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Original Research Article

Electrically evoked compound action potential in children following cochlear implantation and its correlation with cochlear nerve diameter

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ABSTRACT

Background: The study evaluated changes in the threshold of ECAP recorded during cochlear implantation, at switch on, after three months and six months following cochlear implantation. It further assessed the correlation between the ECAP threshold with T and C levels and the cochlear nerve diameter measured preoperatively.
Methods: A prospective study of 42 prelingually deaf children who underwent cochlear implantation was conducted. The ECAP threshold values intra-operatively, at switch on, three months and six months were recorded and analysed. The T and C levels were assessed six months postoperatively, and correlation with the ECAP threshold was analysed. The diameter of the cochlear nerve was recorded, and its correlation with the ECAP threshold was determined.
Results: Over six months, the basal, central and apical electrodes showed a statistically significant reduction in ECAP threshold of 11.64%, 4.67% and 25.81%, respectively, in candidates implanted with Advanced Bionics implant and 18.89%, 12.78% and 14.08%, respectively in candidates implanted with Nucleus implant. The ECAP thresholds were lower for the apical electrodes. No correlation was found between the ECAP threshold and T and C levels. A correlation between the cochlear nerve diameter and ECAP was not statistically significant.
Conclusions: There was a statistically significant change in the ECAP threshold over six months. There was no statistically significant correlation between the ECAP thresholds and T and C levels. The value of ECAP thresholds to measure C and T values need to be relooked. There was no correlation between the cochlear nerve diameter and the ECAP threshold.

Keywords: Cochlear implant, Evoked compound action potential, Cochlear nerve

INTRODUCTION

Cochlear implants (CI) are the only successful treatment for profound sensorineural hearing loss (>90dBHL).[1] Despite cochlear implantation, variable results in speech perception between implanted patients are reported.[2] The reason behind this variability is not entirely understood.[3] After cochlear implantation, the cochlear nerve is stimulated via the electrodes placed in the cochlea and the electrical activity is measured by Electrically evoked Compound Action Potential (ECAP). ECAP measures the synchronous firing of a large group of auditory nerve fibres in response to a brief electrical stimulus. ECAP is not affected by age, attention, or learning as it is peripherally generated and can be measured easily, quickly and non-invasively by Neural Response Telemetry (NRT).[4] It gives clinicians valuable information for programming the T (Threshold) and C (Comfort) levels of the recipient's speech processor map.[5]

ECAP provides an efficient method of monitoring stimulation-induced changes over time and is used to

predict the levels required for programming the speech processor of the cochlear implant. Mapping includes programming minimum and maximum stimulation levels based on subjective measurements of thresholds (T level) and most comfortable levels (C level). These are obtained to create an optimal dynamic range, enabling the CI recipient to communicate effectively. The goal in selecting these levels is to make everyday conversational speech comfortably loud and as clear as possible. The time needed for stabilisation of thresholds and MALs (Maximum acceptable loudness levels) varies from one individual to another. It is said to be stable once no further changes in minimum and maximum stimulation levels are needed. For some, it may be as short as two weeks; for others, it may be as long as 2.5 months.[6] There are only a few studies in the literature documenting the variations of ECAP from the time of implantation. It is important not to overstimulate or under-stimulate the cochlea, as it can lead to delayed speech production. Thus, it is essential to know the optimal current needed in each electrode during each follow-up visit so that it is comfortable for the patient and the patient can hear optimally.

Objectives

The present study evaluated changes in the threshold of ECAP recorded intraoperatively during cochlear implantation, at switch on, three months and six months following cochlear implantation. It further assessed the correlation between the ECAP threshold with T and C levels. It also evaluated the correlation between the cochlear nerve diameter and the ECAP threshold.

METHODS

This was a hospital-based longitudinal study at a major tertiary referral centre. Forty-two prelingually deaf children with profound deafness were recruited from the outpatient clinic of the Department of ENT. Written informed consent was obtained from the guardians of all study subjects. The study was conducted in accordance with the principles of ethical research as per the Declaration of Helsinki in 1975 and revised in 2008 and the Indian Council of Medical Research Guidelines for Biomedical Research in Human Participants.

