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Original Article

Comparison of a Traditional and Novel Evoked Compound Action Potentials Recording Approach and Evoked Auditory Brainstem Responses in Pediatric Cochlear Implants Users

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OBJECTIVES: Electrically evoked compound action potentials (eCAP) recordings are widely used in functional evaluation and fitting of cochlear implants (CI) in clinics. We compared the results from two eCAP recording approaches (StandardART and FineGrain, MED-EL, Austria). The FineGrain method is more advanced than the Auditory Nerve Response Telemetry (StandardART) method in terms of the stimulation and algorithm for the eCAP threshold detection. To understand the benefits of these alterations, we compared the two methods on a larger scale in pediatric CI users alongside evoked auditory brainstem responses (eABR).

MATERIALS and METHODS: We collected the eCAP recordings obtained with both methods from a population of pediatric subjects with CI, either intra- or post-operatively. The eABR recordings were only collected post-operatively. For comparability reasons, we used the same stimulation rate and similar amplitude levels for all three approaches.

RESULTS: Our results demonstrate that, although the success rates are similar, the FineGrain method outperforms traditional StandardART in terms of robustness and measurement duration. The eCAP recordings in general outperform the eABR in terms of speed.

CONCLUSION: We conclude that the eCAP recordings are the method of choice for measuring the auditory neural activity, and FineGrain outperforms StandardART. From the three investigated approaches, we conclude that FineGrain performed best and should be the first-choice method in pediatric patients.

KEYWORDS: Cochlear implant, hearing loss, pediatrics, action potential, electrically evoked compound action potential

INTRODUCTION

Cochlear implants (CIs) are successful and reliable electronic prosthetic devices that are surgically placed in the inner ear to restore the severe to profound hearing loss [1]. By 2012, approximately 324,200 registered devices were implanted worldwide [2]. The more recent estimates suggest that approximately 25,000 children are implanted with CIs annually [3].

The CI device bypasses the malfunctioning inner ear by collecting acoustic stimuli from its environment and converting them into electric signals that are delivered through the implanted electrode array in the cochlea directly to the auditory nerve fibers [1]. There, the electric signals induce action potentials, which travel to the auditory brain stem and evoke acoustic sensations [1].

After surgery, CI devices need to be programmed and customized for the new user in a process referred to as fitting. Part of the fitting procedure involves objective measures, such as electrically evoked compound action potentials (eCAP) or evoked audito-

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ry brainstem responses (eABR). Both measures are commonly used techniques in clinical practice. Whereas additional equipment is necessary for the eABR recordings, eCAP can be recorded directly via the CI, which is one of the advantages over the eABR.

For acoustically evoked brainstem responses, the peripheral action potentials of the auditory nerve can be identified in the recording (wave I), but for electrically evoked responses recorded with an ABR recording setup, these potentials are embedded in the stimulus artifact [4]. Notably, different stages of the auditory pathway are evaluated using the eCAP recordings (peripheral action potentials of auditory nerve, corresponding to wave I) and eABR recordings (central responses of the VIII nerve, wave II; cochlear nuclei, wave III; nucleus of the lateral lemniscus, wave IV-not pronounced in eABR; inferior colliculus, wave V) [5].

The eCAP profiles typically show a curve with a negative peak followed by a positive one [6]. The eCAP amplitude is defined as the difference between those two peaks. It increases with the stimulation current and can be plotted in a so-called amplitude growth function (AGF) [7]. The eCAP AGF can be used to determine the eCAP threshold, that is, the minimum stimulation current from where a valid eCAP response is being detected. Typically, these thresholds are the final read-out of the eCAP recordings. In general, eCAP recordings provide information about the integrity of the electrode-nerve interaction, and eCAP thresholds can be used as rough estimates for initial loudness differences between electrodes during the first fitting [3, 8, 9]. In addition, certain eCAP measures have been proposed for assessing neural health during regular check-ups [10]. Despite the availability of additional objective measures for fitting, the eCAP recordings remain one of the most frequently used objective measures in clinics [9]. Therefore, the accuracy of the eCAP threshold determination is of high interest for clinicians and researchers alike.

