*, 2003; Gordon *et al.*, 2006; Sharma and Dorman, 2006; Thai-Van *et al.*, 2007). Hence, it constitutes a second reason for per-operative measures extension.

In conclusion, since the correlation we found between eABR detection thresholds and T-levels were similar to each other, these results indicate that eABR detection thresholds are likely also a reasonable estimator for T-levels. In addition, Wave-V amplitude, which is shown to correlate to the loudness, could potentially be used to program C-levels. Therefore, using eABR as a fitting method could find an important place in the pediatric patients setting considering the children's limited attention span.

Disclaimer statements

Contributors

G.G. developed this study, collected the data, and wrote the manuscript. J.L. worked on data processing and drafting. B.P. collected the data. P.R. and P.B. participated in patient recruitment. C.P.-W. worked on patient recruitment and drafting.

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Conflicts of interest

None.

Ethics approval

An ethical approval was not necessary. The study was conducted in a routine visit. The data has been processed in accordance with anonymity.

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To Jonathan Laudansky.

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