Sample size calculation

The sample size was estimated from the expected mean difference in ECAP thresholds from the intra-operative recording to the recording at switch on. A previous study by Brill et al found the mean change in the ECAP threshold to be 15 mV with a standard deviation of 30 mV.[7] The minimum sample was estimated to detect this difference with 80% power at a 5% significance level. IBM PASW statistics v19.0 (SPSS version 19.0) software was used for calculation.

Study population and workup

Prelingually deaf children with profound sensorineural hearing loss of more than 90dB, below age 6, and anatomically normal cochlea were included. Patients who had an incomplete electrode array insertion during implantation were excluded. Cochlear nerve horizontal diameter was determined using a parasagittal oblique view perpendicular to the fundus of the internal acoustic canal in a T2 weighted MRI (Magnetic Resonance Imaging) image.

Eleven patients received the Nucleus C124RE Straight Freedom implant®, and 31 received the Advanced Bionics HiRes 90K Advantage implant with straight J electrode®. Customised software, the AB Sound Wave 3.1.18 version for Advanced Bionics implant® and Custom Sound EP version 4.4® for Nucleus implant, were used to record the ECAP from the participants implanted with cochlear implants. This testing was carried out during the intraoperative period, at switch on and three months and six months following cochlear implantation.

Statistical analysis

The Kolmogorov-Smirnov test assessed the normality of continuous data. The ECAP threshold, T and C levels and cochlear nerve diameter were described as mean±standard deviation (SD). The changes of ECAP threshold over time were calculated for the apical, central and basal electrodes over four-time points, i.e., intraoperatively, after four weeks during switch on, three months and six months using a repeated measure of ANOVA, and between time points posthoc analysis was used. The Correlation between cochlear nerve diameter and ECAP values at six months was assessed using correlation analysis (Pearson's Correlation test). Statistical analysis was done using IBM PASW statistics v19.0 (SPSS version 19.0). Analysis was performed at a 5% significance level, and $p<0.05$ was considered statistically significant.

RESULTS

Forty-four patients were recruited for the study during the study period. However, two patients were excluded. A total of 42 patients were included in the study, of which 26 were male and 16 were female. The average age of implantation was 3.01±1.18 years. Thirty-one patients received the Advanced Bionics implant, and 11 received the Nucleus implant. The NRT measured ECAP threshold values in CU (Charge Unit) in AB and CL (Current Level) in Nucleus. The ECAP threshold values were individually analysed at three separate electrodes: Basal, central and apical, using NRT, which was at the 1st, 8th and 16th electrode in Advanced Bionics and 1st, 11th and 22nd electrode in Nucleus. Each patient had ECAP measurements done four times: intra-operative, switch-on, three months and six months.

Table 1: ECAP threshold changes with time.

Parameters	Intra-op	Switch-on	3rd month	6th month	P value (ANOVA)
Advanced bionics implant (ECAP measured in charge units-CU) (mean±SD)					
Basal electrode ECAP	172.5±51.0	160.3±42.9	148.9±36.0	152.4±45.6	0.0357
Central electrode ECAP	167.7±45.5	151±35.7	147.5±35.2	160.0±41.3	0.0261
Apical electrode ECAP (CU)	141.6±29.2	124.7±29.5	115.2±25.0	105.1±27.6	<0.00001
Nucleus Implant (ECAP measured in current level-CL) (mean±SD)					
Basal electrode ECAP	219.9±18.2	201.5±18.6	190.6±15.4	178.4±25.7	0.0001
Central electrode ECAP	194.8±14.7	186.2±12.1	179.6±13.9	169.9±23.8	0.00003
Apical electrode ECAP	175±17.0	170.4±16.8	164.1±15.1	150.4±25.6	0.00007

Table 2: ECAP threshold across basal, central and apical electrodes.

Parameters	Basal electrode ECAP	Central electrode ECAP	Apical electrode ECAP	P value (One-way ANOVA)
Advanced bionics implant (ECAP measured in charge units-CU) (mean±SD)				
Intra-op	172.5±51.0	167.7±45.5	141.6±29.2	0.0119
Switch-on	160.3±42.9	151±35.7	124.7±29.5	0.0006
3rd Month	148.9±36.0	147.5±35.2	115.2±25.0	0.00007
6th month	152.4±45.6	160.0±41.3	105.1± 27.6	<0.00001
Nucleus Implant (ECAP measured in current level-CL) (mean±SD)				
Intra-op	219.9±18.2	194.8±14.7	175±17.0	<0.0001
Switch-on	201.5±18.6	186.2±12.1	170.4±16.8	0.0004
3rd Month	190.6±15.4	179.6±13.9	164.1±15.1	0.0009
6th month	178.4±25.7	169.9±23.8	150.4±25.6	0.0389

Table 3: T level, C Level and dynamic range at 6 months.