Another routinely used objective measure to assess if the auditory nerve can respond to electrical stimulation is eABR. For an eABR measurement, the CI or an electrode placed at the round window delivers electrical pulses, and electrodes placed on the CI users' scalp transmit responses along the auditory path to a recording device [11]. In clinical settings, the eABR can be used pre-operatively to determine if a CI is useful for the patient, as well as post-operatively for validation and fitting purposes. It has been demonstrated that there is a relationship between eABRs and auditory performance and speech intelligibility in children [12]. In spite of that, they seem to be rarely used in regular fitting procedures and only marginally in longitudinal follow-ups [9].

In summary, the eCAP and eABR are among the most commonly used methods for monitoring auditory neural responses, are used in the clinical routine to validate the functionality of the CI, and are programming tools to customize the CI settings.

The purpose of this paper was to study success rates and time required to obtain the eABR and eCAP recordings. In addition, an automated method to record eCAPs was evaluated and compared to the manual state-of-the-art method.

There are two approaches to eCAP recording and threshold determination from the CI manufacturer MED-EL: their original method as implemented in the Auditory Nerve Response Telemetry (StandardART) feature of their Clinical Software MAESTRO 6 and a research software where stimulation/recording and the algorithm for threshold determination were altered and allegedly improved (FineGrain). By now, parts of the research software used in this study have been implemented in the new feature AutoART in MED-EL's clinical software MAESTRO 7 [13]. Additionally, we recorded the eABR following a standardized procedure according MED-EL's guidelines [14].

We analyzed parameters such as measurement success, accuracy, and measurement duration. As a short measurement duration combined with the highest possible success is particularly desirable for young subjects, we choose a pediatric population of CI users for the study.

MATERIALS AND METHODS

Participants

The study group consisted of 13 pediatric CI users between the age 0 and 9 years (2 females, 1 bilateral; 11 males, 10 bilateral) with a total of 24 cochlear implanted ears (for overview, see Table 1). We carried out measurements on 21 of the 24 implants within this group: Only one implant each could be measured from three bilateral participants due to time limitations within the session and increased stress level of the subjects. The study was approved by the Ethics Committee of La Fe University and Polytechnic Hospital, Valencia, Spain. Written informed consent was obtained from participants' parents.

Equipment and Software

Hardware

The hardware used for the eCAP recordings in this study was consistent with the standard clinical setup including a MAX Programming Interface and a PC with MAESTRO 6.0.1 Clinical Software (MED-EL, Innsbruck, Austria). In addition, for the eABR recordings, a Nicolet EDX Synergy device [15] manufactured by Nexus Healthcare was used. A three-electrode-setup (an active electrode on the vertex, reference electrode on the contralateral mastoid, and ground electrode on the center of the forehead) using solid-gel adhesive electrodes was applied. For all recordings, impedances <5 kOhm could be achieved.

eCAP recordings

Intra-operative eCAP recordings with StandardART and FineGrain were collected from 5 implants. Post-operative eCAP recordings with StandardART and FineGrain were collected from 16 implants. The eABR recordings were performed only in post-operative sessions on the electrode number 6. For FineGrain eCAP recordings, the FineGrain research tool (MED-EL, Innsbruck, Austria) was used. This software enabled a quasi-continuous stimulation intensity growth, where the stimulation rate of single pulses and the stimulation intensity growth per second could be adjusted. For both eCAP recording paradigms, alternating polarity and signature subtraction were used for artifact reduction [16]. For the StandardART analysis, an alternative selection of a sub-threshold recording with stimulation intensity >0 was allowed to be used as signature recording. For StandardART AGFs, experts manually selected traces showing neural responses.

