Comparison between Behavioral, Modified Brown ECAP, ESRT Approaches in Cochlear Implants Fitting in Adults.

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List of Abbreviations

CI: Cochlear Implant

ECAP: Electric Compound Action Potential

ESRT: Electric Stapedius Reflex Thresholds

EABR: Electric Auditory Brainstem Response

MB-ECAP: Modified Brown ECAP

MCL: Most Comfortable Level

THR: Thresholds

SRT: Speech Recognition Thresholds

WRS: Word Recognition Score

ART: Auditory Nerve Response Telemetry

NRT: Neural Response Telemetry

NRI: Neural Response Imaging

ESR: Electric Stapedius Reflex

dB: Decibel

cu: Current Unit qu: Charge Unit FF: Free Field

pps: Pulse per second

Abstract

This study aimed to find out and compare 3 important approaches used in programming adult cochlear implants patients, which are behavioral approach, modified brown Evoked Compound Action Potential (ECAP) approach and Electric Stapedius Reflex Threshold (ESRT) approach. Total 11 CI recipients (aged 17 to 68 years) were involved implanted with MEDEL SYNCHRONY implant and SONNET audio processor. Comparison was based on their audiological outcome, session's time and correlation between the three approaches parameters. The results of this study will help to know the best approach to be used with adult CI recipient also to validate the modified brown ECAP based approach and compare it with well-known approaches like behavioral and ESRT based approach. This study showed good correlations and outcomes when using the modified brown ECAP based approach comparing with pure ECAP thresholds which can also help during children CI recipient fitting which consider more challenging than adult.

Keywords: Cochlear Implant; Fitting; ESRT; ECAP; Brown ECAP

Introduction

Cochlear Implant has become an important hearing solution for a large portion of patients who are not getting any benefits from other solutions like hearing aids, it targets patients group that have severe to profound hearing loss. Cochlear implant is the only device that replaces a sense organ in the human body; outcom es of cochlear implants have many aspects to be considered like audiological, social and psychological aspects. It also has no age limit for implantation and that's why clinician that works with cochlear implants face wide range of patient's ages starting from young babies (<1 year) to old adults (> 60 years). And to understand exactly how cochlear implant becomes a benefit assistant to hearing loss patients we have to know what is hearing loss and how cochlear implant is working to overcome this disability.

Hearing and Hearing Loss

Hearing is one of the sensory systems in our bodies and it is considered one of the most important sensations. Ear is the organ responsible for hearing and it consists of 3 parts: the external ear, middle ear and the inner ear. Sound funnels into the ear canal and causes the eardrum to move. The eardrum vibrates with sound and then sound vibrations move through the ossicles to the cochlea. Sound vibrations cause the fluid in the cochlea to move which will cause the hair cells to bend. Hair cells create neural signals which are picked up by the auditory nerve. Hair cells at one end of the cochlea send low pitch sound information and hair cells at the other end send high pitch sound information (Figure 1) [1]. Hearing loss appears when one or more parts have a problem in doing their functions and depending on the defected part; type of hearing loss is specified.
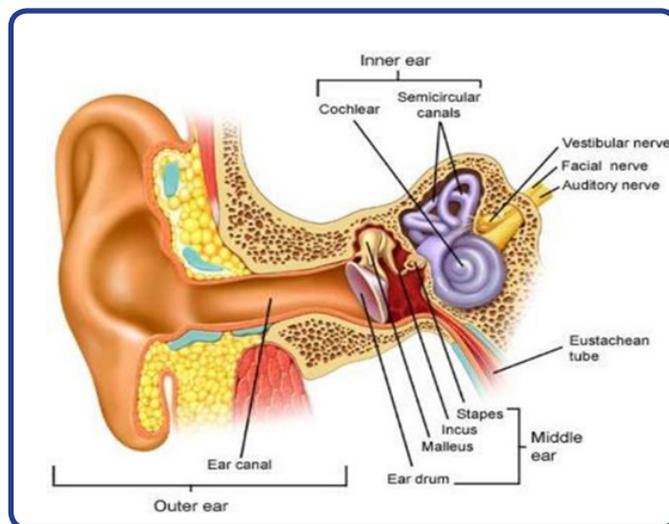
Figure 1: Ear Anatomy (Gross Anatomy of the ear).

The four main types of hearing loss

a. Conductive Hearing loss: it occurs when the sound is not conducted properly through the external ear canal, the tympanic membrane and the ossicles. It usually leads to reduction in the hearing sensation of the soft sounds. It can be corrected whether surgically or medically. Some of the conductive hearing loss causes are:

a)   Fluid in the middle ear from colds o Ear infection (otitis media)

b)   Allergies (serous otitis media) o Poor Eustachian tube function

c)   Perforated eardrum o Benign tumors

i.   Impacted earwax (cerumen)

ii.   Infection in the ear canal (external otitis) (ASHA-Conductive Hearing Loss)

b.   Sensorineural Hearing Loss: It occurs when there is damage in the cochlea hair cells or in the auditory nerve up to brain. It cannot be medically or surgically treated. It affects the hearing ability of the soft sounds and the speech as well. Some of its causes are:

i.   Drugs that are toxic to hearing

ii.   Hearing loss that runs in the family (genetic or hereditary)

iii.   Aging

iv.   Head trauma

v.   Malformation of the inner ear

vi.   Exposure to loud noise (ASHA- Sensorineural Hearing Loss)

vii.   Mixed Hearing Loss: combination of conductive and sensorineural hearing loss, it is the result of a problem in the outer or/and middle ear and inner ear as well.

Also, hearing loss is classified according to their severity starting from mild end by profound hearing loss (Figure 2).
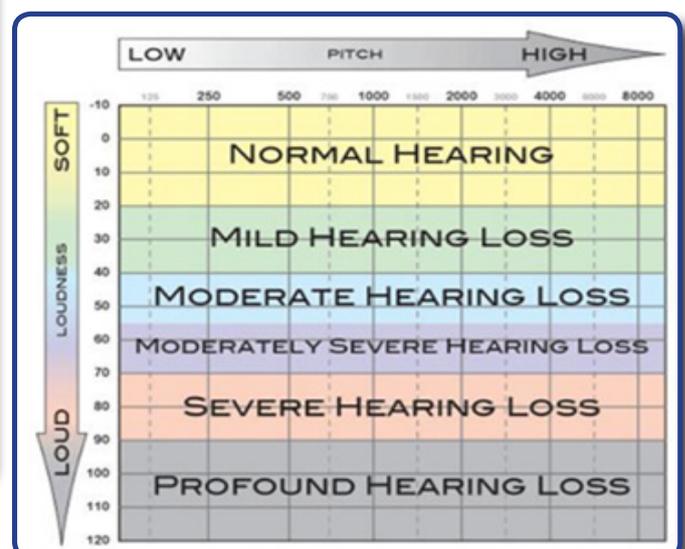
Figure 2: Hearing Loss Degree (How to Read an Audiogram and Determine Degrees of Hearing Loss).

Hearing Loss Statistics Worldwide

According the updated World Health Organization Fact sheet-February 2017:

a) 360 million people have hearing loss disabilities, divided into 328 million adult and 32 million children (Figure 3).
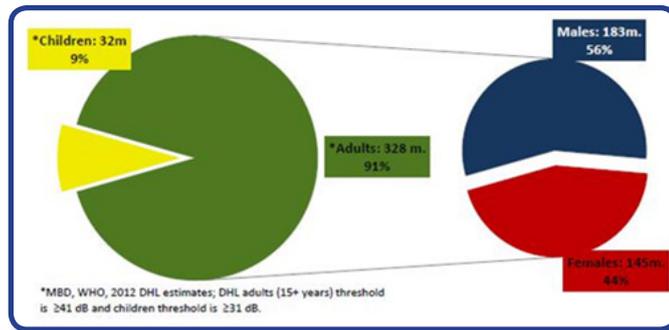
Figure 3: Hearing Loss Statistics Worldwide (WHO Fact Sheet –Feb 2017).

b) Hearing loss may result from genetic causes, complication of birth, certain infection diseases, chronic ear infection, ototoxicity, noise exposure and aging.

c) 60% of childhood hearing loss is due to preventable causes.

d) One third of people over 65 years old are affected by disabilities of hearing loss. And from these numbers we can feel the importance of having such hearing assistance devices that could help these patients to restore hearing sensation which will affect their quality of life dramatically. One of these system or devices is the cochlear implants which is mainly targeting the severe to profound patients. (Deafness and Hearing Loss, 2017).

Cochlear Implant

Figure 4: Cochlear Implant.

Cochlear implant is an electronic device that bypasses the nonfunctioning parts in the inner ear and directly stimulate the neural cells inside the cochlea electrically which will be transmitted to the brain through the auditory nerve, it is also considered as the only medical device that can replace a sense. [1]. Cochlear Implant system consists of 2 parts. The internal part, which is called "Implant" (Figure 4) and the external part, which is called "External Audio Processor" (Figure 5). The internal part or the implant consists of coil, magnet, demodulator and electrode while the external part or the audio processor

consists of a microphone, speech Processor, transmitter coil and power source.

Figure 5: External Audio Processor.

How does the Cochlear Implant work?

Sound is collected by the microphone embedded in the external audio processor which processes the sound signal through some complicated analog and digital algorithms and then sends the signal to the internal part through Radio Frequency waves through the transmitter coil. The internal part under the skin receives and demodulates the signal and sends it to the electrode that was implanted inside the cochlea. Each electrode consists of numbers of contacts; each contact responsible of some range of frequencies and stimulates the neural cells in some way to match the incoming sound.

Candidacy of Cochlear Implants

According to ASHA technical report about cochlear implants. Guidelines for cochlear implant candidacy are given with the FDA approval of each system and are based on the participant criteria used for the clinical investigation of the system's safety and efficacy. These guidelines have changed substantially over time. In the 1980's cochlear implants were recommended for post-linguistically deafened adults with hearing losses greater than 100 dB and no discernable communication benefit from a hearing aid. Berliner [2] Meyer [3] Schindler [4]. By the year 2000, FDA approval had extended the implantable age down to 12 months and broadened the general hearing criteria.