Parameters	Basal Electrode	Central Electrode	Apical Electrode	P value (One-way ANOVA)
Advanced bionics implant (ECAP measured in charge units-CU) (mean±SD)				
T level	19.4±7.4	19.6±7.8	17.2±5.7	0.3372
C level	195.7±45.5	192.1±43.5	154±38.2	0.0002
Dynamic range	176.3±40.7	172.4±37.9	136.8±34.3	0.00009
Nucleus Implant (ECAP measured in current level-CL) (mean±SD)				
T level	18.6±5.0	17.1±5.5	16.8±5.6	0.719
C level	210.3±15.1	197.7±11.3	176.7±20.6	0.0001
Dynamic range	191.8±15.2	180.6±11.0	159.9±20.1	0.0002

Table 4: Correlation of ECAP threshold to T level and C Level at 6 months.

Parameters	Basal Electrode	Central electrode	Apical Electrode
Advanced bionics implant (ECAP measured in charge units-CU) (mean±SD)			
ECAP Threshold	152.4±45.6	160.0±41.3	105.1± 27.6
C-Level	195.7±45.5	192.1±43.5	154±38.2
Correlation of ECAP & C level*	0.596 p=0.0004	0.695 p=0.00001	0.210 p=0.25
T-Level	19.4±7.4	19.6±7.8	17.2±5.7
Correlation of ECAP & T level*	0.610 p=0.0003	0.657 p=0.00006	0.0393 p=0.835
Correlation of T & C level*	0.6956 p=0.000014	0.7534 p<0.00001	0.7353 p<0.00001
Nucleus Implant (ECAP measured in current level-CL) (mean±SD)			
ECAP Threshold	178.4±25.7	169.9± 23.8	150.4± 25.6
C-Level	210.3±15.1	197.7±11.3	176.7±20.6
Correlation of ECAP & C level*	0.588 p=0.058	0.456 p=0.158	0.805 p=0.0028
T-Level	18.6±5.0	17.1±5.5	16.8±5.6
Correlation of ECAP & T level*	-0.0159 p=0.965	0.018 p=0.959	-0.091 p=0.792
Correlation of T & C level*	0.1364 p=0.6892	0.2962 p=0.3765	0.2304 p=0.4955

*Pearson's Correlation Coefficient (R score)

Advanced bionics

Using repeated measure ANOVA, it was found that the ECAP threshold reduced significantly over six months ($p < 0.05$) for all electrodes, but there was no significant reduction in ECAP threshold between each time interval in the basal electrodes (Figure 1). The intra-operative mean ECAP thresholds were the highest, measuring 339 CU, 324 CU and 197 CU in basal, central and apical electrodes, respectively. It significantly reduced ($p<0.05$) over six months with basal, mid and apical electrodes showing a reduction in ECAP threshold of 11.64%, 4.67% and 25.81%, respectively, from intra-operative period to 6 months post-operatively (Table 1).

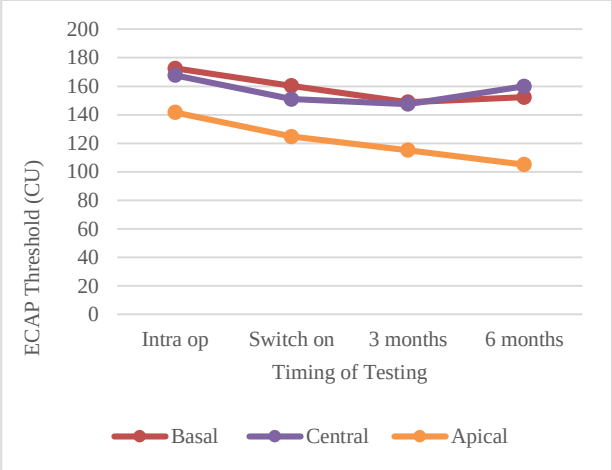

Figure 1: Changes in ECAP threshold with time-AB implant.