Table 1. Demographic data of the study group

Subject ID	Gender	Implant type	Ear	Side	Age at implantation (years)	Time of use (years)	Measurement	eABR measured
S1	f	SONATAti100	Left	unilateral	8	2	postop	yes
S2	m	CONCERTO	Right	unilateral	9	0	postop	yes
S3_1	m	CONCERTO	Right	bilateral	7	2	postop	yes
S3_2	m	SONATAti100	Left		6	2	postop	yes
S4_1	m	SYNCHRONY	Left	bilateral	8	1	postop	no
S4_2	m	SONATAti100	Right		Not measured due to subject feeling stressed			
S5_1	f	SONATAti100	Right	bilateral	1	5	postop	yes
S5_2	f	SONATAti100	Left		1	5	postop	yes
S6_1	m	CONCERTO	Right	bilateral	4	2	postop	yes
S6_2	m	CONCERTO	Left		4	2	postop	yes
S7_1	m	SONATAti100	Left	bilateral	0	4	postop	yes
S7_2	m	SONATAti100	Right		0	4	postop	yes
S8_1	m	SONATAti100	Left	bilateral	1	4	postop	yes
S8_2	m	SONATAti100	Right		1	4	postop	yes
S9_1	m	SONATAti100	Right	bilateral	0	4	postop	yes
S9_2	m	SONATAti100	Left		0	4	postop	yes
S10_1	m	SONATAti100	Left	bilateral	0	3	postop	yes
S10_2	m	CONCERTO	Right		Not measured due to subject feeling stressed			
S11_1	m	SYNCHRONY	Left	bilateral	1	0	intraop	no
S11_2	m	SYNCHRONY	Right		1	0	intraop	no
S12_1	m	SYNCHRONY	Right	bilateral	1	0	intraop	no
S12_2	m	SYNCHRONY	Left		1	0	intraop	no
S13_1	m	SYNCHRONY	Left	bilateral	0	0	intraop	no
S13_2	m	SYNCHRONY	Right		Not measured due to time pressure			

The key differences between the two approaches lie within the intensity growth of the AGF and eCAP manual vs. automated threshold determination. When recording the AGF of eCAPs with StandardART, the stimulation intensity increased in discrete, predefined steps and averages over set number of iterations at the same intensity to reduce the measurement noise. The novel method, FineGrain, used a much smaller step size, and the necessary iterations to reduce noise were gathered by averaging over recordings of sequential stimuli within a small range of intensities (Figure 1). This resulted in the collection of more data with FineGrain than with Standard ART, while retaining a very short measurement duration.

In terms of eCAP threshold determination, both methods applied a fit to the data, but while for StandardART, a linear fit is used, for FineGrain, a sigmoid fit (S-shaped) was applied, and from the steepest point, a linear extrapolation determined the threshold automatically [17, 18] (Figure 2, bottom panel). Thereby the FineGrain method bypasses the need for a "by-eye" adjustment through a specialist, which can save clinicians time and provide more standardization in the eCAP threshold determination.

eABR recordings

The eABR task of MAESTRO 6.0.1 Clinical Software in combination with the Nicolet EDX Synergy device was used. Settings of the Nicolet EDX Synergy device were in accordance with the "EP Guide-Recommended protocols with MED-EL series cochlear implants" [14].

Statistical Analysis

Statistical analyses were performed using the R software version 1.1.419 [19]. All recordings on a given subject were performed in a single day. For comparability reasons, we choose the same stimulation rate and similar intensity steps for all three measurements.

Software and settings

eCAP Settings ART Task MAESTRO 6.0.1 (StandardART)

Min. charge	0
Max. charge	Individual based on maximum accepted loudness
Measurement gap	125 μs

Phase duration	30/40 µs
Amplitude levels	5 and 19
Stimulation rate	34Hz

The stimulation rate was set by adjusting the parameter "measurement gap" (17 ms) to achieve an inter-pulse interval of 29.4 ms (necessary for 34 Hz) for the used settings in the study.