Currently cochlear implantation is permitted for patients of age 2 years of age and older with severe-to-profound deafness and in children of 12 to 23 months of age with profound deafness. In addition, Speech evaluation (outcomes from word and sentence recognition testing) are also used to determine candidacy. Regarding adults, Guidelines permit implantation with open-set sentence recognition scores of approximately 50% to 60% words correct. Candidacy listed above will remain the same and will require evaluation of the patient's medical, audiological, and psychosocial/ habilitative condition. Technical Report - Cochlear Implants [5].

Fitting of Cochlear Implant

Fitting of cochlear implants means the way of programming the external audio processor in such a way to manage all

parameters affecting the sound processing and sound perception of the patient and it is customized to each patient individually. Fitting of Cochlear implant recipient depends on the patient age group; whether adults, children and young children. Researchers and clinical audiologists often give a great deal of attention to programming parameters including stimulation rate, input dynamic range, and frequency allocation. Although these parameters clearly can impact performance, the most important aspect of programming is the optimization of the recipient's stimulus levels Wolfe & Schafer [6].

There are mainly 3 cochlear implants manufactures, MED-EL based in Innsbruck-Austria, Cochlear based in Australia and Advanced Bionics and based in United States. Cochlear Corporation device uses 22 electrodes spaced along its array; Advanced Bionics implant has a 16 element array, while the MED-EL electrode has 12 pairs of electrodes (each pair sharing the same position along the array). The speech processor filter-bank generates amplitude envelope signals representing the output of each of the filter-bands HearCom [7]. A Cochlear implant generally stimulates the auditory nerve with series of short biphasic electrical pulses. The pulses are biphasic because the net current through the tissue should be zero to avoid unwanted long-term electrochemical effects.

Since stimulating multiple electrodes at the same time can give an unpredictable loudness percept because of channel interactions (addition of stimulus voltage fields) most current commercial coding strategies use sequential stimulation. The rate of pulse stimulation to an electrode depends on processing strategy. The slowest pulse rates in use are 200 pulses/s(pps). A pulse rate of around 800 pps is common to several strategies, while higher rates of up to 5000 pps can be used in some recent strategies. With pulsatile stimulation within these ranges of rate, the percept is not of a burst of pulses, but rather as a continuous signal. The most crucial aspect of fitting for a cochlear implant is to establish the lowest and highest usable stimulation level for each electrode in the array, and this is a common feature of all cochlear implants HearCom [7].

Since the auditory nerve limited dBs dynamic range for electrical stimulation, we need to compress the +100 dB acoustical window available to normal hearing considerably. This is done by first 'selecting' a small part of the acoustical window (normally about 30 dB; the speech dynamic range) by means of an Automatic Gain control. The width of this window is referred to as the instantaneous input dynamic range (IIDR). The IIDR is further compressed in an instantaneous non-linear compression to match the very small dynamic range for electrical stimulation HearCom [7].

Fitting methods can only be implemented through tools provided by the manufacturer. This is essential for device safety. It also ensures that the basic fitting methods use the same parameters are in every country. The most important fitting parameters are listed below. It must be noted that these parameters are somewhat strategy and device dependent, some parameters will occur in different devices under different names. Almost all of these parameters are used in the fitting of all three manufacturers; implants HearCom [7].

a. Fitting Parameters

A.   Channel: A combination of electrodes (sources and sinks) that typically is associated with the output of one of the spectral analysis band filters [7].

B.   Current Unit: Numeric values that are unique to each system are used to designate the amount of current delivered by each electrode (First years, 2010)

C.   Pulse width: The duration of the biphasic pulse, In MED-EL it is called Duration, AB and Cochlear call it Pulse Width.

D.   Charge Unit: It is the multiplication of current unit and pulse duration introduced to each channel.

E.   Electrical dynamic range: The difference between the lowest and the highest amount of current. (First years, 2010)

F.   Most Comfortable Level (MCL, M or C): The maximum comfortable level or the upper stimulation level.

G.   Threshold Level (THR, T): The maximum inaudible level for the patient of each channel.

H.   Number of channels: The total number or stimulation channel available depends on the device and also on the number of electrodes that are usable for any given Implant recipient [7].

I.   Number of maxima: The number of stimulated channels in each cycle for n-of-m strategies such as ACE [7].

J.   Rate: The rate of the biphasic pulses per second introduced per channel.

K.   Strategy: The sound coding protocol applied on the signal inside the speech processor (HDCIS, FSP, FS-4, FS-4P, ACE… etc.).

L.   Compliance Level: The stimulation current level at which the implant reaches the cut off voltages.

M.   Electrode impedance: The resistance of the electrodes to the stimulated current. It depends on the media surrounding the intracochlear electrodes. Lower impedance values mean less resistance or better electrical conduction. (Firstyears, 2010)

N.   Frequency Band: The acoustic frequency range of the processor.

O.   Map law: It control the progress of amplitude growth function and its compression characteristics.

P.   Sensitivity: It defines the sensitivity of the speech processor microphone. It is the range that the microphone can detect.

Q.   Directionality: Several microphone modes which control the incoming signal to eliminate noises and mimic natural hearing (Omni, Adaptive, Natural, Scan, etc.).

CI Fitting Approaches for adults

As this study is mainly concerned with adults. It is important to illustrate the classifications of CI fitting approaches for them in details; mainly it can be divided into two approaches.

Behavioral (subjective) Approach: Behavioral fitting methods require the patient to indicate when he or she has heard

a specific stimulus. An electrical stimulus is presented through the implant via interactive software and a fitting system designed by the device manufacturer Gross [8]. Usually some loudness scale charts are used during this approach and it can be with different forms (Figure 6). So the patient will be asked to select the stimulation level he is hearing through the implant from the chart starting from (No sound) till (Uncomfortable sound) and then depend on the definition of the upper stimulation levels (M or MCL levels) of each manufacture, the MCL is been set.
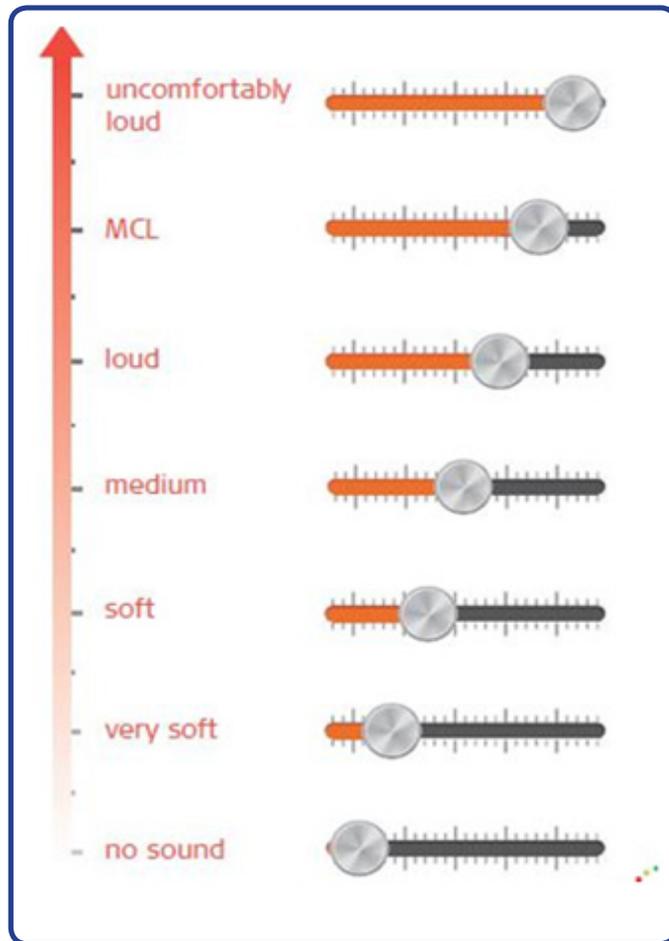

Figure 6: Loudness Scale Chart for adults.

Usually for some patients especially in the switch on session it is difficult for them to specify the stimulation level and in some times it become stressful and inaccurate. The THR and MCL levels are psychophysical judgments of loudness that are measured in clinical units of electrical current, referred to as current units (cu) or charge units (qu). Threshold levels are comparable to acoustic threshold levels and are related to the softest inputs detected through the implant. Most Comfortable Loudness levels indicate the level at which a sound is loud but comfortable. Together, the two values determine an individual's electrical dynamic range Gross [8].

In adult cochlear implant patients, THR and MCL levels are typically measured using verbal feedback from the patient. Threshold levels may be obtained using an ascending presentation, followed by a standard bracketing procedure. In some cases, patients may require a reference tone prior to and/ or during use of an ascending approach. MCLs are obtained

through a method referred to as loudness scaling. The level of current is gradually increased, while the patient reports on the level of loudness and comfort. Ideally, MCL levels should also be balanced across the electrode array. Loudness balancing requires comparison on at least two electrodes at a time until all MCLs are perceived as equally loud Gross [8].

A cochlear implant performs optimally when THR and MCL levels are set accurately and MCL loudness is balanced across electrodes Stephan & Welzl-Müller [9]. Researches indicate that MCL level and loudness balancing have a greater influence on patient performance than THR level. Smoorenburg et al. [10] found that a reduction in THR levels of 25 to 30 current units does not adversely affect speech perception scores. Alternatively, a change in the slope of MCL values may negatively impact speech understanding Gross [8]. Based on speech acoustics, Dawson et al. hypothesized that inadequate and/or unbalanced MCL levels would adversely affect amplitude cues and spectral information important for phoneme identification.

Loudness scaling and loudness balancing of the MCL require subjective responses to sophisticated listening tasks. Even adult patients who have experienced a relatively short duration of deafness can find the fitting process to be stressful and fatiguing. For children, who often lack the listening experience, language, or conceptual development to perform specific fitting tasks, the challenge is much greater. AW, SM, CR [11], clinicians must often rely on clinical intuition and trial and error in order to estimate appropriate comfort levels for very young patients Gross [8].

