THE CLINICAL SIGNIFICANCE OF eCAP AND eSRT IN CHILDREN USING COCHLEAR IMPLANT: A SYSTEMATIC REVIEW

BHUVANESHWARI R

20AUD008

This Dissertation is submitted as part

of fulfillment for the degree of Master of Science in Audiology

University of Mysore, Mysuru

ALL INDIA INSTITUTE OF SPEECH AND HEARING

Manasagangothri, Mysuru 570 006

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CERTIFICATE

This is to certify that this dissertation entitled '**THE CLINICAL SIGNIFICANCE OF eCAP AND eSRT IN CHILDREN USING COCHLEAR IMPLANT: A SYSTEMATIC REVIEW'** is a bonafide work submitted as a part of the fulfillment of the degree of Master of Science (Audiology) of the student Registration No: 20AUD008. This has been carried out under my guidance and has not been submitted earlier to any other University for the award of any other Diploma or Degree.

Mysuru
August 2023

Dr. Prawin Kumar
Guide
Associate Professor,
Department of Audiology,
All India Institute of Speech and Hearing
Manasagangothri, Mysuru 570 006

DECLARATION

This is to certify that this dissertation entitled '**THE CLINICAL SIGNIFICANCE OF eCAP AND eSRT IN CHILDREN USING COCHLEAR IMPLANT: A SYSTEMATIC REVIEW**' is the result of my study under the guidance of Dr. Prawin Kumar, Associate Professor, Department of Audiology, All India Institute of Speech and Hearing, Mysore and has not been submitted earlier to any other University for the award of any other Diploma or Degree.

Mysuru **Registration Number: 20AUD008**

August 2023

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ABSTRACT

Sensorineural hearing impairment affects around 5% of over a million people worldwide, lying into the category of disability with which people live for years. Cochlear Implant (CI) is a neuro-prosthetic device that is viable and has been used as the standard treatment option for individuals with severe-to-profound sensorineural hearing loss. Modern CI devices assist programming by enabling objective metrics like electrically evoked compound action potential (eCAP) and electrically evoked stapedius reflex threshold (eSRT) to be used, to supplement behavioural assessments. In order to begin the mapping process, especially when it comes to infants and young children, objective measures are used in the CI process. These measures provide specific values that serve as the starting point for the mapping process.

The present systematic review throws light on the efficiency of the objective measurements used in cochlear implantation. Further, the correlation between the objective and the subjective measures, as a clinical tool in patients with the cochlear implant is also discussed. The review was conducted based on the PRISMA statement, and the data sources used include PubMed/Medline, Google Scholar, and ResearchGate, a List of references, and citations. A systematic search for articles regarding eCAP and eSRT was done between the years 2000-2020 with relevant keywords, and a study population of up to 10 years of age was considered. Out of 4614 articles, there were 8 full-length articles that fulfilled the inclusion criteria defined in the study and were considered for further discussion. Most of the studies investigated either correlation of eCAP or eSRT with behavioural measures. Overall, studies showed a straightforward estimation of the eSRT in comparison to the eCAP thresholds. Further, there is a high correlation reported between eSRT *and behavioural thresholds obtained for comfort levels compared to eCAP thresholds. Thus, the present systematic review concludes that eSRT is a reliable tool, if present compared to eCAP for mapping CI in the paediatric population.*

Keywords: Cochlear Implants, Mapping, Paediatric population, Electrically evoked stapedial reflex threshold (eSRT), Electrically evoked compound action potential (eCAP), Behavioural measures of comfort levels.

CHAPTER I

INTRODUCTION

Hearing impairment affects around 466 million individuals worldwide, among which 34 million are found to be paediatric population (Kushalnagar et al., 2019). One to three cases of sensorineural hearing impairment occur for every 1000 live birth, making it the most prevalent congenital sensory impairment. Unaddressed hearing impairment has an adverse effect on speech and language development, performance in school, employment opportunities, psychosocial well-being, and aspects of family life (Yumba, 2017). Due to decreased audibility, frequency resolution, and temporal resolution, traditional amplification is often ineffective for most individuals with severe-to-profound sensorineural hearing impairment (Entwisle et al., 2018). Deafness in children can have a negative impact on language development, as well as academic and socio-economic growth. The benefits from traditional auditory amplification cannot suffice in cases of severe-to-profound hearing impairment to enable adequate language development (Vincenti et al., 2014).

The cochlear implant is a prosthetic electronic device that is implanted under the skin and the electrodes are surgically inserted into the cochlea to stimulate the auditory nerve. Hearing aids are devices that amplify a sound which consists of an amplifier, an analog-to-digital converter, and a receiver that amplifies a given sound. Whereas, cochlear implants, consists of two parts (internal & external component): a receiver-stimulator package and a speech processor. The external part which includes the battery, headpiece, and the speech processor placed behind the ear acts as a microphone and transmits the sound to the internal part. The internal part, which is the receiver-stimulator consists of a magnet, an electronics package, electrode lead, and a small electrode that is wired into the cochlea. Even though speech or sounds are collected by a microphone and converted as electric current as in hearing aids they are transformed and coded externally through a processor using different coding strategies. The coded signals are then fed as electrical currents directly to electrodes that are surgically implanted in the cochlea of the recipient. Unlike hearing aids, the cochlear implant bypasses the hair cells that stimulated the auditory nerve fibres directly with the coded speech through the electric current.

Since its debut, more than 30 years ago, cochlear implants' performance has increased to the point where they are currently regarded as the gold standard of care in the treatment of children who have severe-to-profound hearing loss (Ramsden et al., 2012). The paediatric population criteria for implantation are constantly changing due to advancements in the field of cochlear implant device, patient candidacy has expanded and varied throughout time. The surgically placed system has to be activated after a period of healing and programmed accordingly for the device to function properly.

To begin with, programming or mapping is the art of providing appropriate input into the auditory system by directing the input to the electrodes on the array that is implanted into the cochlea. Establishing threshold and/or comfort levels is necessary for the speech processor to ensure optimal hearing sensitivity. The threshold (T-Level) is nothing but the minimum amount of electric current required for the sound to be perceived. Whereas, the comfort level (C-level) is the current level at which the quality of the sound is most comfortable. And the dynamic range is indicated as the difference between the threshold and the comfort level. The audiologist uses programming methods as in behavioural and objective measures, in order to obtain T and C levels. Reliable behavioural responses can be obtained from older children and adults, thereby behavioural methods can be used to set the levels. Whereas, objective measures would be more appropriate for younger children and individuals who have difficulty in responding reliably to sounds.

Programming platforms are divided into two ways: Streamlined and Comprehensive programming. Programming that involves a comprehensive battery of measures to determine stimulation levels at each of the electrode contacts that is present in an array is called comprehensive programming. In contrast, streamlined approaches involve measurements in only few electrodes that are present in an array and extrapolate the levels for remaining electrodes (Roush, 1992). In the behavioural approach, the T-level assessment involves initiating the test at a low-frequency channel, by using an adaptive-bracketing procedure to establish the point at which the recipient indicates audibility that is presented through an ascending direction. Once the T levels are set, optimal upper stimulation levels have to be set. One way to measure the C levels is to gradually increase the stimulus level until the client indicates it to be comfortably loud. Another way is to use a loudness scaling chart to point out the loudness percept that the individual perceives (Wolfe & Schafer, 2014).