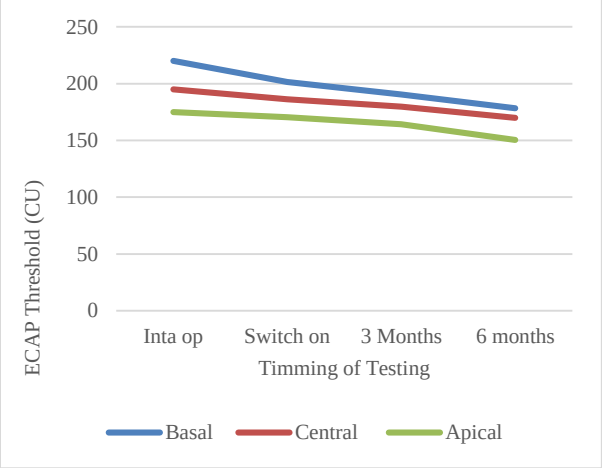

Figure 2: Changes in ECAP threshold with time-Nucleus implant.

Using post-hoc analysis, there was no statistically significant reduction in ECAP threshold at each time period in the basal electrodes. Still, in central electrodes, ECAP changes between intra-op and switch on and intra-op and three months of 9.96% and 12.03% were statistically significant ($p<0.05$). In the apical electrodes at each time point, there was a statistically significant reduction in ECAP threshold being 11.91% (between intra-op and four weeks), 18.62% (between intra-op and three months), 25.81% (between intra-op and six months), 115.77% (between switch on at four weeks and six months). The T level, ECAP threshold, and C Levels compared at six months showed that the ECAP threshold at six months fell in between the comfortable level and the threshold level, closer to a comfortable level with an approximate difference of 40-50 CU in children with advanced bionics cochlear implant (Figure 2, Table 2).

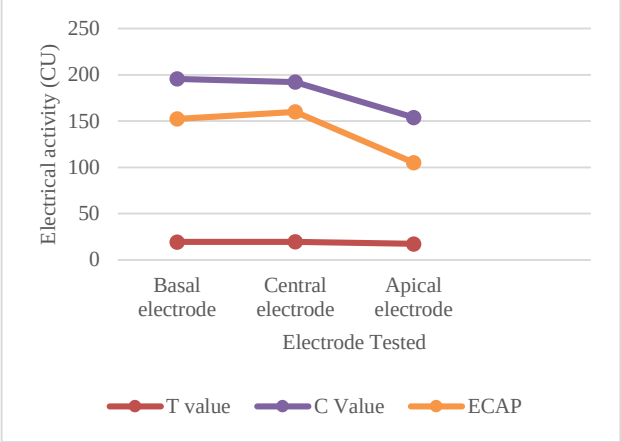

Figure 3: T Level & C Level at 6 months -AB implant.

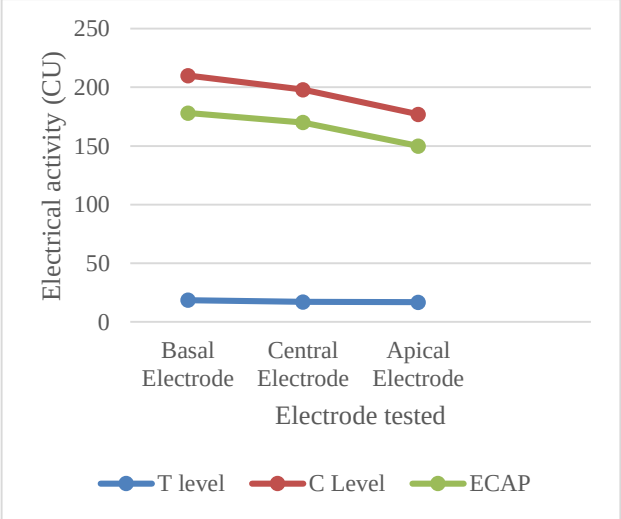

Figure 4: T Level & C Level at 6 months -Nucleus implant.