Settings Test Software (FineGrain)

Min. charge	0
Max. charge	Individual based on maximum accepted loudness
Charge change per second	1.5
Phase duration	40 µs
Stimulation rate	34 Hz

Settings eABR Task in MAESTRO 6.0.1 Software

Cycles	1500
Rate	34 Hz
Biphasic pulse	
Alternating polarity	
Phase duration	30 µs
Step size	250 at first step, 200 at second step followed by sequential steps of 100

Settings Nicolet EDX Synergy

Amplifier range	100 µV
Sampling frequency	48 kHz
Frequency-pass region	30 Hz–3 kHz
Trace duration	10 ms
Automark algorithm	

RESULTS

Success rate was similar for the eCAP recording methods but lower for eABR (Table 2)

The success rates of FineGrain, StandardART, and eABR recordings within our group were defined as obtaining a valid recognizable nerve response together with successful threshold determination. Overall success rates of the FineGrain and StandardART approaches resulted in high success rates of 95.2% and 90.3% respectively. Intra-operative and post-operative eCAP recordings showed similar success rates, with the StandardART intra-operative rate being slightly lower than FineGrain. For time reasons, we recorded eABR only on a single electrode. The electrode number 6, which is typically located in the middle region of the cochlea, was chosen. As illustrated in Table 2, the success rate for eABR on electrode 6 was at 73.7% as opposed to a 100% success with the eCAP recordings on the same electrode with either measurement approaches. Impedance measurements at the electrode number 6 were within the normal range for all participating subjects.

The two eCAP measurement approaches delivered similar thresholds with some exceptions

As expected, the thresholds determined with StandardART were generally lower than the thresholds determined with FineGrain (Figure 3) [17]. There were no obvious differences between the thresholds from intra-op and post-op recordings (Figure 3).

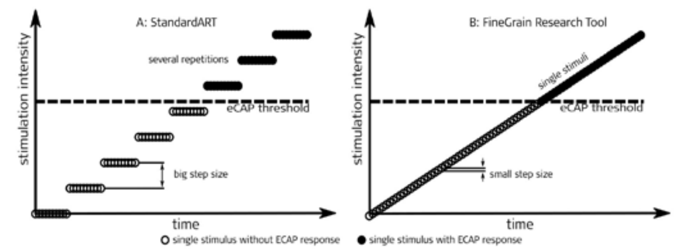

Figure 1. Schematic description of stimulation/recording differences during the eCAP measurements with the StandardART approach and the FineGrain research tool.

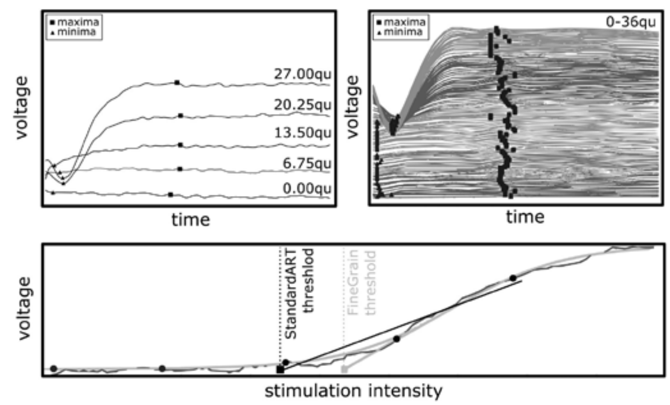

Figure 2. Example of a threshold that diverged depending on the measurement approach (StandardART and FineGrain). The eCAP responses recorded with StandardART and FineGrain are depicted in the top-left and top-right panel, respectively. The bottom-panel shows the eCAP amplitudes for recorded stimulation intensities of both methods, StandardART (black dots, n=5), and FineGrain (dark grey line, n=125). In addition, the used fitting functions, linear fit for StandardART resulting in the StandardART threshold (black line), and the sigmoid fit for FineGrain resulting in the "FineGrain threshold" (light grey line) are shown combined in one graph to highlight differences between the approaches.

The structure of the two sets of the eCAP thresholds was very similar, and a correlation analysis revealed a fair correlation with a Pearson's r=0.754 (H0: r=0 was rejected, $p=2.4 \times 10^{-14}$) between the two methods.