The objective measures of cochlear implant programming mainly involve electrically evoked stapedius reflex threshold (eSRT), electrically evoked compound action potential (eCAP), electrically evoked auditory brainstem response (eABR), etc., The two main measures that are frequently used in mapping procedures involve eSRT and eCAP.

In the case of eSRT, electrical stimulation is used to activate the stapedial muscle through the non-implanted ear, using standard immittance equipment by ascending approach. eSRT's are time-locked to each stimulus presentation and appear as a downward deflection (Stephan & Welzl-Müller, 2000). A repeatable response that is visible at the lowest stimulus level is taken as the threshold (Hodges et al., 1999).

An aggregate population of the auditory nerves that provides a synchronous physiological response when stimulated through electrical mode is called an Electrically evoked compound action potential. The eCAP is represented by a negative deflection N1 and a positive plateau P2. It is a gross potential, whose negative and positive peaks occur at a latency of 0.2ms to 0.4ms and 0.6 to 0.8ms respectively (Cullington, 2000).

eCAP thresholds are likely to exceed behavioural thresholds and mostly exceed the most comfortable levels (Jeon et al., 2010). Whereas, studies have shown that there exists a strong correlation between eSRT's and upper comfort levels (Greisiger et al., 2015; Lorens et al., 2003, 2004; Roshani & Aparna, 2019). The sensitivity and the specificity of these objective measures vary across studies ranging from moderate-to-strong correlation with that of behavioural measures in the case of eSRT and a slight-to-moderate correlation in eCAP. With the increasing need for research in this area, it is essential to systematically evaluate the available sources for assessing which of these objective measures (eCAP/eSRT) provides a better prediction of the threshold and comfort levels.

NEED FOR THE STUDY

The objective of programming in cochlear implants is to configure several variables, so that the electrical signal generated by the device in response to sound provides better speech intelligibility. It is essential to carefully tune the amplitudes to a better dynamic range at each electrode to optimize the speech signal via the electrical signal, recorded digitally in the patient's speech processor. Using subjective methods to program speech processors of the cochlear implant, particularly young children, who are uncooperative, is a tedious and challenging task as they cannot provide adequate feedback to the clinician. In such cases, objective methods such as eCAP and eSRT play a vital role in obtaining the responses to program the cochlear implant after switch-on of the device. The electrical stapedius reflex test can be used to program both adult and paediatric implant patients objectively. Several researchers have found a strong association between post-operative eSRT thresholds and map the most comfortable levels (MCLs) (Kosaner et al., 2009; Spivak & Chute, 1994). Overall, studies have shown that both eCAP and eSRT exhibit a good correlation with that of the behavioural MCLs (Çiprut & Adıgül, 2020; McKay & Smale, 2017; Sampathkumar et al., 2013). Similarly, the eCAP response correlates with the perceptual threshold and maximum comfortable level of the electrical stimulus (Hoth & Dziemba, 2017).

However, there is no detailed evidence to state that either of the ones has the higher sensitivity to assist with the programming of the sound processor and verify questionable behavioural responses. Thus, present systematic review might provide an insight to the Audiologist about better objective tool among eCAP and eSRT, for appropriate programming measures for cochlear implantees.

AIM OF THE STUDY

The current study aims at reviewing various studies that assess the utility of the eCAP and eSRT measurements in cochlear implant users and state which measure constitutes a better fitting method, if possible.

OBJECTIVE OF THE STUDY

Research Question:

1. Does eCAP serve as a better objective fitting method for users with a cochlear implant?
2. Does eSRT serve as a better objective fitting method in cochlear implant users?
3. To compare eCAP and eSRT measurements, to define the better objective fitting method for cochlear implant users.

CHAPTER 2

REVIEW OF LITERATURE

The cochlear implant is a prosthetic electronic device that is implanted under the skin and the electrodes are surgically inserted into the cochlea to stimulate the auditory nerve. Programming or mapping is the art of providing appropriate input into the auditory system by directing the input to the electrodes on the array that is implanted into the cochlea. Establishing an electrical dynamic range that offers appropriate speech perception and is regarded as comfortable by the listener is the primary objective of cochlear implant (CI) programming (Gordon et al., 2002; Shapiro & Bradham, 2012). Cochlear implant is typically programmed using a combination of both objective and psychophysical loudness measurements. Methods of assessment that don't necessitate the listener to provide any behavioural or psychophysical input are regarded as accurate measurements. Investigations into the interaction between the CI and the physiology of the auditory system can be done using objective measures. Programming devices for children or individuals who find it challenging to provide accurate psychophysical loudness judgments can benefit from objective measurements.

When threshold (THR) and most comfortable levels (MCL) are precisely tuned based on the patient's need, and the loudness is balanced across the electrodes, it is indicated that the cochlear implant is functioning appropriately. The loudness balance and MCL level is known to impact patient performance more than the THR level itself (Stephan & Welzl-Müller, 2000).

The two main objective measures that are frequently used in mapping procedures involve electrically evoked stapedius reflex threshold and electrically evoked compound action potential.

Electrically evoked Stapedial Reflex Threshold (eSRT)

Static admittance of the ear canal (in particular, the stapedius muscle contraction) is recorded in response to a range of sound input levels presented through the CI. This objective assessment is comparable to the acoustic reflex thresholds. The capability of eSRT to predict an individual's maximum comfort/stimulation (C/M) levels is helpful in CI programming. It has additionally been shown to remain stable and constant over time postoperatively.

INSTRUMENTATION

Equipment typically needed to measure eSRT includes the cochlear implants' external components, programming cables connected to a computer running CI manufacturing software, a traditional immittance bridge with a reflex decay protocol, and a probe tip with a suitable size for the placement inside the ear canal of the CI user.

In standard acoustic immittance measurement, the stapedial response is assessed by providing a loud, pure tone (especially at 500, 1000, or 2000 Hz) as a result of which there occurs a rise in the SPL of the 226-Hz probe tone in the ear canal, thereby resulting in a contraction of the stapedial muscle in response to the stimulation. The tympanic membrane then becomes stiffer due to stapedial contraction, thereby limiting the transmission of the probe tone into the middle ear system.

In the case of eSRT measurement, the immittance probe is commonly positioned in the external ear canal, to the side opposite to that of the cochlear implant. A 226-Hz testing tone is constantly provided into the ear canal, and the static admittance is recorded while biphasic pulses are provided via the cochlear implant in an ascending pattern. When the intensity of the cochlear implant stimulus is high enough to trigger the stapedial reflex, a decrease in the admittance associated with time locked with stimulus presentation occurs. Since the stapedial reflex is a bilateral response, a reduction in the admittance is observed in the ear opposite to that of the cochlear implant (Wolfe et al., 2018).