Nucleus implant

Using repeated measure ANOVA, it was found that the ECAP threshold reduced significantly over six months ($p < 0.05$) for all electrodes (Figure 3). The intra-operative ECAP thresholds were the highest, the maximum being 245 CL, 220 CL and 192 CL in basal, central and apical electrodes, respectively. It significantly reduced ($p<0.05$) over six months with basal, mid and apical electrodes

showing a reduction in ECAP threshold of 18.89%, 12.78% and 14.08%, respectively, from intra-operative period to 6 months post-operatively (Table 3). Using posthoc analysis, the changes between intra-operative ECAP and switch in three months, six months of 8.9%, 13.35% and 18.89%, respectively, were found to be statistically significant along with the ECAP threshold changes between switch on and 3rd month of 5.4% in the basal electrodes. In the central electrodes, the differences in ECAP between intraoperative ECAP and three-month ECAP of 7.79% and 12.78%, respectively, were found to be statistically significant ($p<0.05$). Whereas in the apical electrodes, ECAP changes between the intra-operative ECAP and six months ECAP, Switch on ECAP and six months ECAP of 14.08% and 11.73%, respectively, were found statistically significant. The ECAP threshold at six months fell between the comfortable level and the threshold level, closer to the comfortable level, with an approximate difference of 25-30 CL (Figure 4, Table 4).

Cochlear nerve diameter

Cochlear nerve diameters were measured for only 40 patients as two patients did not have 3D reconstructive images at a parasagittal oblique plane perpendicular to the fundus of the IAC in T2 weighted MRI with 3D reconstruction of the inner ear. Since the software could not accurately calibrate the diameter in millimetres, it was approximately determined by comparing it with the facial nerve. The average horizontal cochlear nerve diameter was calculated to be 0.905±0.25 mm and 0.895±0.25 mm on the right and left ear, respectively. These approximate values were correlated to the ECAP threshold values and did not correlate. ECAP threshold values were produced irrespective of the cochlear nerve diameter.

DISCUSSION

ECAP is the electrical activity recorded in the auditory nerve on stimulation of the modiolus of the cochlea. This measurement uses bidirectional telemetry using the implant's electrodes without needing external electrodes and custom-made software from each manufacturer. The process is named “Neural response telemetry (NRT)” for the Nucleus® implant and “Neural response imaging (NRI)” for the Advanced Bionics® implant.[4] On plotting the stimulation amplitude of the electrode in □V on the x-axis to the ECAP amplitude in Charge Units (CU) or Current Level (CL) on the y-axis, the amplitude growth factor is plotted, and its linear portion intercepting at the x-axis gives the threshold NRT (t-NRT) or ECAP threshold.[2] Intraoperative NRT, in conjunction with electrode impedance data, can help indicate the integrity of the implanted electrodes and the electrode/auditory nerve interface, confirming that the implant functions correctly intraoperatively.[8]

There have been differences of opinion regarding the usefulness of the intraoperative ECAP threshold in setting the map of the speech processor.[9,10] There is significant variation in neural response from patient to patient, and it indicates differences in stimulated neural population due to myelination, the presence of a dendritic population, and axonal integrity in the residual auditory neural population, according to Tanamati et al.[11] It was also found that all the intraoperative ECAP thresholds were the highest values recorded. It could be explained by the presence of blood clots, air bubbles and loss of perilymph during surgery that increases the resistance to the current flow, warranting an increased amount of current for stimulating the neurons intraoperatively. It significantly decreased with time as lost perilymph was replaced and blood clots and air bubbles resolved. After the cochlear implant surgery, the children were asked to come at four weeks postoperatively to link the inner device with the speech processor. During this point, the child hears the sound for the first time. The minimum (threshold) and maximum (comfortable) levels are set based on the behavioural response, and the child is asked to review twice a week for the next six months for speech therapy. During the next six months, the threshold and comfortable levels were modified multiple times to facilitate better hearing and speech outcomes. This narrow band of stimulus amplitude called dynamic range is set for each electrode so the child hears sound optimally and develops speech. This band varies from the time of surgery and needs to be repeatedly adjusted to reach the optimum.

Various studies have been done to determine the reasons for an overall change in neural response amplitude with time. In the literature, animal studies showed that auditory nerve fibres stimulated chronically significantly increased neural density and preservation of the myelin sheath, which helped increase the N1 peak amplitude of NRT in segments close to the pair of stimulation electrodes.[11] According to Gordon et al greater amplitude indicated increased synchronism due to stimulation of primary neurons or decreased firing time variations among neurons during the first year of cochlear implant use Field.[12] However, according to Shepherd et al neural response changes in time reflect changes in the distribution of the intracochlear current. Changes in the state or recruitment of auditory fibres cannot explain them.[13] Other studies have shown that cochlear implant electrical stimulation provides neurotrophic support for auditory neurons by changing synaptic and electrical activity on the neuronal membrane. It has also been explained by the changes in electrical current flow reaching neural tissues with cochlear implant use, which could be due to a hydric layer on the electrode surface and bony or fibrous tissue forming around the electrodes.[14] In the present study, for the Advanced Bionics implant, when the changes in mean ECAP threshold over six months were analysed for the Basal and central electrodes, the mean value at six months showed a slight rise compared to the 3rd month, which could be explained as a rise in resistance due to formation of fibrous tissue around the electrode. Still, it was not seen with the apical electrode or the electrodes of the Nucleus implant.