Other Approaches Derivative from the Behavioral Approach Interpolation of THR and MCL levels: The main concept of this approach is to measure few channels stimulation levels (THR and MCL levels) and use the Interpolation task available in the manufacture software to estimate the other channels levels; it saves time especially for difficult patients or young children.

Streamlined fitting: Since this method was developed for Nucleus implants the terminology in this section is Nucleus focused. Based on this finding the streamlined method was proposed. This method works as follows:

a)   Measure THR-level in the normal way on 5 electrodes (1, 6, 11, 16, and 22).

b)   Interpolate the intermediate THR-levels.

c)   Set the MCL-levels slightly above THR-level and switch on the processor in live mode.

d)   Increase MCL-levels globally (all electrodes at the same time) until speech sounds comfortable HearCom [7].

A study with recipients showed no significant change in speech performance when comparing these maps to standard maps Plant et al. [12].

Reduced parameter space fitting: shift and tilt without ECAP profile

In a study by Smoorenburg C & JE [10] the THR, MCL and ECAP data were analyzed using a principal component analysis. This

analysis showed that more than 96% of the total variance in the data could be described by 2 or 3 components: one relating to the overall level of the profile (shift), the second related to the slope or tilt of the profile and the last one relating to the curvature. It must be noted that although we use the terms shift and tilt, these are not linear straight shifts or tilts: they are profiles that come from the data of the group. For instance, a tilt will result in less tilt at the complete extremes of the array than what would be expected from a straight tilt.

The next step was not to look at the correlation between ECAP, THR and MCL levels but to look at the correlation between shift and tilt in the ECAP, THR and MCL level profile. As expected the correlation between ECAP and THR and MCL shift was very low (0.64/0/39), however, the correlation between the THR-level tilt and the ECAP tilt was significant and in the 0.82 range. This means that the ECAP could 'predict' the shape of the THR-profile; however, a follow-up analysis on a larger dataset Cafarelli et al. [13] did not show a significant correlation. From these results Smoorenburg proposed to use a method based on the average profile across clients (assuming the ECAP profile does not give any additional information) and using the shift/tilt:

a)   THR-level is set to the average profile.

b)   MCL-level set just above THR.

c)   Whole profile (THR and MCL) is dropped down until sub-threshold.

d)   In live mode the complete profile is increased (shifted up) until just audible.

e)   THR level is fixed; MCL level is increased (applying shift) until sound is comfortable.

f)   To adjust for optimal sound quality a tilt to the MCL and or THR levels can be applied HearCom [7].

Objective Approaches

As the name of this approaches reflect, it is using objective measurement (electrophysiology) to determine the upper stimulation level (MCL) of the patient without any participation from the patient, it is very useful in case of children fitting and poor reliable adult patients. And it uses many data sources like:

i.   ECAP (Electric Compound Action Potential)

ii.   ESRT (Electric Stapedius Reflex Thresholds)

iii.   EABR (Electric Auditory Brainstem Response)

Electric Compound Action Potential (ECAP)

What is ECAP?

The ECAP represents a synchronous response from electrically stimulated auditory nerve fibers and is essentially the electrical version of Wave I of the auditory brainstem response (ABR). The ECAP is recorded as a negative peak (N1) at about 0.2-0.4 ms following stimulus onset, followed by a much smaller positive peak or plateau (P2) occurring at about 0.6-0.8 ms (Figure 7) Abbas et al. [14] Brown et al. [15] Cullington [16].
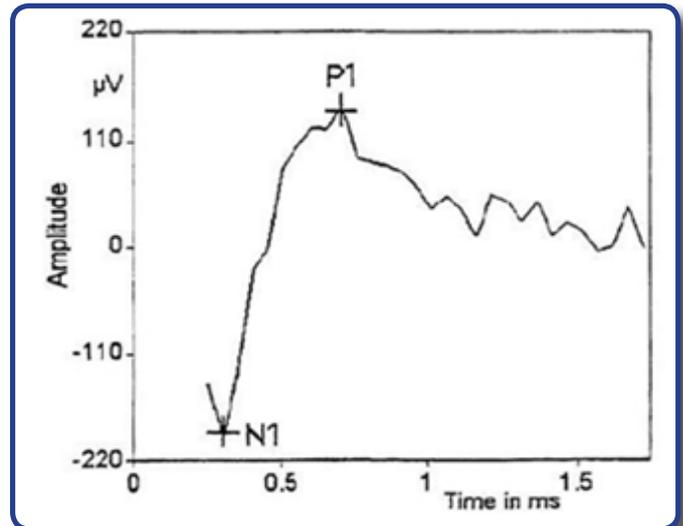
Figure 7: ECAP signal.

ECAP measures have become a popular alternative to clinical EABR testing due to ease of recording and reduced testing time. In contrast to the EABR, ECAP measures do not require surface recording electrodes, sleep/sedation, or additional averaging equipment. The ECAP is recorded via the intracochlear electrodes of the implant; therefore, the neural potential is larger than the EABR and thus fewer averages are needed, which significantly reduces testing time [17].

All newer CI systems are equipped with two-way telemetry capabilities that allow for quick and easy measurement of electrode impedance and the ECAP. Telemetry simply means data transmission via radio frequency from a source to a receiving station Hughes ML [17]. Each manufacture has his own software and name for the ECAP, in Cochlear Co. it is called Neural Response Telemetry (NRT), NRT was first introduced in 1996 and FDA approved in 1998 as its own software application separate from the clinical programming software Hughes ML [17] ,while in Advanced Bionics it is called Neural Response Imaging (NRI), It was first introduced in 2001 and FDA approved in 2003 as an integrated part of the Sound Wave clinical programming software Hughes ML [17] ,while in MED-EL it is called Auditory Nerve Response Telemetry (ART) , It was FDA approved in 2007 as an integrated part of the Maestro clinical programming software Hughes ML [17].

Using Amplitude Growth Function to determine ART Threshold

The concept of Amplitude growth function is to divide the maximum stimulation level introduced to each channel into several ascending levels. Theoretically the auditory response will increase as far as the stimulation is increased. If the measured signal is an artifact; it will be independent on the growth of the stimulation level, therefore by simply plotting the n and p points on all the levels. It will show inclined slope intersect with x-axis (current units) showing the threshold value for each electrode.

Figure 8 shows a screenshot from Maestro 6.0.1 Medel Software for the ART task using amplitude growth function. On

the left side it shows the stimulation and recording electrodes used in this test. On the upper right side shows the ECAP response divided into several stimulation levels set before running the test. The lower part shows the amplitude growth function slope and ECAP threshold is the intersection point between the slope and the x-axis. Usually the software automatically detects the P and N points but sometimes it may need manual adjustment to have accurate results.
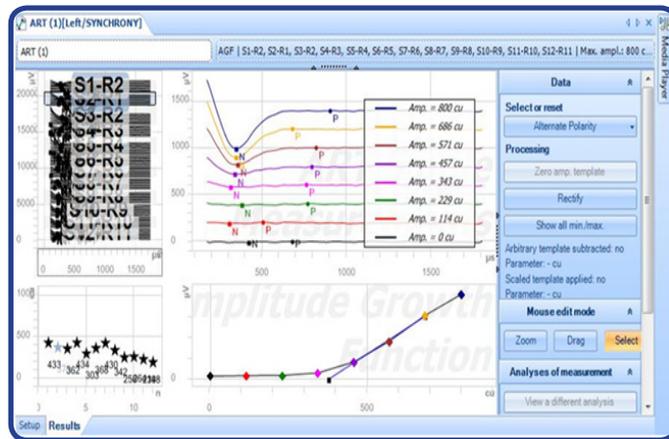

Figure 8: Amplitude Growth Function in MED-EL Maestro 6.0.

ECAP and CI fitting

Researches show that the direct correlation between THR and MCL levels and ECAP threshold is not good enough to warrant a map based directly on ECAP thresholds. For example, Brown CJ [18] found only a moderate correlation between THR (r=0.55) and MCL (r=0.57) levels and ECAP thresholds, other authors found similar numbers Cafarelli et al. [13].

There are two important reasons for this weak correlation:

a)	The ECAP is a purely peripheral measure and does not take into account central loudness effects (summation, masking, etc.).

b)	The MCL-levels set in a map are highly subjective and differ between subjects and even between audiologists making the measurements HearCom [7].

So the features of ECAP thresholds when used in fitting can be summarized in the following points:

a)	For adults, ECAP thresholds also generally fall between THR and MCL-level; however, for roughly 1/3 of this population ECAP thresholds may exceed MCL-level Brown CJ [18] Cafarelli et al. [13] Smoorenburg C & JE [10].

b)	In many cases, ECAP thresholds fall within approximately the same percentage of map dynamic range across electrodes within a subject Hughes, Brown J, Abbas [15].

c)	For adults, ECAP thresholds fall closer to MCL-level: the average was at 91% of the MAP dynamic range Hughes, Brown J & Abbas [15].

According to Holstad, Sonneveldt, Fears, Davidson, [19] Figure 9 shows that in many cases ECAP threshold cannot predict

map profile .There are some new fitting methods trying to increase the correlation and to have better map profile using the ECAP ; from these methods:
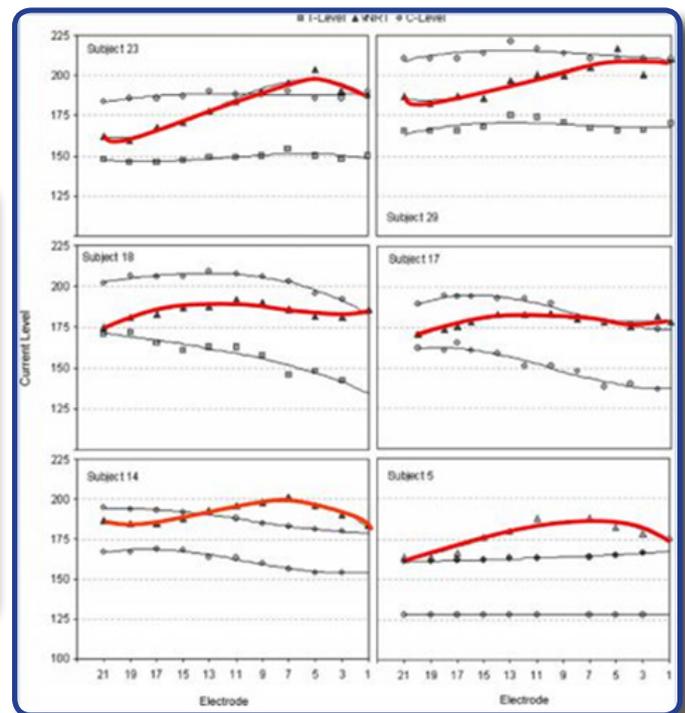
Figure 9: Holstad et al. (2009).