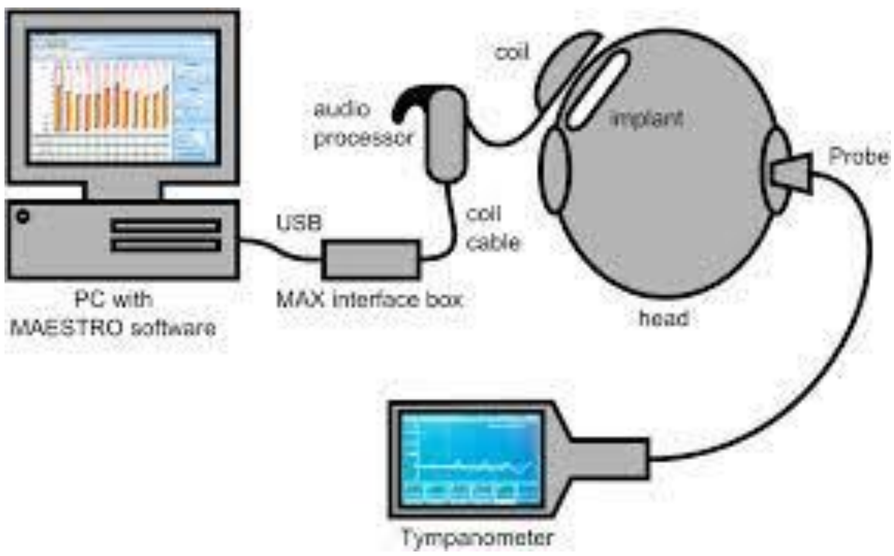

FIGURE 2.1: Instrumentation for eSRT measurement.

(Adapted from Julie Kushner, Philipp Spitzer, Svetlana Bayguzina, Muammar Gultekin & Laurie Arum Behar (2018). Comparing eSRT and eCAP measurements in paediatric MED-EL cochlear implant users. Cochlear Implants International, 19:3, 153-161, DOI: 10.1080/14670100.2017.1416759)

Electrically evoked stapedial reflex thresholds can be obtained both while intraoperatively as well as postoperatively. Studies indicate a stronger correlation between behaviourally assessed MCL levels and eSRT outcomes performed post-operatively. Intra-operative eSRT's were significantly greater than that of the post-operative eSRT's obtained after one month of fitting (Baysal et al., 2012). The proportion of intra-operative eSRT's to that of post-operative eSRT's were found to be around 63% (Caner et al., 2007). But there was no association to be found between intra- and post-operative eSRT's. The existence of blood and bone particles in the cochlea from drilling during the CI surgery might be the cause for such an outcome (Paprocki et al., 2004).

CONTRAINDICATIONS TO eSRT MEASUREMENT

Interestingly, eSRT cannot be assessed in all CI users; it has been approximated that eSRT cannot be quantifiably measured in around 20% to 30% individuals with CI. Damage to the stapedial muscle during the surgical procedure could be one of the probable causes of absence of eSRT. A patient's aberrant tympanogram, facial nerve involvement, difficulty staying still during measurement, or inability to endure the level of stimulation tone necessary to record a response are a few examples of additional circumstances in which an eSRT is not quantifiable.

In around 30% of paediatric patients, the reflexes were diminished (Spivak & Chute, 1994). No observable responses were seen in 31% of the population studied (Asal et al., 2016). Conductive problems that are not resolvable is also one of the primary causes for the absence of eSRT's when elicited. In cases of ossification and non-auditory stimulation, the inability to generate adequate charge to elicit reflex was the possible cause. In the paediatric population with flaccid tympanic membranes, sudden movements challenge the clinician in distinguishing reflex from background noise. In some cases, there is no apparent explanation for the lack of measurable reflexes. For the eSRT to be quantifiable, the middle ear and the various parts of the auditory system must function. The cochlear nerve has to be properly functioning and capable of responding synchronously to high-intensity signals. Additionally, the superior olivary complex and cochlear nucleus auditory neurons must be able to respond to high-level stimuli as well. The stapedius muscle as well as the stapedial branch of the facial nerve must be intact and functional.

Although the probe tone frequency employed to measure the eSRT is not typically reported in considerable research studies, the default probe frequency of 226Hz was probably chosen for most investigations. The eSRT obtained using 226, 678, and 1000 Hz probe tones in a group of adult Advanced Bionics Cochlear Implant recipients revealed that measurable eSRT was obtained in 82% of subjects with the use of the 226Hz probe tone and 100% of the individuals with the use of the 678 or 1000 Hz probe tones (Wolfe et al., 2018).

CORRELATION BETWEEN eSRT AND BEHAVIOURAL THRESHOLDS

No significant discrepancies were found between the upper comfort level to that of the threshold required to produce electrically evoked stapedial reflex, thereby stating that eSRT in cochlear implant programming allows the patient to experience auditory perception. Irrespective of age or the cause of the hearing loss, the average auditory threshold estimated by the eSRT was considerably smaller than the behavioural threshold. eSRT might facilitate CI programming for children less challenging, through the objective and systematic measurement of auditory dynamic ranges (Pérez-Rodríguez et al., 2023).

Generally, the comfortable levels must be set close to eSRT's rather than at a higher level in case of all cochlear implant recipients. Establishing upper stimulation levels above the eSRT value may cause the stapedial reflex to be contracted continuously, eliciting a response even at moderately loud signals, such as typical conversational speech, which is generally unusual in case of normal hearing individuals.

The use of eSRT's to create programs is facilitated by significant associations between behavioural MCL and eSRT levels in adult and paediatric CI users, with an r-value of about 0.9 (Asal et al., 2016). The higher frequencies tend to exhibit a more significant eSRT than low frequencies (Degen et al., 2020).

A comparison of behavioural C-level and eSRT data indicated that the latter invariably exceeded behaviourally derived C-levels for all electrodes (Roshani & Aparna, 2019). The correlation between C-level and eSRT ranges from moderate-to-very strong which is around 0.68 to 0.93 when compared to that of older children, which ranges from strong-to-very strong levels around 0.80 to 0.92 (de Andrade et al., 2018).

USES OF eSRT

eSRT can potentially be employed to determine the C-level during cochlear implant programming in individuals who cannot exhibit consistent behavioural responses. In case of uncooperative children, correction parameters can be used to compute the C-level from eSRT values. On the whole, eSRT's are useful for confirming device function, assessment of the auditory pathway to the level of the brainstem, and assisting with the estimation of the maps' upper comfort levels.

Electrically evoked Compound Action Potential (eCAP)

An aggregate population of the auditory nerves that provides a synchronous physiological response when stimulated through electrical mode is called an Electrically evoked compound action potential. eCAP can be measured with the software provided by the CI manufacturer to record the data. The children's cochlear implant can be programmed using the eCAP data by utilizing the same device that is used for programming the sound processor.