In the present study, ECAP thresholds showed significant change with time (Tables 1, 3). This is similar to the study by Telmesani et al. Field 5 who showed ECAP thresholds fell till six months after surgery before stabilising. However, this was not seen in other studies like the publication by Zarandy et al found no variations in ECAP, measured at 1, 3 and 6 months postoperatively.[15] Another study by Asal et al. found the intraoperative ECAP remained constant and did not decrease with time in 15 deaf children implanted with MED-EL cochlear implants. [16] In the present study, in both cochlear implant designs used in the study, it was observed that the apical electrodes had lesser ECAP thresholds, 35-40 CU and 20-30 CL less than the central and basal electrodes. Hence, the present study could confirm that the current required to stimulate the neurons at the apex of the cochlea is lesser than the current needed to stimulate the rest of the neurons at the centre or the base of the cochlea because at the apex the electrode lies closer to the neurons compared to other regions of the cochlea as explained by Brill et al.[7]

Muhaimeed et al compared the ECAP threshold with the behavioural threshold and the comfortable level measured at one month post-surgery in 47 children implanted with Nucleus cochlear implant in a period of 8 years in 4 different electrodes (5, 10, 15 and 20).[17] There was a positive correlation between T and C levels with the measured NRT threshold, and it could be used to predict the T and C levels. The present study could measure the T and C levels only six months post-cochlear implantation, as predicting it based on behavioural responses in a paediatric population was difficult. The study found a statistically significant correlation between ECAP thresholds and C levels at six months. (Tables 2, 4) ECAP thresholds at six months were closer to the C levels with a difference of at least 25-30 CL or 30-40 CU. The correlation to T levels was seen only with the AB implant (Figure 2, 4, Table 2). Studies conducted in animals have shown that excessive current stimulation of the cochlea and auditory nerve can cause irreversible damage.[18] Hence, the minimum and maximum levels should be changed at least once a month as the present study showed changes in the ECAP thresholds as early as four weeks (time at switch on), which are statistically significant in specific electrodes. Stimulating the cochlea with a constant level set during surgery will eventually lead to overstimulation and poor speech response. Shennawy et al studied 44 implant candidates and concluded that post-operatively, after one year of implantation, there was no correlation between speech outcome and ECAP threshold.[19]

After 30 years of starting cochlear implantation, ECAP is believed to be the most important modality in determining and creating a map to facilitate optimum communication in a cochlear implant recipient. Hence, determining its variability over time from the time of implantation intraoperatively to up to 6 months postoperatively should facilitate accurate mapping. In the present study, the results agree with this premise. As the ECAP values in the present study show a significant correlation with C levels, we can use the ECAP thresholds to set C levels. The actual values show a statistically significant change with time and correlate to C levels. According to Takeshi Morita et al and Kim et al who studied the relationship between cochlear implant outcome and the diameter of the cochlear nerve depicted on MRI, there was no significant association between the cochlear nerve diameter and ECAP postoperatively.[20] Similarly, our study did not find any correlation between the diameter of the cochlear nerve and the ECAP threshold. There is no better method than repeatedly measuring ECAP thresholds while mapping cochlear implantees to prevent over or under-stimulating cochlea. Till a better or more accurate objective measurement technique is available, ECAP thresholds are here to stay.

CONCLUSION

The ECAP threshold recorded shows statistically significant change over months before stabilisation. It must be repeatedly checked for accurate mapping to prevent either over-stimulation or under-stimulation of the cochlea. The ECAP threshold alone may not be enough to map the T and C levels as the correlation is less than ideal. The cochlear nerve diameter does not correlate to the ECAP threshold and cannot be used as the only determinant to decide the side of cochlear implantation.

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