The 'offset' or 'Brown method: Carolyn Brown noted that in her data the weak correlation between THR and MCL levels and ECAP is mostly determined by large individual shifts in the profiles, this means that the ECAP cannot predict the absolute level of THR and MCL levels, but it could predict the shape of the profile Brown CJ [18]. Brown et al. proposed a method in which the ECAP profile was used in combination with one classical THR and MCL level measurement in the center of the array. By adding/subtracting a constant offset to each channel, the profile was shifted to match the measured THR and MCL level. Using this method they found that the average group correlation between the 'predicted' THR and MCL level and the measured THR and MCL level was higher than when using the uncorrected ECAP. However, Cafarelli et al. [13] showed that the expected difference between predicted and real THR and MCL level (the mapping error) was still unacceptably large. Furthermore, it was shown that when using a profile determined by the average across a large group of subjects instead of the ECAP profile, the mapping error was even less. Surprisingly, clinical studies showed no significant drop in performance with maps made following the method proposed by Brown et al. [7].

The 'preset' map series method: The preset map series method uses only the ECAP information to create initial maps for children: The ECAP profile is shifted down 40 cu to determine the THR-levels, the MCL-levels start at THR-level +10 cu and is increased over time until they are at the ECAP thresholds. Then after some time the THR-levels are checked by measuring a sound field audiogram. HearCom [7] A multi-center study with 100 subjects (children) is ongoing Ramos et al. [20]. The preliminary results (60 children) show no difference between

preset map series and conventional mapping but a significant time saving, especially in the first fitting. This was a randomized trial (randomized for treatment) where the quality of the map was measured both with parental questionnaires and with sound field audiograms. In adults, this method does not work so well, presumably because they have some memory of the sound and dislike any map that is very different from what they remember. In other words, maybe they do not have the plasticity in their brain to adapt to the map, so we have to adapt the map to their brain HearCom [7].

The 'shift and tilt' or 'Smoorenburg' method: First, Smoorenburg, assumed that live mode fitting would give better results than arbitrary single-electrode bursts Smoorenburg C & JE [10] However, Smoorenburg argues to apply this method not only to the MCL levels but also to the THR-levels. Second, Smoorenburg assumed as Brown CJ [18] that although the correlation between THR and MCL levels and ECAP thresholds is weak, the profile shapes have some correlation. In an initial study, Smoorenburg C, JE [10] tested a fitting method that is based on these two assumptions. In this fitting method the following happens as shown in Figure 10.
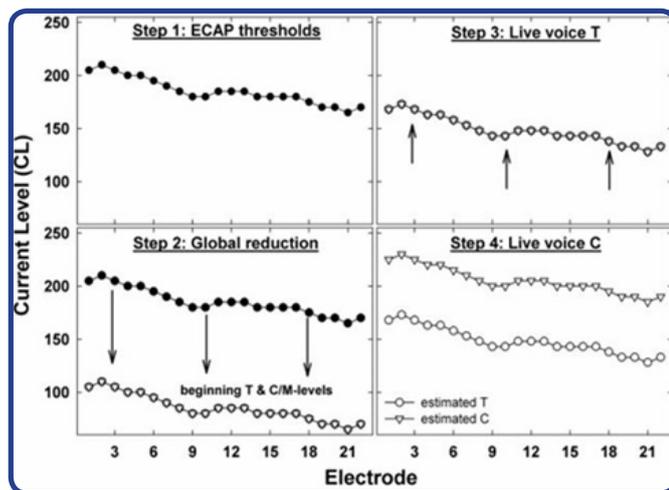
Figure 10: Smoorenburg et al. (2002).

a)   The ECAP threshold profile is measured.

b)   The THR-levels are set to the ECAP profile but dropped down until subthreshold.

c)   The MCL-levels are set just above THR-level.

d)   The processor is switched on in live mode.

e)   Both THR and MCL levels are increased until a soft auditory sensation is heard.

f)   At this moment the THR-level profile is fixed and only the MCL-level profile is increased further until the live sound is comfortably loud.

This fitting method resulted in some findings:

i.   The THR-levels of the maps set in this way were on average very much lower (by around 25 CU) than conventional THR-levels. This effect was mainly caused by temporal integration.

ii.   In a group of 7 experienced users, there was no group mean significant change in performance, although 2 individuals performed better with their old map [7].

A.   Electric Stapedius Reflex Threshold (ESRT)

a.   What is ESRT?: A stapedius reflex involves contraction of a tiny muscle in the middle ear in response to loud sounds. In the normal hearing ear, the reflex is elicited bilaterally in response to acoustic stimulation in either ear. The reflex can be measured in either the ipsilateral or contralateral ear using a standard tympanometer Gross [8]. The muscle contraction is due to sound, that's why it is called an acoustic reflex. The stapedius tendon attaches to the posterior portion of the neck of the stapes. When the stapedius muscle is contracted, the stapes moves to the side and tenses the membrane in the oval window, reducing the amplitude of vibration (Figure 11).
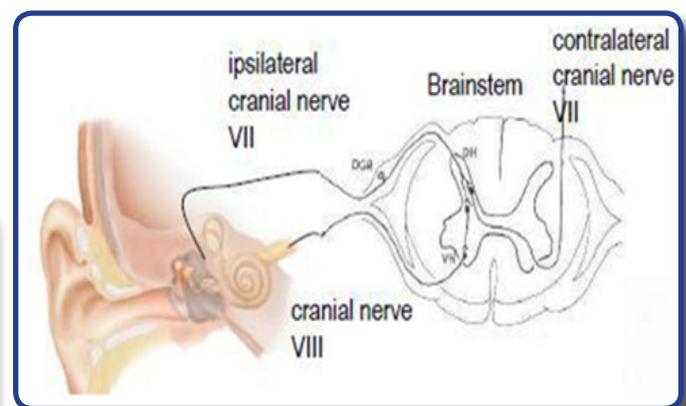
Figure 11: Stapedius reflex.

In cochlear implant patients, a stapedius reflex can be measured in the contralateral (non-implanted) ear in response to electrical stimulation through the implant. An Electrically Evoked Stapedius Reflex Threshold (ESRT) is defined as the lowest level of electrical stimulation that elicits a measurable response. Measurement of the ESRT requires passive cooperation, meaning that the patient should remain relatively still and quiet during each recording. Excessive swallowing, talking, or head movements could disrupt the measurement. To record an ESRT, the patient must exhibit a healthy middle ear status. Fluid in the middle ear or dysfunction of the eardrum or middle ear ossicles can prevent measurement of the ESRT. In some cases, a patient with normal middle ear function may not exhibit a measurable reflex response Gross [8].

b. ESRT set up and procedure

As Figure 12 shows, the set up for measuring the ESRT is a standard tympanometry, cochlear implant software, and the patient's cochlear implant equipment. A soft recording probe is placed in the ear contralateral to the cochlear implant. Tympanometry is performed to confirm normal middle ear status. A good seal of the recording probe and peak compliance of the middle ear should also be confirmed prior to recording an ESRT. The tympanometry is set for measurement of reflex decay, providing a longer recording window. Electrical stimulation is presented through the cochlear implant via interactive software. Stimulation is gradually increased until a sufficient deflection is

observed in the reflex decay window, and a standard bracketing procedure is used to determine the stapedius reflex threshold Gross [15]. Parameters used in the fitting software need to be optimized according to manufacturer recommendations e.g. use of a 500 ms MCL burst is recommended to elicit SR's closest to behavioral MCL for the MEDEL COMBI 40+ Brickley [21]. Electrical charge should be increased with caution, on individual electrodes until a reflex is elicited or the CI user shows signs of discomfort Kosaner J [22].
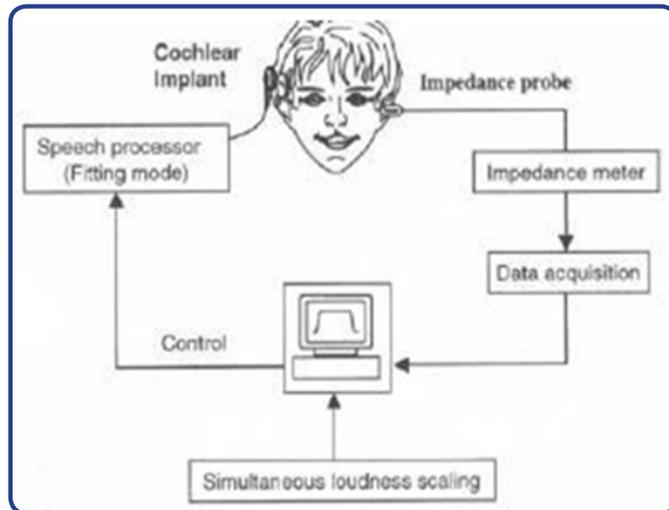

Figure 12: ESRT Fitting Setup.

c. Electric Stapedius Reflex (ERS) Features

According to Kosaner J [23] ESRT has some important features to be considered:

i.   High Incidence of ESR: Literature reports a high incidence of ESR's in the pediatric CI population ranging from 63-83% Hodges AB [18], 16 children fit with a MEDEL PULSARCI100 below the age of 24 months having had at least 3 fitting sessions were included in a study analyzing fitting methods and child state during the fitting process (awake, asleep) Kosaner J [24]. Data from 76 fitting sessions was analyzed, 14 of these 16 children's programs were routinely generated from ESRT measures, 2 children with non-recordable ESR's had middle ear problems, this problem was later resolved for one child allowing subsequent ESRT recordings. 83% of programs were generated from ESRT data.