The eCAP is also employed to examine neuronal longevity, spectral and temporal encoding of electrical stimuli in the auditory nerve and their correlations with perception of sound in CI users (Abbas et al., 1999; Eisen & Franck, 2005; Franck & Norton, 2001; Gordon et al., 2002; Han et al., 2005; Jeon et al., 2010; Wolfe & Kasulis, 2008). Present-day cochlear implants are equipped with a "reverse" telemetry feature allowing intra-cochlear electrodes to record the eCAP in the near field (He et al., 2017). Modern CI system includes two-way telemetry features, which renders the eCAP and impedance measurement easier.

NOMENCLATURES OF eCAP ACCORDING TO DIFFERENT MANUFACTURERS

Each company has its own software application for programming. The name eCAP is represented as the term Neural Response Imaging (NRI) by Advanced Bionics, Neural Response Telemetry (NRT) by Cochlear Limited, and Auditory

Nerve Response Telemetry (ART) by Med-EL company (Allam & Eldegwi, 2019; Arnold et al., 2007; Christiaan et al., 2019; Hughes & Stille, 2009).

Cochlear Limited uses Neural Response Telemetry as their main source for the determination of the thresholds and comfort levels, Med-EL utilizes electrically evoked stapedius threshold to obtain the levels, whereas, Advanced Bionics uses Neural Response Imaging as their tool to obtain the levels.

MEASUREMENT OF eCAP

Regular intra-operative and post-operative eCAP measurements are carried out to learn more about the electrode-nerve interaction. eCAP's are proven to be a valuable tool for determining the way acoustic signals are processed at the level of the auditory nerve. With surface electrodes positioned on the scalp, these evoked responses are tracked. This generally involves the presentation of a sequence of two long-duration sounds. At the initial detection of the stimulus, a response occurs, which is typically taken as an indication that the stimulus has been acknowledged.

A negative peak (N1) and a positive peak (P2) define the eCAP measurement. The initial negative peak of the eCAP (N1) tends to become untraceable due to its short latency, thereby resulting in a waveform that is either distorted or obscured by the stimulus. As the current level elevates, the peak's (N1-P2) amplitude increases.

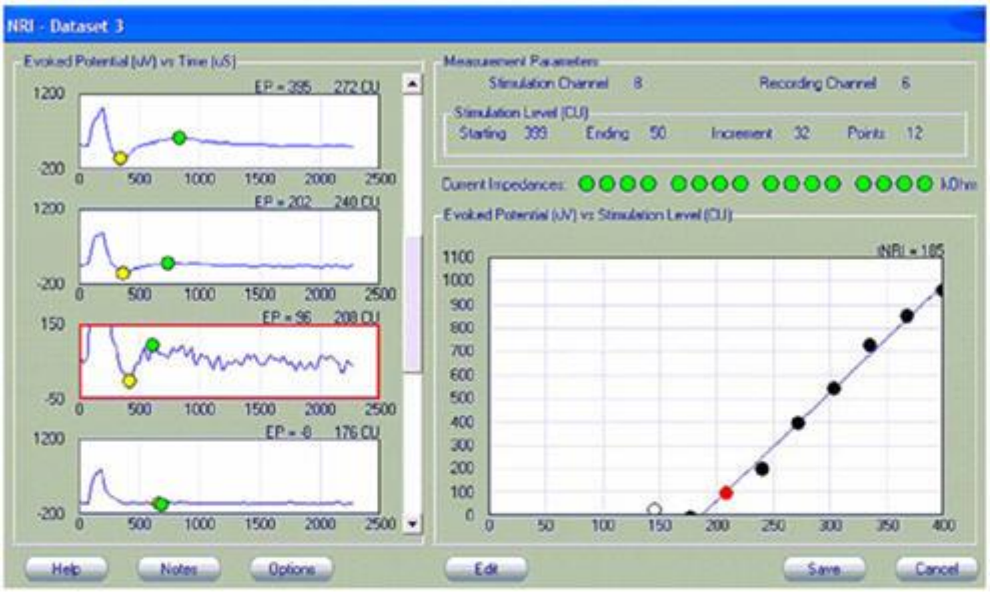

FIGURE 2.2: Screenshot of NRI measurement.

(Adapted from https://www.audiologyonline.com/articles/fundamentals-clinical-ecap-measures-in-846)

TECHNIQUES INVOLVED IN STIMULUS ARTIFACT REDUCTION IN OBTAINIING eCAP

To address the issue of the stimulus artifact, three alternative approaches have been utilized, each with their distinct benefits and drawbacks. This includes 'Alternating Polarity', 'Forward Masking Paradigm' and 'Template Scaling'. The first technique that is the alternating polarity, is applied, given the fact the polarity of the eCAP response is identical for both stimuli. The stimulus artifact is eliminated by averaging the data for the two different stimulus types; resulting in only the neuronal response. Whereas in case of second technique, that is the forward masking approach, uses the auditory nerve's refractory qualities. Three different stimuli contexts known as frames are integrated to produce response. The third method is template scaling, which is an electrical or digital subtraction, which emphasizes using a model of an artifact of the input as opposed to a neuronal response. The amplitude of the artifact template is scaled to that of the suprathreshold stimulus, which is then subtracted, thereby resulting in a neural response only (Cooper & Craddock, 2005). Cochlear Corporation utilizes the forward-masking subtraction paradigm as the default artifact reduction strategy, although alternating polarity is also one of the available options. Med-EL as well as Advanced Bionics makes use of alternating polarity as the artifact reduction technique.

CORRELATION BETWEEN BEHAVIOURAL THRESHOLDS AND eCAP VALUES

eCAP thresholds are likely to exceed behavioural thresholds and mostly either approximate or exceed the most comfortable levels (Jeon et al., 2010). The thresholds of post-operative NRT responses shown to improve substantially, that were either elevated or undetectable, during the intra-operative session. Gains in NRT thresholds are apparent after six months of surgery compared to the initial measurement obtained when the device was switched on (Kumari et al., 2023). A majority of electrodes exhibited a significant correlation between intra-operative tNRT, T and C levels after 1 month, 3 months, and 1-year post-activation (Sawaf et al., 2022).

A minimal correlation is observed between T and C levels as determined by psychophysics and eCAP predictions (Botros et al., 2010; Brown et al., 2000; Dillier et al., 2002; Holstad et al., 2009; Kirby et al., 2013; McKay et al., 2013; Morita et al., 2003; Potts et al., 2007; Thai-Van et al., 2001, 2004; Willeboer & Smoorenburg, 2006). eCAP’s can be utilized in clinical settings to verify device functionality, auditory nerve function and help to program the sound processor, and verify questionable behavioural responses (Wathour et al., 2021).

USES OF eCAP MEASUREMENT

Comprehensive tests of eCAP measurements also includes the spread of excitation and rate of recovery measures. They are not commonly employed in the clinical care of individuals with cochlear implants. By employing the spread of excitation functions, one can determine the current spread. This evaluates the degree to which the electrodes stimulate the overlapping neural cells. In order to accomplish this, by stimulating the various masker electrodes, the resulting electrically evoked compound action potentials are measured (Jawad et al., 2022). By utilizing neural response telemetry (NRT), electrically induced compound action potentials may also be used to measure the refractoriness and facilitation of auditory nerve fibres as well. An electrical stimulation method can record the auditory nerve's recovery function. eCAP’s significantly influence the auditory nerve’s refractory qualities, which are determined by the neural response’s magnitude as a function of the stimulus interval (Umashankar & Jayachandran, 2020). eCAP measurements are beneficial in an array of situations, such as objective evaluation of the response to electrical stimulation of the auditory nerve, objective evaluation of electrode and device performance and verification of the integrity of ambiguous behaviour responses.