Interestingly, several thresholds differed substantially, depending on the measurement approach (Figure 3). While marginal differences between the two approaches were expected, these substantial differences were rather surprising. To understand which thresholds were more accurate, we examined those data points in more detail.

FineGrain eCAP measurement approach delivered more accurate thresholds in particular cases

In a randomly selected example from the substantially diverging eCAP thresholds (Figure 3), we found that the FineGrain approach set the eCAP threshold to 17.72 qu, while the same measurement with the StandardART method resulted in a threshold of 10.2 qu (Figure 2). The morphology of the eCAP responses at the same stimulation current appeared very similar for both methods (Figure 2, top panel), but differences arose during the creation of the AGF. FineGrain used many more measurements than StandardART (125 vs. 5 stimulation amplitudes) for plotting the AGF. For visual support, we indicated the 5 data points from the StandardART in the plot of the FineGrain AGF (Figure 2), revealing that 1 amplitude data point used for the linear fit

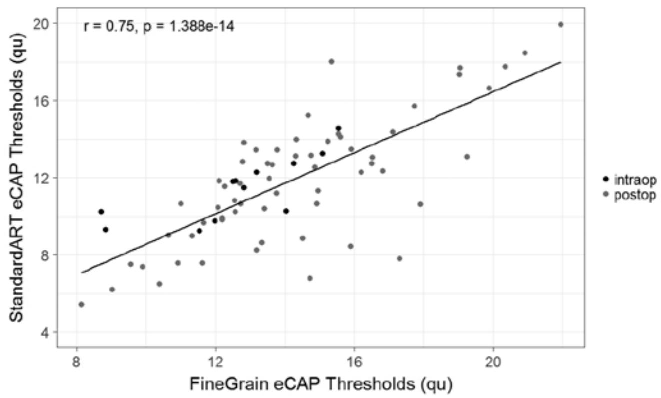

Figure 3. Correlation analysis between the eCAP thresholds determined with FineGrain and StandardART. The figure contains both, intra- and post-operative measurements (black and grey, respectively). Pearson's correlation coefficient and the corresponding p-value ("H0: correlation coefficient equals zero" can be rejected) are depicted in the top-left corner.

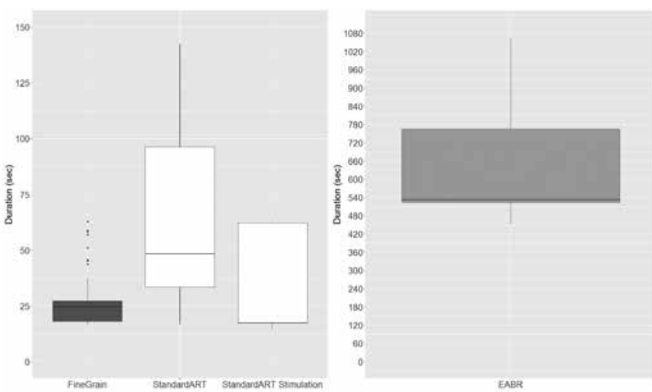

Figure 4. Measurement duration of the eCAP recordings with FineGrain and StandART (left panel) and EABR (right panel) expressed in seconds shown as boxplots (lower limit of the box refers to 25% percentile, top limit to 75% percentile, the horizontal line within the box refers to median values; whiskers yield from 5% to 95% percentiles, respectively). Within the left panel, "FineGrain" shows durations for the automatism, whereas "StandardART" shows overall durations stimulation plus evaluation times of the traditional method, and the Standard Stimulation refers to duration of stimulus for the traditional method only. The right panel shows durations for eABR recordings; note the different scaling of the y-axis.

in StandardART was in fact still within the noise floor in the FineGrain AGF (Figure 2).

FineGrain eCAP measurement method was faster than traditional ART and eABR

For the clinical application of objective measures in children, duration of the measurement is a crucial factor for obtaining accurate and complete results. The longer a measurement takes, the higher the chance of children stopping to cooperate.