During ESRT measurements 76% of time children were awake, 13% asleep, 8% crying and restless and 3% sedated Kosaner J [24] All pre-lingual deafened pediatrics CI users switched on and followed up from June - September, 2008 were included in a study examining fitting methods used at initial and one year later (fourth or fifth) fitting sessions, 10 children had MEDEL PULSARCI100 and 12 had SONATATI100 cochlear implants. These 22 CI users had a mean age of 39 months at first fitting. The percentage of CI users fit using ESRT method increased from 68% at first fit to 82% (18/22) at fourth fit. 22 children had no recordable ESR's. One had mondini malformation, one had an ossified cochlea and one had chronic middle ear problems. The fourth child cried at each session and would not sleep preventing ESRT measures. This incidence of ESR's and the reasons for not

being able to record an ESR are very similar to findings reported by Kosaner, Anderson, Turan, Deibl [23] on a larger pediatrics population.

d.   Stability of ESRT measures

If telemetry measurements remain stable CI users after 4-6 months device experience tend to have stable ESRT's. According to Kosaner J [22] a comparison of MCL's set at ESRT level for 28 pediatric PULSARCI100 users at two fitting intervals. The first MCL data for each child was taken from a program generated at least 6 months after initial stimulation and the second MCL from a program generated 6-12 months later (mean time interval between fits 7.75 months). The mean charge at the earlier fit was 18.938qu and the mean charge at the later fit was 19.991qu. Using a one sample T test these findings were found to be significantly similar (p <0.01). A very high correlation of r=0.963 (p < 0.01) was found between these 2 ESRT measures even though there was a time interval of over 6 months between measurements.

e.   ESRT map performance

Researchers have compared speech perception results between maps with ESRT-based MCL values and maps based on behavioral measurements of MCL. Spivak et al. [25] showed that 5 of 7 subjects performed either better with the ESRT map or equally well with both maps. This study also found that 4 of 7 subjects preferred the sound quality of the ESRT map when compared with conventionally determined maps Spivak PM [25]. Hodges et al. [26] found that the majority of adult subjects with the Nucleus multichannel cochlear implant system prefer a map set using ESRTs over a map set behaviorally, "generally describing the sound as sharper and clearer. Hodges et al. [26]. Spivak PM [25]. concluded that ESRTs "may be an adequate substitute for comfort levels when programming the implant for patients who are unable to make reliable psychophysical judgment Spivak PM [25]." Finally, because the ESRT has been shown to be a more stable measurement over time than behavioral MCL values, it has been speculated that the ESRT may be "a more reliable and consistent measure on which to base the map" Spivak PM [25].

B. ESRT and CI Fitting
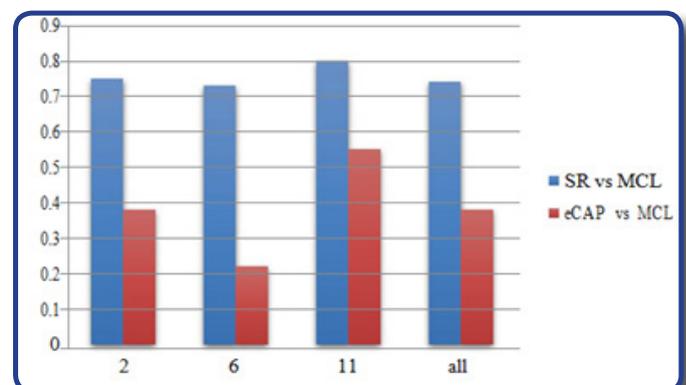
Figure 13: ESRT and ECAP vs MCL for adults.

Many studies show that there is a strong correlation between ESRT and behavioral Most Comfortable Levels on each electrode in adult patients. According to A. Walkowiak et al. study the

mean correlation coefficient between MCL and ESRT levels is significantly higher (0.75) than that between MCL levels and the ECAP threshold (0.39) (Figure 13) Walkowiak, Lorens, Polak, Kostek, & SkarŜyński [27] . Collection of ESRT data on all stimulating electrodes can be completed in less than one hour in most cases Hodges et al. [26], Based on findings that patterns for ESRT and behavioral MCL responses are similar across the array Stephan, Welzl-Müller [9] it may not be necessary to record ESRT data for every stimulating electrode. For young children, recordings can be performed on a sampling of basal, medial, and apical electrodes. In this way, ESRT measurements could likely be completed on a total of 3-5 electrodes in approximately 15 minutes Gross [8].

Finally, because the ESRT has been shown to be a more stable measurement over time than behavioral MCL values, it has been speculated that the ESRT may be "a more reliable and consistent measure on which to base the map" Spivak PM [25]. Also according to Kosaner 2009 study, Averaging data for all electrodes (n=420) a correlation of 0.82 was found between ESRT and behavioral MCL. Figure 14 shows individual correlations for each electrode. All correlations were statistically significant (p<0.001). Kosaner, Anderson, Turan, Deibl [26].
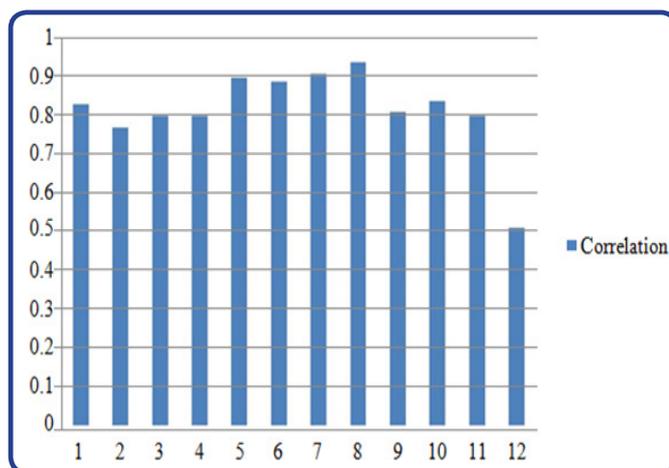

Figure 14: Correlations between ESRT determined programs and Behaviorally determined fitting programs for each electrode are shown. A correlation coefficient of greater than 0.7 indicates a high to very high correlation between the two variables.

C. Electric Auditory Brainstem Response (EABR)

a. What is Auditory Brainstem Response (ABR)?

The ABR is recording of bioelectric activity originating from the auditory nerve and portions of the brainstem in response to sound. In cochlear implant patients, the ABR can be elicited and utilized in much the same manner that the ECAP is used Balkany

TJ [28]. Like the ECAP, an EABR measures the response from neural elements in response to electrical stimulation through the cochlear implant. Recording the EABR requires external recording equipment and surface recording electrodes. To obtain adequate waveforms, the patient must remain still and quite. Results can be difficult to obtain on infants and children while they are awake. Prescription of a sedative may increase quality of the waveform and reduce testing time. Sedation allows the child to remain calm and still, reducing the noise floor and muscle artifact Gross [8].

According to Brown et al. recording the EABR is fairly straightforward. With the EABR, no subtraction procedure is used and because wave 5 of the EABR has a latency of approximately 4 m sec, the response is fairly easy to record, even in situations like deformed cochlea or instances where extensive drilling of the cochlea was required Brown CJ [18]. For this reason, the EABR has been more successful in recording neural responses than the ECAP for patients with cochlear malformations and ossification Brown CJ [18]. Hughes, Brown J, Abbas [17]. Another significant difference between EABR and ECAP recordings involves the population of nerve cells that contribute to the response. "The EABR is recorded using scalp electrodes and is a gross potential that reflects contributions of all the neural units that respond to the electrical stimulus." Brown C J [18].

The ECAP, however, is recorded from an electrode within the cochlea and may, therefore, reflect activity from a smaller population of nerve cells. The ECAP does not reflect neural activity from higher levels in the brainstem Brown CJ [18], for this reason, information about processing at higher levels, such as temporal summation effects, cannot be determined by ECAP recordings. Correlation coefficients between the EABR and behavioral responses are similar to those obtained with the ECAP. Like ECAP data, EABR measures require a correction factor to be of any predictive value. Interestingly, EABR thresholds have been found to occur at levels slightly below the ECAP threshold in adult patients. This difference is potentially due to differences in the noise floor between the two measures and in the number of sweeps used to record each measure Brown CJ [18]. The EABR offers advantages and disadvantages when compared to the ECAP. The EABR is used less frequently, because it requires external recording equipment, scalp electrodes and, in some cases, sedation. Additionally, EABR measurements can be more time-consuming and more susceptible to problems with artifact. With slightly lower overall response levels, however, the EABR may be less likely to result in overstimulation. Finally, an EABR may be present in patients for whom the ECAP cannot be recorded (Gross [8]. Finally, after we mention all the CI fitting for adults Table 1 summarize all approaches and their advantages and disadvantages .

Table 1: Advantage and Disadvantage of all CI fitting approaches for adults.