CHAPTER 3

METHODS

The systematic review was conducted based on the Preferred Reporting Items for Systematic Review and Meta-analyses statement (PRISMA statement) (Page et al., 2021). A systematic literature search was carried out for peer-reviewed articles published from 2000-2020.

3.1 Information sources

The following databases were extensively searched for studies on the objective measures of eCAP and eSRT in children using cochlear implants: PubMed/Medline, Google Scholar, and ResearchGate, List of references and citations were searched manually for further relevant studies.

3.2 Search strategy

The search was carried out using key terms, related search phrases, derivatives, and MeSH words relevant to the study combined with Boolean operators such as ‘AND’, ‘OR’, and ‘NOT’.“eCAP” AND “eSRT” AND “NRT” OR “NRI” OR “ART” OR “Electrically evoked stapedius reflex threshold” OR “Electrically evoked compound action potential” OR “Neural response imaging” OR “Neural response telemetry” OR “Auditory nerve response telemetry” AND “Children” NOT “Adults” AND “Paediatrics” NOT “Geriatrics” OR “Objective Measures” AND “Cochlear Implants” AND “Behavioural Measures” OR “T Level” AND “C Level” AND “Correlation” AND “Postoperative Measures” OR “Intraoperative Measures” AND “Thr Level” AND “MCL Level” OR “Threshold Level” OR “Most Comfortable Level”

3.3 Study Selection

The specific inclusion and exclusion criteria for the selection of studies were as follows:

3.3.1 Inclusion Criteria:

The articles fulfilling the following criteria were included for the study.

- Original articles with human participants, appropriate samples, assessment approaches, and statistics.
- Articles that have been published in peer-reviewed journals over the past twenty years (2000-2020) were included.
- The studies were selected based on the quality of the method, data, and outcome.
- Articles containing paediatric population up to 10 years of age.
- Studies in which objective measure of cochlear implant fitting is included.
- Only articles published in the English language were reviewed.

The selection criteria were based on PECO method (Methley et al., 2014).

- Population – Children with Cochlear Implantation
- Exposure – Objective measures (eCAP & eSRT) of Cochlear Implantation
- Comparison – Behavioural measures of Cochlear Implantation
- Outcome – Results of objective measures and their correlation with the behavioural measures.

3.3.2 Exclusion Criteria:

Those articles having the following criteria mentioned below were excluded.

- Studies done on children above 10 years of age/adults/older adult population.
- Articles having poor methodological quality or published in a language other than English language.
- Review articles, case reports, letter to the editor, editorials, animal studies, studies with insufficient data, heterogeneous groups of data, and studies with duplicated data.

3.4 Data Extraction

The research results were combined using the Rayyan QCRI (Qatar Computing Research Institute) and Mendeley Desktop Reference Manager System and the duplicate studies were eliminated. The studies that met the inclusion criteria were identified by screening the titles and abstracts retrieved from the search strategies. Later, the full text of the potential studies was retrieved and matched to see if they were eligible. The extracted data includes the article title, author details with their affiliation, sample size, age group, comparison group, method of outcome measures, and keywords specific to objective measures of cochlear implantation in children.

CHAPTER 4

RESULTS

A total of 4614 articles were identified using database searches with 127 duplicates eliminated. Out of 4614, a total of articles 4487 were included for the title/abstract screening. Following the title/abstract screening, there were 60 articles (1.30%) selected for the full-length screening. Out of 60 articles, there were 8 articles (0.17%) which matched the inclusion criteria and were considered for the final study. The remaining 52 articles were excluded mainly because of the study design, a language component, and an irrelevant study population. A detailed Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow chart for the selection of the study is shown in Figure 4.1

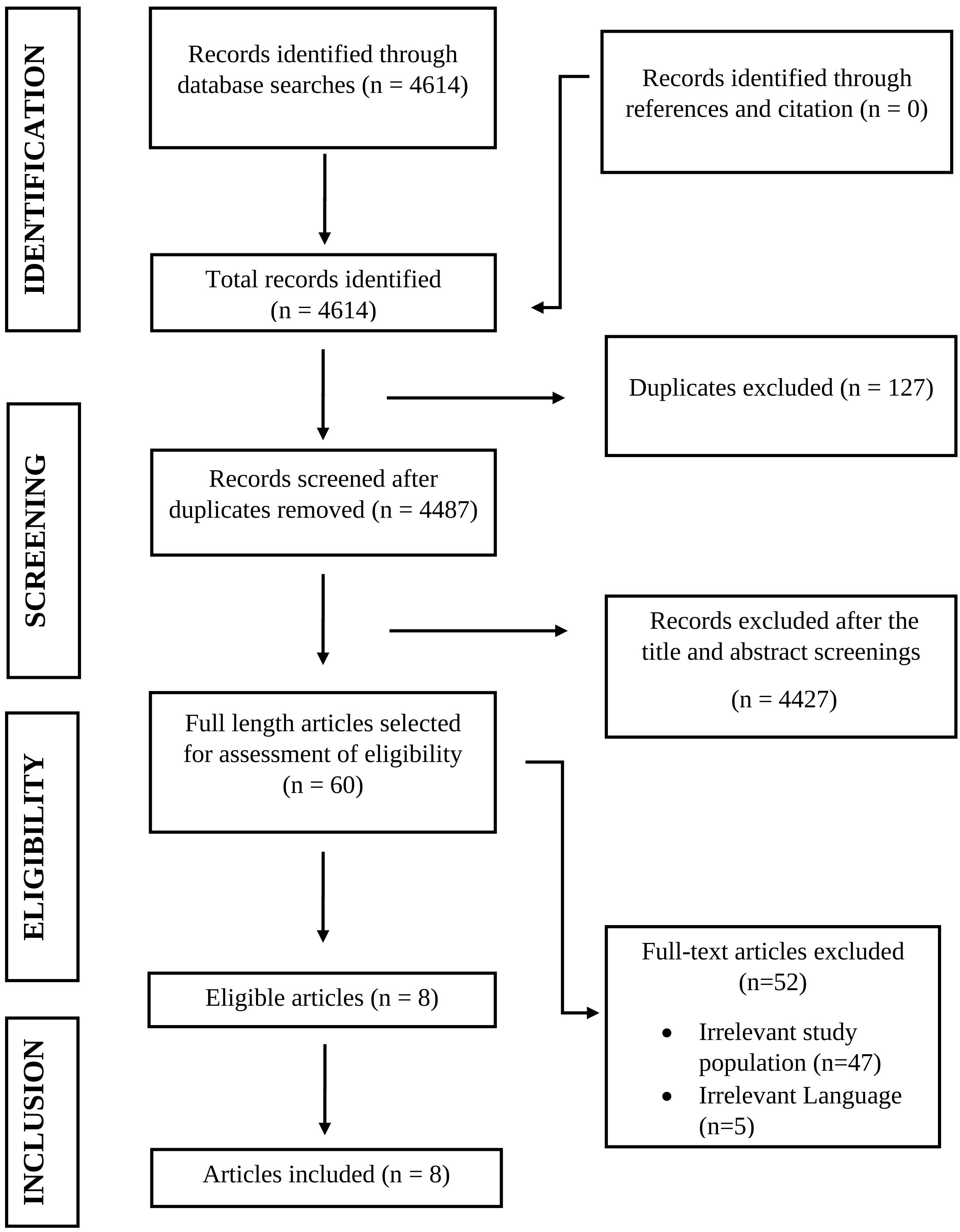

FIGURE 4.1: PRISMA flowchart for the selection process of articles included in the review.