Unsurprisingly, we found that the eCAP recording methods were substantially faster than the eABR recordings (Figure 4): an eCAP recording took on average below 69 sec/electrode, while the average duration of the eABR recordings was at 10.8 mins/electrode.

When comparing the two eCAP recording methods, stimulation duration of FineGrain was faster than StandardART with 25 and 30 seconds per electrode, respectively. Notably, for FineGrain the final

Table 2. Success rates of the FineGrain, StandardART, and eABR recordings (electrode 6 only) from our study group defined as a valid nerve response together with successful threshold determination. For FineGrain and StandardART, all measurements combined (overall) and intra- and post-operative measurements separately are depicted. The eABR was only recorded at electrode 6, and the success rates for FineGrain and StandardART are shown for comparative reasons

Success Rates Overall	
FineGrain	95.2%
StandardART	90.3%
Success Rates Intra- and Post-operative Recordings	
FineGrain intra-op	100%
FineGrain post-op	94.6%
StandardART intra-op	88.8%
StandardART post-op	90.5%
Success Rates Electrode 6 Only	
FineGrain	100 %
StandardART	100 %
EABR	73.3 %

eCAP thresholds were obtained automatically after 25 seconds of stimulation, while for the StandardART manual evaluation steps-(1) checking for correct artifact reduction and eCAP presence; (2) setting extrems; and (3) selecting traces including neural responses-had to be performed after the recording. The average duration of the manual evaluation performed by an experienced expert was 38 sec/electrode, increasing the complete measurement duration of StandardART to 68 sec/electrode (Figure 4). Therefore, the FineGrain approach was more than twice faster than the traditional StandardART.

DISCUSSION and CONCLUSION

In terms of measurement success, the eCAP recordings generally outperformed eABR in our study population. There are various potential reasons for this decreased eABR success rate. First, technical issues during the individual recordings (i.e., high impedances, noise) could have influenced the outcomes. Second, the etiology of the hearing loss could play a role. For instance, it has been shown that in subjects with auditory neural spectrum disorder (ASND), it is not always possible to detect the eABR responses, or the waveform quality is worse compared to non-ASND subjects [20, 21, 22]. And third, the duration of profound hearing loss before the CI implantation could be relevant for measures that target central processing, because cochlear damage can result in degeneration of spiral ganglion cells and/or changes in the auditory pathways over time [23]. In our study, the subjects in whom we were unable to successfully register the eABR suffered deafness of different duration (0-7 years), and the etiology of hearing loss was largely unknown. Impedance measurements at the electrode number 6 were within the normal range for all participating subjects. To truly identify the underlying reasons, a more detailed evaluation of the affected subjects is necessary.

Both eCAP recording approaches, StandardART and FineGrain, had very high success rates, whereby the FineGrain approach did result in a 5% higher success rate compared to StandardART. The more pronounced advantage is the much higher number of different stimulation intensities, offering a more robust determination of present eCAP signals, especially for stimulation intensities close to the eCAP threshold level. In combination with a well-matching fit for the FineGrain AGF (Sigmoid), the selection of traces showing neural responses can be omitted, and thus the source of error is eliminated. Due to a fully automated analysis, human errors in the analysis are completely excluded, and additional time for analysis is unnecessary, resulting in a standardized procedure, which was more than twice as fast compared to the traditional method (StandardART).

The duration of fitting sessions is subject of optimization, since clinics are faced with an increasing number of implantations and follow-up sessions [3]. In addition, the duration of fitting sessions in pediatric patients is a crucial factor to complete objective measurements. In general, the eCAP measurements were much faster than the eABR recordings, and additional equipment was not needed. In terms of accuracy and speed, FineGrain outperformed StandardART.

Therefore, we conclude that eCAP recordings are the method of choice for measuring the auditory neural activity. From the three investigated approaches, FineGrain performed best and should be the first-choice method for pediatric patients.

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