Approach Type	Approach Name	Advantage	Disadvantage
Subjective	Behavioral Approach	Precise, Each electrode tested very low chance of over- stimulation.	Time- consuming, often overly precise
Subjective	Interpolation of T and C	Save time	Low accuracy due to interpolation deviation from the true T and C levels
Subjective	Streamlined Fitting	Very Fast C levels determined in live mode	Sometimes need fine tuning Low accuracy
Subjective	Shift and Tilt without ECAP	Fast, No need for ECAP Takes temporal integration into account	Effect of very low T-levels may be suboptimal speech scores at very low levels Low accuracy
Objective	Brown offset method using ECAP	Quick, Easy to do. Only 1 T and C measurement needed	Fixed dynamic range across array Low accuracy
Objective	Preset Map using ECAP	Very fast No behavioral input needed	Low accuracy Need fine tuning over time
Objective	Shift Method using ECAP	Fast Takes temporal integration into account	Effect of very low T-levels may be suboptimal speech scores at very low levels Low accuracy
Objective	ESRT	High Correlation with behavioral Good Speech performance	Need patient cooperation Healthy middle ear is required
Approach Type	Approach Name	Advantage	Disadvantage
Objective	EABR	Less likely to result in over stimulation	Time consuming External device required

Aim of the work

This study was conducted to compare between three main approaches for adult cochlear implants fitting which are:

a)   Behavioral (conventional) Approach

b)   Modified Brown ECAP Approach (MB-ECAP)

c)   ESRT based Map Approach

Also To validate the second approach which is MB-ECAP which is a new way of fitting based on ECAP using the concept of the "offset or brown" approach but with additional modification to increase the accuracy of the map.

Material and Methods

Subjects

Total 11 post lingual patients with 11 implants were participated (8 male, 3 female), all are implanted with MED-EL SYNCHRONY implant and using MED-EL SONNET external processor, their age range from 17 to 68 years with average of 39 years old. All have normal cochlea with average hearing loss duration of 10 years and all were using hearing aids before implantation. Subjects were implanted in the same clinic.

Methodology

Subjects have been asked to visit the clinic 4 times as per the following plan

a) **1st Visit:**

   i. Behavioral fitting

b) **2nd Visit:**

   ii. After 2 weeks from the 1st visit,

   iii. Subjects undergo aided audiological assessment with their processors using the behavioral fitting uploaded during the 1st visit.

   iv. Filling Questionnaire o ECAP measurements

   v. Modified Brown ECAP maps fitting

c) **3rd Visit :**

   vi. After 2 weeks from the 2nd Visit.

   vii. Subjects undergo aided audiological assessment with their processors using maps uploaded during the 2nd visit.

   viii. Filling Questionnaire o ESRT measurements

   ix. ESRT based map fitting

d) **4th Visit:**

   x. After 2 weeks from the 3rd Visit ,

   xi. Subjects undergo aided audiological assessment with their processors using maps uploaded during the 3rd visit.

   xii. Filling Questionnaire

Measurements of Behavioral Levels

Levels were measured using MED-EL loudness scale charts, once the patient indicate very loud sounds, MCL levels sets 2 steps (6%) down this level, THR was locked to 10% in all patients, all 12 channels levels are measured and no interpolation used with all patients, Processor uploaded with 4 ascendingly progressive maps with (6%) difference in the MCL levels between each map.

Measurements of ECAP (ART)

ECAP was measured for all patients using Maestro 6.0 MED-EL software. Automatic growth function inside "ART" task is used. The maximum amplitude and phase duration is set to achieve maximum charge equivalent to the behavioral average MCL values used already by the patient in all 12 channels. ART has been recorded in the 12 channels by recording from a channel and stimulating from the successive one (Stimulate E3, Record from E2). Amplitude levels are set to be 8 instead of the default 5 levels in order to increase the accuracy of THR calculation. In MED-EL software you can manually adjust the P and N points to determine the ART thresholds. For the channels that the maximum ART stimulation level is more than the behavioral MCL levels, we asked the subjects to raise hands for any discomfort sounds to skip that level, but no patient felt any discomfort so all the levels are recorded completely [29].

Modified Brown ECAP Approach

As mentioned before, in brown ECAP approach, the behavioral THR and MCL levels in one central channel are measured and together with the ECAP thresholds in all channels, a constant offset is used for all channels to generate the map profile. Cafarelli et al. [13] Showed that the expected difference between predicted and real THR and MCL level (the mapping error) was still unacceptably large leading to low accuracy map, we applied what we call the "Modified Brown ECAP Approach" which can be summarized in the following points:

A. The 12 channels were divided into 3 groups; each group consists of 4 channels.

B. Group 1(E1,E2,E3,E4) , Group 2 (E5,E6,E7,E8) , Group 3(E9,E10,E11,E12) (Figure 15).
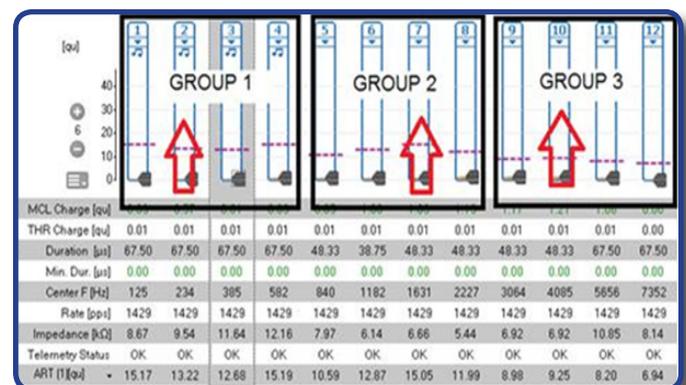
Figure 15: Modified Brown-ECAP approach methodology.

C. One electrode in each group has been selected to have real MCL levels measured behaviorally. All threshold levels are locked to 10%, so thresholds levels have not been considered in our map.

D. E2 in Group 1, E7 in Group 2, and E10 in Group 3 had their MCL levels measured behaviorally.

E. Overlap the ART thresholds in all 12 channels to the fitting map task.

F. Calculate the difference between the measured MCL and ART Thresholds in the selected channels (E2, E7, E10)

G. Apply the difference of the selected channel to all their group neighbor channels.

H. Go live and fine tune some channels to smooth and enhance sound quality for the patient.

I. Upload 4 ascending progressive maps with (6%) difference in the MCL levels between each map.

Measurements of ESRT

Electric Stapedius Reflex was measured using GSI Tympstar V.2 for all subjects. The measurements procedure can be summarized in the following points:

a) Normal Tympanometry for both ears is measured for all subjects.

b) Reflexes were measured from the ear with better middle ear tympanometry.

c) All subjects are adult so no problem is faced during the measurements as far as cooperativeness is concerned.

d) All subjects are awake during the measurements.

e) Fitting Task in Maestro 6.0 software is used to generate the stimulation in each channel.

f) MCL Burst is set to 300 m sec from the fitting settings (Figure 16).
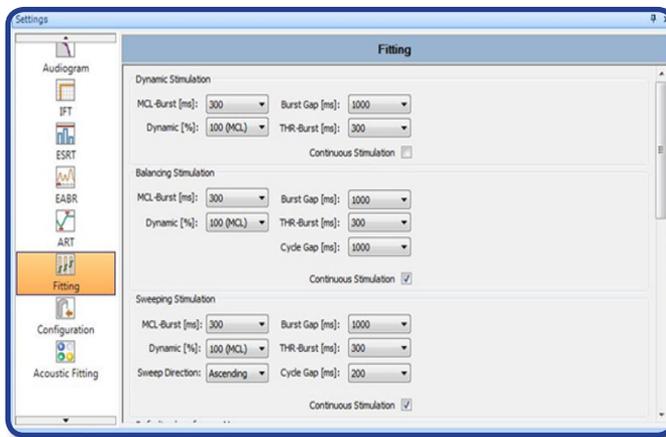
Figure 16: ESRT settings in Maestro 6.0.

g) ESR measured in all 12 channels to all subjects, no interpolation is used.

ESRT Based Map

After measuring the Electric Stapedius Reflexes in all 12 channels, Map is activated and loudness level is set based on the overall channel reflexes during loud sounds, along with the patient feedback and comfortable level. THR levels are locked to 10% of the MCLs. Four progressive descending maps (6 % difference between the MCLs of each map) are configured to the processor. One Subject suffered from severe facial nerve stimulation in one side, ESRT couldn't be done on that as the FNS appeared before the ESR, another two subjects had absent ESR so no ESRT could get from them.

Audiological Assessment

All Subjects underwent audiological assessment using each approach after 2 weeks of using it except the behavioral as it was the approach they were using. These assessments include aided audiometry and speech audiometry [30].

Free Field Aided Audiometry: All subjects were tested using GSI 61 Clinical Audiometer in the same sound booth with 2 clinicians, they were asked to press the button once they hear the stimulation, and FM tone is used in all subjects using speakers [31].

Speech Audiometry

The language used is Arabic language and it was introduced live to the patient, no recorded material was used, SRT and WRS using Arabic spondees and mono syllabic word list of 25 words were used respectively without visual clues. And the WRS was introduced at level of 65 dB.

Questionnaire

The Hearing Implant Sound Quality Index (HISQUI19) is used in Arabic to have a subjective self-reported feedback on the sound quality after each approach (Appendix 1).

The Questionnaire measures, how good or poorly you find the sound quality from your hearing implant in your personal, everyday listening situation.

Please check the answer boxes which correspond the closest to your everyday experiences. Each answer option also includes a percentage value. This percentage value will help you answering the questions: "almost always", for example, means that your statement is currently correct about 87% of the time.

If a specific situation/statement is not applicable, please check the box "N/A = not applicable".