4.1 Study Characteristics

Population: The study population included children with unilateral or bilateral cochlear implantation. All the articles included in the review comprised of participants using cochlear implants. Out of all the 8 articles, five studies did not mention whether the participants were implanted unilaterally or bilaterally. Only one article reported about syndromic population involved in their study group.

Exposure: The exposure of interest in this study is objective measures (eCAP & eSRT) of cochlear implantation. The selected article assessed either eCAP, eSRT, or both. Electrically evoked compound action potential were measured in 3 studies (Asal et al., 2018; Kaplan-Neeman et al., 2004; Telmesani & Said, 2016), Electrically evoked stapedial reflex threshold were carried out in 4 studies (Bresnihan et al., 2001; Lorens et al., 2003, 2004; Palani et al., 2020) and both the measures of cochlear implantation was done in one study (Sampathkumar et al., 2013).

Comparison: Behavioural measures of cochlear implantation were taken for comparison to that of the objective measures. All the 8 articles included in the review comprised the same (Asal et al., 2018; Bresnihan et al., 2001; Kaplan-Neeman et al., 2004; Lorens et al., 2003, 2004; Palani et al., 2020; Sampathkumar et al., 2013; Telmesani & Said, 2016)

Outcome: The outcomes of all the selected 8 articles involve the results of objective measures and their correlation with the behavioural measures.

Table 4.1 Study characteristics (Author, Year, Study design, No. of participants, Age range, Test performed, Method, and Outcomes) of the selected articles.

Sl. No.	Author/Year	Study design	No. of Participants (N)	Age Range	Tests Performed	Methods used	Outcomes ++/NS
1.	Asal et al (2018)	Cross-sectional study	15 CI children with MED-EL Sonata Implant	2 to 6 years	Electrode impedance, eCAP	To monitor eCAP thresholds and the electrode impedance	NS (eCAP showed insignificant changes intra- and post-surgically. Electrode impedance decreased significantly and became stable by 3 months post-implantation)
2.	Bresnihan et al (2001)	Prospective study	26 CI children with Nucleus24 Implant	2 to 9 years	Behavioural thresholds, eSRT	Compare behavioural versus objectively recorded measurement of C-levels	NS (C levels obtained with eSRT were lower compared to those obtained with behavioural levels)
3.	Kaplan-Neeman et al (2004)	Prospective Cross-sectional study	10 CI children with Nucleus24 Implant	12 to 39 months	Behavioural-based maps, NRT	Compare map T and C-levels, and speech perception abilities	++ (MAP profiles in the apical segment at initial

						using NRT-based and behavioural-based maps	stimulation showed differences but by 1 month of implant use, the difference diminished. NRT-based MAPs and behavioural-based MAPs are similar)
4.	Lorens et al (2003)	Prospective study	6 CI children with MED-EL Combi 40+ Implant	2 years 3 months to 5 years 7 months	eSRT	Determine the relation between the maximum comfort loudness levels and the eSRT	++ (Better repeatability and correlation existed between the comfort levels and eSRT)
5.	Lorens et al (2004)	Correlational study	7 children with MED-EL COMBI 40+ Implant	2 years to 5 years 9 months	eSRT	Evaluate the use of eSRT thresholds for programming speech processors in difficult-to-fit-population	++ (High correlation between CI programs created using behavioural procedures and eSRT recordings to determine MCL levels)
6.	Palani et al (2020)	Prospective cross-sectional study	14 Nucleus CI24RE Implant	5 to 8 years	eSRT	To assess the effect of probe-tone frequencies on eSRT measurements and	++ (eSRT thresholds obtained with higher probe tones correlated well with

						their relationship with behavioural comfort levels	behavioural comfort levels)
7.	Sampathkumar et al (2013)	Prospective study	10 CI children with AB HiRes 90K Implant	2 to 7 years	Behavioural testing, eABR, eCAP, eSRT	To study the trends in multi-modal electrophysiological tests and behavioural responses	++ (NRI, eSRT, and eABR thresholds correlated well with behaviourally obtained M-levels)
8.	Telmesani and Said (2016)	Cross-sectional study	25 children with Nucleus 24 Implant	1.2 to 5 years	eCAP	Compare eCAP thresholds measured at the time of surgery and at initial, 3, 6 and 12 months after initial stimulation	NS (No statistically significant differences in eCAP thresholds at the different time points)

NOTE: *eCAP – Electrically evoked Compound Action Potential; eSRT - Electrically evoked Stapedial Reflex Threshold; eABR – Electrically evoked Auditory Brainstem Response; NRT – Neural Response Telemetry; T–LEVELS - Threshold levels; C-LEVELS – Comfort levels; MCL Levels – Most Comfortable Levels; ++ Statistically significant; NS – Not statistically significant.*

4.2 QUALITY ASSESSMENT

The quality of the studies was assessed using the critical appraisal skills programme (CASP) for diagnostic test study. It is a generic tool for appraising the strengths and limitations of any qualitative research methodology. It consists of 11 questions to assess the article in depth across each section to reduce bias. The questions in the tool are marked as “Yes”, “No”, or “Can’t tell,” depending on the question’s requirement.

The results of the following questions for all selected studies are provided in Table 4.2

Section A: Are the results of the trial valid?

Q1. Was there a clear question for the study to address?

Q2. Was there a comparison with an appropriate reference standard?

Q3. Did all patients get the diagnostic test and reference standard?

Q4. Could the results of the test have been influenced by the results of the reference standard?

Q5. Is the disease status of the tested population clearly described?

Q6. Were the methods for performing the test described in sufficient detail?

Section B: What are the results?

Q7. What are the results?

Q7a. Are the sensitivity and specificity and/or likelihood ratios presented?

Q7b. Are the results presented in such a way that we can work them out?

Q8. How sure are we about the results? Consequences and cost of alternatives performed?

Q8a. The results have not occurred by chance?

Q8b. Are there confidence limits?

Section C: Will the results help locally?

Q9. Can the results be applied to your patients/the population of interest?

Q10. Can the test be applied to your patient or population of interest?

Q11. Were all outcomes important to the individual or population considered.

AUTHOR AND YEAR	QUESTIONS												
	Section A: Are the results of the trial valid?						Section B: What are the results?				Section C: Will the result help locally?		
	Q1	Q2	Q3	Q4	Q5	Q6	Q7		Q8		Q9	Q10	Q11
							Q7a	Q7b	Q8a	Q8b			
Palani et al (2020)	✓	✓	✓	✗	✓	✓	✗	✓	✗	✓	✓	✓	✓
Asal et al (2018)	✓	✓	✓	✗	✓	✓	✗	✓	✗	✗	✓	✓	✓
Telmesani et al (2016)	✓	✗	✓	✗	✓	✓	✗	✓	✗	✓	✓	✓	✓
Sampathkumar et al (2013)	✓	✗	✓	✗	✓	✓	✗	✓	✗	✓	✓	✓	✓
Lorens et al (2004)	✓	✗	✓	✗	✓	✓	✗	✓	✗	✓	✓	✓	✓
Kaplan-Neeman et al (2004)	✓	✗	✓	✗	✓	✓	✗	✓	✗	✓	✓	✓	✓
Lorens et al (2003)	✓	✗	✓	✗	✓	✓	✗	✓	✗	✗	✓	✓	✓
Bresnihan et al (2001)	✓	✗	✓	✗	✓	✓	✗	✓	✗	✗	✓	✓	✓
Total percentage indicated as YES	100%	25%	100%	0	100%	100%	0	100%	0	62.5%	100%	100%	100%

On analysis, as depicted in Table 4.2, it was found that all the studies were of good quality. Most of the research questions were addressed. The status of the test population was provided in detail in all 8 studies. All the studies reported enrolment of participants for the diagnostic tests (100%). The test procedure was explained in detail in all the studies (100%). However, since Q4, Q7a and Q8a were not relevant for the selected articles, the responses are reflected as none (0%).

CHAPTER 5

DISCUSSION

This systematic review focussed on the objective test measures used in mapping procedures in paediatric cochlear implant users.

5.1 ASSESSMENT PROCEDURES

The two assessment procedures included in this review are as follows:

- Electrically evoked Stapedial Reflex Threshold (eSRT)
- Electrically evoked Compound Action Potential (eCAP)

5.1.1 Does eCAP serve as a better objective fitting method for users with a cochlear implant?

eCAP is an early latency-evoked potential, obtained as a result of synchronous stimulation of auditory nerve fibres through electrical mode. This component corresponds to the Wave I of electrically evoked responses of the brainstem evoked response (e-BERA).

Telmesani and Said (2016) aimed to assess changes in eCAP in the first year of a cochlear implant to predict thresholds and adjust the program over time. They reported significant decrease in threshold observed between the intra- and post-operative assessments. The results revealed that though there was an increase in threshold and comfort levels post-operatively, there was no significant difference observed between the initial and 12th months of the fitting. This increase in threshold and comfort level is attributed to the anatomical and physiological changes within the cochlea during the surgery and later after implantation. There have been findings regarding individual threshold variations in the trend (Hughes et al., 2001). But majority of the studies state that the ECAP threshold stabilizes with no significant change further at different point of time post-implantation (Henkin et al., 2003; Hughes et al., 2000; Lai et al., 2004). The authors also quote the stability of eCAP thresholds at different points of electrode position. While the comfort level as set by eCAP threshold stabilized at most electrode points by 3 months of implantation, there was reduction in the thresholds observed post-implantation in the electrodes at the mid of the array, which then stabilized by the 6th month of implantation and further. This might be accounted by the several variations that occur as a result of how the soft tissue surrounds itself around the array after being implanted within the cochlea (Clark et al., 1995; Dorman et al., 1992; French, 1999; Kawano et al., 1998). The authors also reported that compared to the first fitting after implantation, a considerable rise in behavioural T and C levels was evident 12 months post-implantation. Few authors reported stabilization of fitting levels after 12 months of implant usage (Brown et al., 1995; Hughes et al., 2001), whereas others reported changes in the parameters till 2 years of implantations (Henkin et al., 2003; Kubo et al., 1996; Lee et al., 2000; Shapiro & Waltzman, 1995). This might be attributed to modifications in the cerebral auditory circuits and morphological and physiological changes inside the cochlea as a result of the surgery and electrical stimulation (Loeb et al., 1983).

Similarly, Asal et al (2017) reported no significant changes in the eCAP thresholds during and post-surgery in the 1st, 2nd, and 3rd months. The authors also stated that the thresholds obtained through eCAP became stable after 2 months of cochlear implantation. This statement was supported by several other studies (Henkin et al., 2003; Hughes et al., 2001, 2000; Telmesani & Said, 2016). The findings on electrode impedance were that there was an increase in the values intra- and post-2 months of surgery after which a steady decline and stabilization of impedance values were observed. The phenomenon of regional healing of tissues post-surgically explains changes in the impedance values which has been supported by several studies (Dorman et al., 1992; Manolache et al., 2012; Tykocinski et al., 2005; Zadrozniak et al., 2011).

In a similar line, Kaplan et al., (2004) indicated no significant difference between maps obtained behaviourally and through NRT. The psychophysical parameters were measure at 5 different time points ranging between initial stimulation to that of 12-month period at apical, medial and basal segment of the electrode array and reported that on the whole, there was a steady increase in T- and C-levels till the 3rd month after which stabilization occurred. Changes in the array of nerve excitations and altered central auditory mechanism may contribute to the spike in T-levels during the activation of the prosthesis (Hughes et al., 2000; Kawano et al., 1998; Pfingst, 1990; Shapiro & Waltzman, 1995). The authors also pointed out that the behaviourally obtained T- and C- levels were almost similar to that obtained through NRT. Moreover, recognition scores obtained in open-set monosyllabic words that were tested 12 months after first stimulation were comparable to that of sound field-assisted thresholds which were better for children utilizing NRT-based maps. The author points out the fact that this might be due to the differences in the age between the groups with one group containing older children with mature cognitive skills thereby responding accurately compared to that of the other group, which has to be investigated later. Further, the time taken to program the children was reported to be shorter when NRT-based map was carried out in comparison to the behaviourally obtained map.

5.1.2 Does eSRT serve as a better objective fitting method in cochlear implant users?

The eSRT is an objective metric for obtaining higher stimulus levels or comfort levels when programming a cochlear implant particularly in paediatrics but also in adults who are unable to provide an accurate behavioural assessment. In the present review, three studies used the eSRT procedure along with behavioural measures for obtaining comfort levels (Bresnihan et al., 2001; Lorens et al., 2003, 2004; Palani et al., 2020).