Appendix:

	Always (99%)	Almost always (87%)	Frequent-ly (75%)	Mostly (50%)	Occasion-ally (25%)	Rarely (12%)	Never (1%)	N/A
1. Can you effortlessly distinguish between a male and a female voice?								
2. When talking on the phone, can you effortlessly understand the voices of familiar people?								
3. When listening to music, can you effortlessly distinguish whether one or multiple instruments are being played simultaneously?								
4. When background noise is present, can you effortlessly participate in a conversation with friends or family members (e.g. at a party/ in a restaurant)?								
5. Can you effortlessly hear noises such as falling keys, the beeping of the microwave or the purring of a cat?								
6. Can you effortlessly distinguish single instruments in a familiar piece of music?								
7. You are watching a movie on TV and music is playing in the background. Provided that the volume of the TV is loud enough, can you effortlessly understand the movie's text?								
8. When talking on the phone, can you effortlessly understand the voices of unfamiliar people?								
9. Can you effortlessly understand a speech/ lecture in a hall (e.g. lecture hall, church)?								
10. Can you effortlessly distinguish between a female voice and a child's voice (6-10 years of age)?								
11. At home when other family members are having a conversation and you are listening to the news on the radio, can you effortlessly under-stand the news?								
12. Can you effortlessly understand the announce-ment in a bus terminal, a train station or an airport?								
13. Can you effortlessly hear the ringing of the phone?								
14. You are listening to friends or family members talking to each other in quiet surroundings. Can you effortlessly identify the talker?								
15. You are seated on the back seat of a car and the driver in the front is talking to you. Can you effortless-ly understand the driver?								
16. Can you effortlessly allocate background noise to a specific sound source (e.g. toilet flushing or vacuum cleaner) using acoustic help only?								
17. When other people in your close surrounding are having a conversation (e.g. talking to a salesperson, a bank clerk at the counter or a waiter in a busy restaurant), can you effortlessly talk to another person?								
18. When background noise is present (e.g. in the office, printer, copier, air conditioning, fan, traffic noise, in busy restaurants, at parties, noisy children), can you effortlessly participate in a conversation with multiple people?								
19. When multiple people are talking simultaneously, can you effortlessly follow discussions of friends and family members?								

In HISQUI19 each selection has a weighted value varies from 0 to 7 as follows: Table 2

Table 2: Weighted values for HISQUI19.

n/a	Never	Rarely	Occasionally	Mostly	Frequently	Almost Always	Always
0	1	2	3	4	5	6	7

And the total score of the 19 questions will reflect the hearing quality index according to the following Table 3

Table 3: Achieved total score and hearing quality.

Achieved Total Score	
Very poor Sound Quality	<30
Poor Sound Quality	31-60
Moderate Sound Quality	61-90
Good Sound Quality	91-110
Very Good Sound Quality	111-133

Session Duration: Session duration for each approach was measured by measuring the time difference between measuring the impedance (which is always measured in the beginning of each session) and the configuration of the processor (which is always the last thing in each session) [32].

Comparison between the three approaches: Comparison will be fulfilled by

a) The correlations between the MCLs levels for the 3 approaches.

b) The correlation between the ART thresholds and the MCLs levels in behavioral and ESRT.

c) The correlation between the ESRT thresholds and the MCLs levels in behavioral approach.

d) Session time between the three approaches

e) Patients performance with using the 3 approaches

f) Patient feedback using the questionnaire.

Validation of Modified Brown ECAP Approach

Validation will be achieved by

a) Effect of using this approach in having MCLs level and compare it with the behavioral levels.

b) Difference between MB-ECAP Approach and the standard ECAP approach

c) Effect of using this approach in patient performance.

Results

The present study included 11 subjects with age range from (16-68) with normal cochlea. Patients were asked to come 4 visits with 2 weeks interval between each visit. During each visit, a specific test battery has been done for each subject.

Behavioral Approach

In this approach, we could get behavioral feedback from all the patients using the loudness scale chart. As shown in Figure 17 the average of all subjects MCLs charge units in all channels is around 25 qu which is considered in MEDEL as the average MCLs value for most of the patients [33].
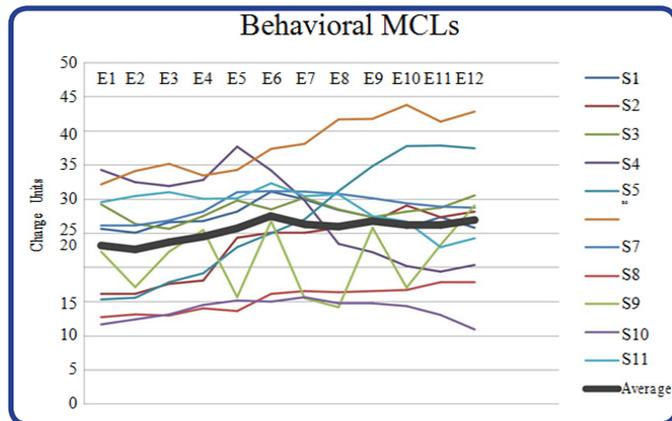

Figure 17: Behavioral MCLs for all subjects.

Audiological Assessment
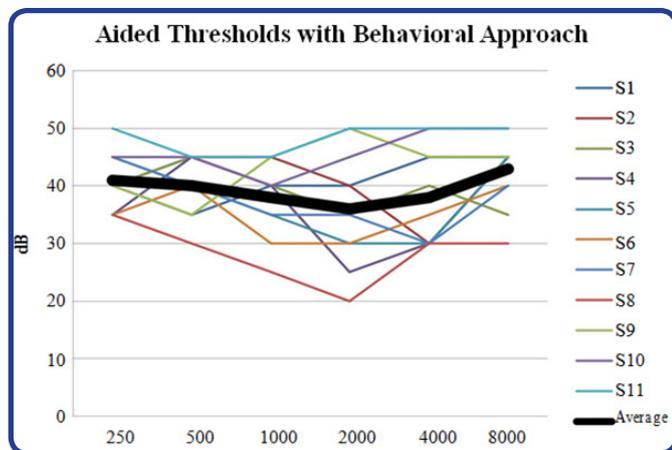
Figure 18: Aided free field for all subjects using behavioral approach

a.   Free Field Aided Audiometry: Figure 18 shows the aided free field hearing thresholds for all subjects using the behavioral approach with average values as shown in Table 4.

Table 4: Average values for aided FF after using behavioral approach.

Frequency(Hz)	250	500	1000	2000	4000	8000
Hearing THR(dB)	41	40	38	36	38	43

Table 5: SRT and WRS using Behavioral approach for all subjects.

Subjects	SRT(dB)	WRS%
S1	45	48%
S2	35	76%
S3	CND	CND
S4	55	36%
S5	50	48%
S6	35	44%
S7	CND	24%
S8	40	76%
S9	50	40%
S10	CND	28%
S11	40	CND
Average	43.75	47%

b.   Speech Evaluation: Table 5 is showing the result of SRT and WRS of all subjects using behavioral approach. The average of SRT was 43.75 dB and the average of WRS was 47% at 65 dB.

c.   Session Time: Figure 19 showing the session's time for all subjects during behavioral approach fitting with average of 27 minutes.
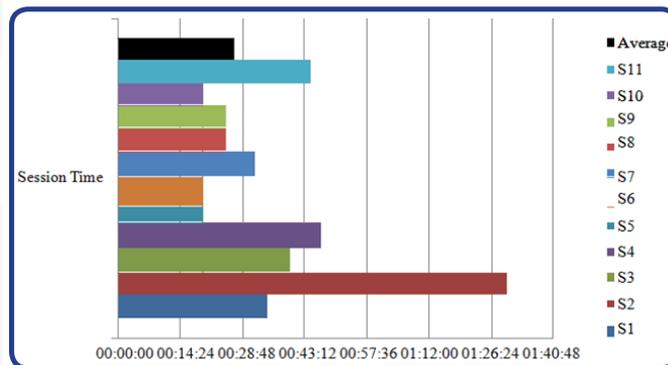

Figure 19: Session time for all subjects during behavioral approach fitting.

Modified Brown ECAP Approach

In this approach we could get ECAP responses from all subjects in all channels except three patients where we could record ECAP only in some channels, with percentage of 96.96%.
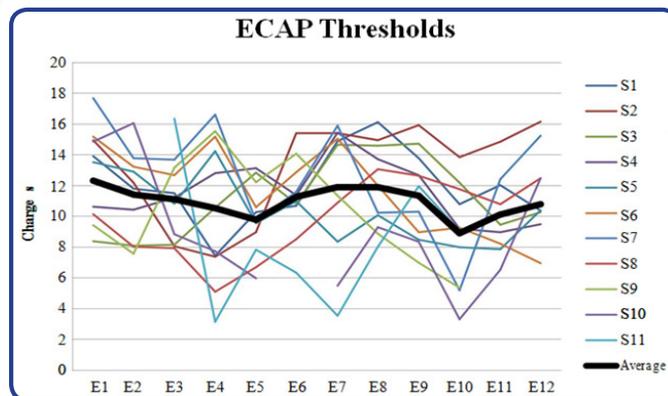

Figure 20: ECAP Thresholds for all subjects in the 12 channels.

ECAP Thresholds: Figure 20 shows the ECAP thresholds in all channel for all subjects using Amplitude Growth Function in ART Task, P and N was adjusted manually to have the thresholds of each channel.
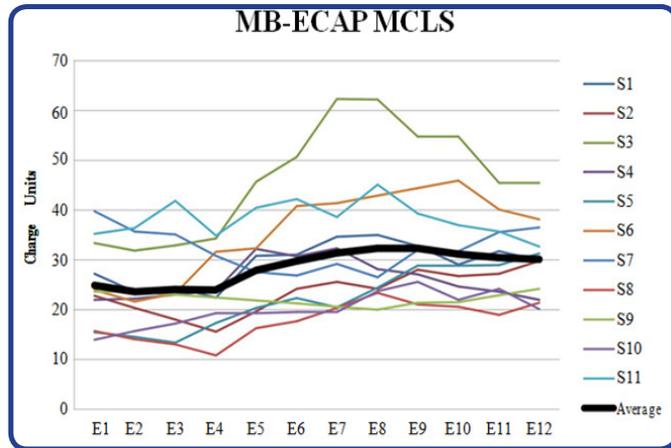

Figure 21: MCLs for all subjects in the 12 channels using MB-ECAP Approach.

MCLs Levels: Figure 21 shows the MCLs level for all subjects after using MB-ECAP approach.

Audiological Assessment
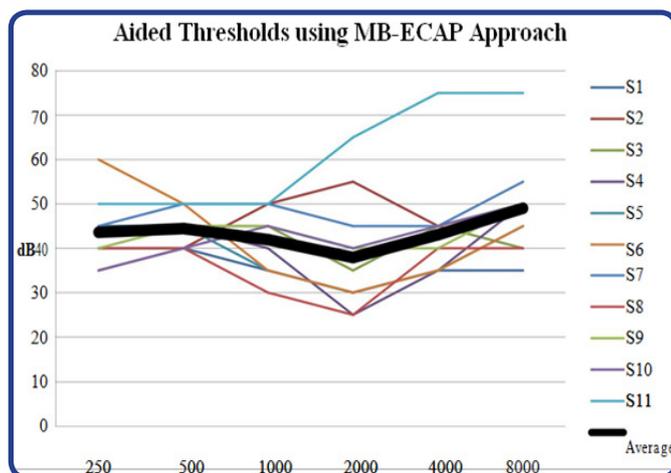
Figure 22: Aided Free Field of all subjects after using MB-ECAP Approach.