Bresnihan and colleagues (2001) compared eSRT of comfort levels to that of behavioural levels. They reported that the comfort levels were consistently lower than that obtained behaviourally. This finding has been found to be true with support by few studies (Battmer et al., 1990; Jerger et al., 1988). But other studies reported that the eSRT is consistently higher throughout the electrode array when compared to the behaviourally obtained C-levels (de Andrade et al., 2018; Hodges et al., 1997). The observed effect may be attributed to the fact that both electrical and auditory stimulation stimulates more neurons simultaneously by lower intensities on more sumptuous areas of the cochlea, thereby resulting in lower eSRT than the behaviourally obtained C-levels. And the questionnaire assessed in the study to determine which programming technique was superior, revealed that eSRT was rated better when compared to behavioural measures for programming in the paediatric population, indicating that the children were not over-stimulated by greater C-levels, that would have rather occurred when MCL was set using behavioural methods.

Study done by Lorens et al (2003) revealed a good correlation between the behaviourally obtained MCL and the eSRT except for two cases, in which few channels had a relatively higher eSRT compared to MCL obtained, with no evidence of discomfort observed. Such high correlation between the psychophysical measure and C-level obtained through eSRT has been reported with a high reliability of about r=0.88 (Kosaner et al., 2009). A correlation of around 0.6 to 0.7 was reported in another study (Brickley et al., 2006), whereas a correlation of 0.91 was reported between eSRT and behaviourally obtained C-level by (Hodges et al., 1997). A high correlation of 0.92 was also reported in another study (Stephan & Welzl-Müller, 2000). This discrepancy between the correlation of eSRT and MCL might be attributed to differences in the measure of eSRT by different experimenters. They also reported the correlation obtained in these cases was similar to that obtained in those of adult cases with no discomfort observed. Thereby, eSRT can be utilized in order to avoid over-stimulation through the cochlear implant, particularly during fitting process in children.

In a similar line, Lorens et al., (2004) evaluated the eSRT for speech processor programming in paediatric cochlear implant users to propose a credible method for comfort level correlation with that of the aforementioned objective method for troublesome patients. They established comfort levels through eSRT and behavioural testing methods. In addition to obtaining the thresholds, the parents were enquired regarding the method that they felt was superior in programming. The results of the study reveal that there is a high degree of interdependence between the eSRT and behavioural methods. Parents reported that the measurements done through eSRT were better or good than the measures obtained behaviourally.

Palani et al (2020) reported that the measurements done through objective method were better when probe-tone frequencies of 1000Hz and 678Hz was used than when compared to the use of 226Hz probe tone frequency. The authors also found that the attainments of the eSRT were of higher probability when higher frequency probe tones were used when compared to the lower frequency probe tone. This statement is well supported by other studies (Carancco et al., 2019; Feeney et al., 2003; Wolfe et al., 2017). The reason that eSRT's obtained through high frequency probe tones exhibit a high success rate is because of the reflex-induced changes that occur primarily between 500Hz to 2000Hz during eSRT measurements. The measurement obtained through 1000Hz is greater than 226Hz can be accounted by taking into consideration the resonant frequency of the middle ear which is around 800Hz to 1200Hz, wherein the 1000Hz probe tone frequency is closer to that of the resonance frequency of the middle ear (Bennett & Weatherby, 1979). The results also revealed that a greater correlation co-efficient between eSRT with higher probe tone frequencies and behaviourally obtained C-levels in the paediatric population studied with a correlation co-efficient of 0.61 to 0.96. Similar correlation range has been estimated in several studies (Bresnihan et al., 2001; Hodges et al., 1997; Kosaner et al., 2009; Stephan & Welzl-Müller, 2000)

5.1.3. To compare eCAP and eSRT measurements to define the better objective fitting method for cochlear implant users.

The review consists of one study that discusses both the measures in comparison to that of programming done psycho-physiologically. Study done by Sampath Kumar et al (2013) investigated the association and trend between varied electrophysiological test and psycho-physically obtained M-levels aimed to generate norms for the same. They reported that the impedance values were higher during the initial fitting which then stabilized in the subsequent months. This statement is well supported by other studies as well (Dorman et al., 1992; Manolache et al., 2012; Zadrozniak et al., 2011). The author also quoted that the psycho-physically obtained M-levels increased between first months of implant use to that of one year of implant use, thereby resulting in increase in the dynamic range. This is attributed to the increase in the capacity of the children's ability to tolerate higher level sounds over the period of implant use. With respect to NRI thresholds, they were stable throughout the period of implant use and generally lower in level than that of the M-levels, which is supported by other studies as well (Asal et al., 2018; Henkin et al., 2003; Hughes et al., 2000; Hughes et al., 2001; Telmesani & Said, 2016). Whereas, the eSRT was found to be at higher level during the initial fitting followed by stabilization in the subsequent months, by one year of implant usage. Similar finding was reported by another author as well (Spivak & Chute, 1994). In case of eABR measurement, the thresholds obtained were higher than eCAP and lower than the eSRT. The authors state that this might be due to the greater energy required for stimulating the brainstem, in order to obtain a measurable action potential. The authors reported that the NRI, eSRT, and eABR thresholds correlated well with behaviourally obtained M-levels. And there was an improvement in the threshold and comfort levels with further stabilization with implant use over the period. This stabilization in the levels could be ascribed to changes in the bio-electro-chemical gradient within the stria vascularis, changes as a result of tissue healing and encapsulation of the array and the auditory nerve's evolution to gradually become more receptive to electrical impulses over the period of time (Shallop & Ash, 1995). They also observed that in difficult-to-test populations, sequential behavioural programming with that of objectively obtained maps provides a better outcome.

CHAPTER 6

SUMMARY AND CONCLUSION

There is a lack of data that determines which measure could be the best for mapping the T- and C-levels, particularly in difficult-to-test cochlear implant users, such as the paediatric population. This study reviewed the objective measures in programming cochlear implants and comparison of these measures to behaviourally obtained maps, to find out which objective measure, if possible, is the best method for mapping cochlear implants, particularly in the paediatric population.

The systematic review has described the electrophysiological measures used in the programming of cochlear implants. The objective measure focussed chiefly was the eCAP and eSRT. The present study shows that the eCAP exhibit a medium-to-good correlation to the behavioural thresholds obtained. In contrast, the eSRT exhibited a good correlation to behavioural thresholds.

When assessing the individual data, researchers could find that the eSRT were easily obtainable in comparison to eCAP thresholds. And eSRT's were faster to record when compared to eCAP. Even in one of the studies that included parental reports of better programming measures, eSRT's were found to be better than behavioural programming according to the parents.

Thus, it can be concluded that a high correspondence exists between eSRT and behaviourally obtained comfort levels, with the values of eSRT being generally larger and more reliable than the eCAP values.

6.1 CLINICAL IMPLICATIONS

- This review explains electrophysiological measures used in the programming of cochlear implantation.
- This review's outcome helps us to understand better, which objective measure can be used in conjunction with behavioural mapping for programming the parameters of a cochlear implant.
- The present study will provide an understanding of the better objective method that can be utilized for fitting cochlear implants to users who are generally unable to offer clear subjective feedback.
- The present review outlines how reliable these two objective measures are in programming cochlear implants.

6.2 LIMITATIONS

- Few studies had only eSRT and behavioural mapping comparison, while others had only eCAP and behavioural mapping comparison. Hence, the precise information about the best objective measure could not be established at this moment with the large data.

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