Free Field Aided Audiometry: Figure 22 shows the aided free field hearing thresholds for all subjects using the MB-ECAP approach with average values as shown in Table 6.

Table 6: Average values for Aided FF after using behavioral approach.

Frequency(Hz)	250	500	1000	2000	4000	8000
Hearing THR(dB)	43.5	44.5	42	38	43	49

Speech Recognition Threshold: Table 7 is showing the result of SRT and WRS of all subjects using MB-ECAP approach. The average of SRT was 39.5 dB and the average of WRS was 41% at 65 dB. SRT couldn't be done with one subject.

Table 7: SRT and WRS using Modified Brown ECAP approach for all subjects.

Subjects	SRT(dB)	WRS%
S1	45	44%
S2	45	84%
S3	CND	4%
S4	40	36%
S5	30	28%
S6	30	24%
S7	45	32%
S8	35	88%
S9	40	64%
S10	45	40%
S11	40	4%
Average	39.5	41%
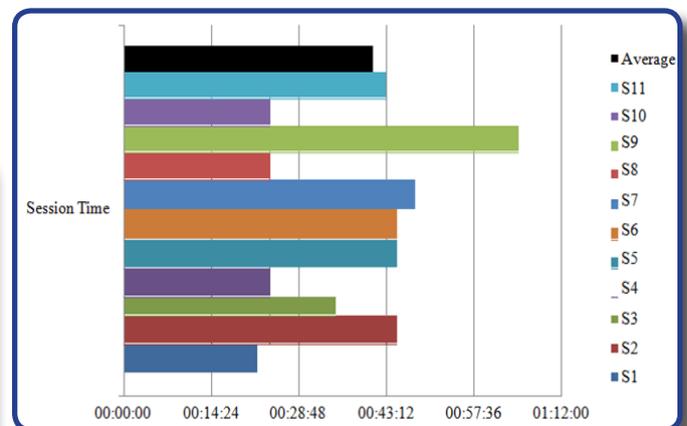
**Figure 23:** Session time for all subjects during MB-ECAP approach fitting.

Session Time: Figure 23 is showing the MB-ECAP session time for all subjects with average of 41 min.

ESRT Based Approach

In this approach we could get electric stapedius reflex (ESR) from 8 out of 11 subjects in all channels with percentage of 72.72%.
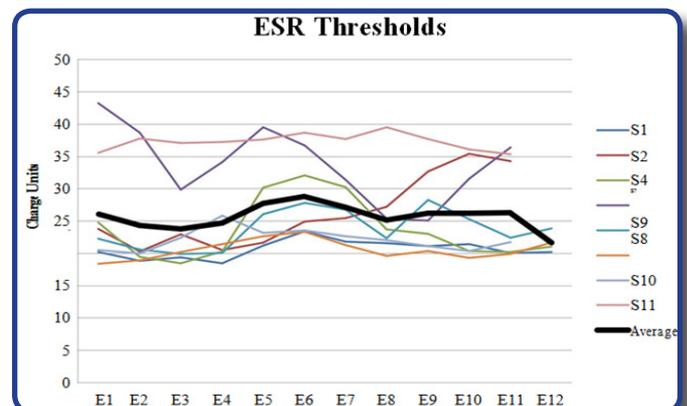

Figure 24: ESR Thresholds for all subjects in the 12 channels.

**ESR Thresholds:** Figure 24 is showing the ESR thresholds for all measured subjects in all channels.
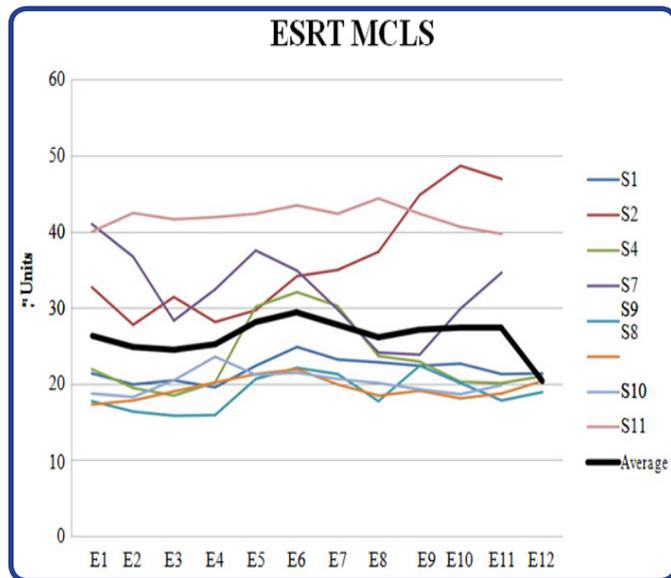
Figure 25: MCLs values for all subjects in the 12 channels using ESRT Approach.

MCLs Levels: Figure 25 shows the MCLs level for all subjects after using ESRT approach.

Audiological Assessment
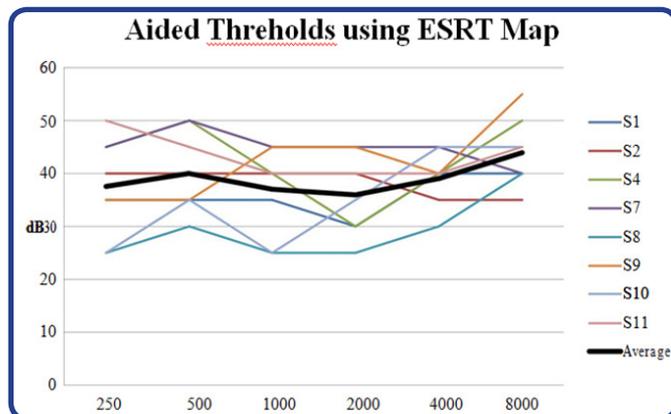
Figure 26: Free Field Aided Thresholds for all subjects after using ESRT Approach.

Free Field Aided Audiometry: Figure 26 shows the aided free field hearing thresholds for all subjects using the ESRT approach with average values as shown in Table 8.

Table 8: Average values for Aided FF after using ESRT approach.

Frequency(Hz)	250	500	1000	2000	4000	8000
Hearing THR(dB)	37.5	40	37	36	39	44

Speech Recognition Threshold: Table 9 is showing the result of SRT and WRS of all subjects using ESRT approach. The average of SRT was 38.12 dB and the average of WRS was 40% at 65 dB. SRT couldn't be done with three subjects.

Table 9: SRT and WRS using ESRT approach for all subjects.

Subjects	SRT(dB)	WRS%
S1	35	40%
S2	40	84%
S3	CND	CND
S4	50	20%
S5	CND	CND
S6	CND	CND
S7	45	4%
S8	30	64%
S9	35	44%
S10	30	48%
S11	40	12%
Average	38.12	40%
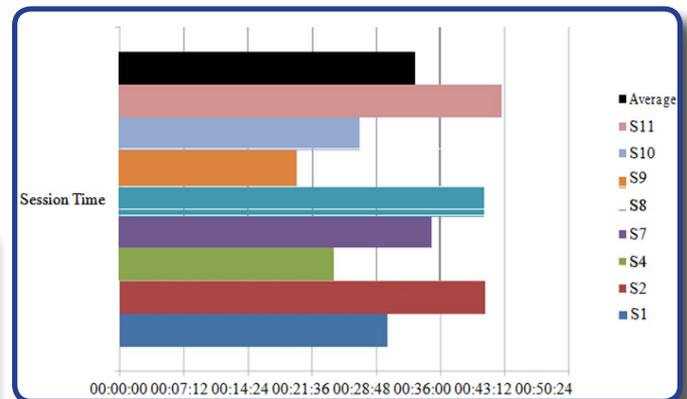
Figure 27: Session time for all subjects during ESRT fitting.

Session Time: Figure 27 is showing the ESRT approach sessions time for all subjects with average of 33 min.

Correlation between 3 approaches
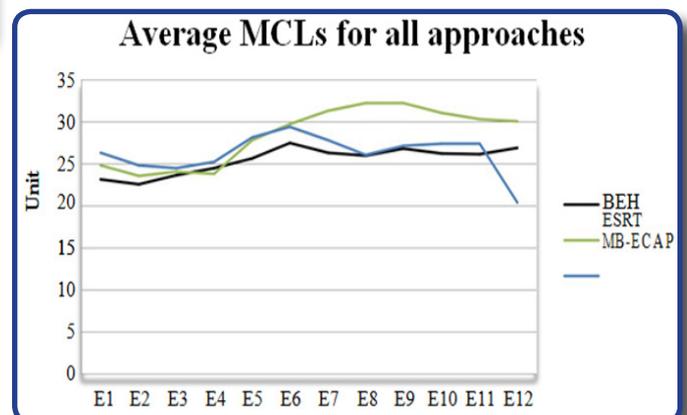
Figure 28: Average MCLs for all approaches.

The correlations between the MCLs levels for the 3 approaches: Figure 28 showing the average of MCLs in the 3 approaches, which demonstrate that the difference between MCLs is higher in mid and basal, compared to apical. Also the

MC-ECAP gives the highest charge units in the mid and basal electrode compared to other approaches. The correlation coefficient between Behavioral MCL and MB-ECAP MCL levels in one side and between Behavioral MCL and ESRT MCL in other side through all channels is showed in Figure 29. What is noticeable is in the first 4 channels (apical channels) the correlation between behavioral and MB-ECAP is higher than the correlation between the behavioral and ESRT. While in the mid and Basal channels, there is no difference between their correlations [34].
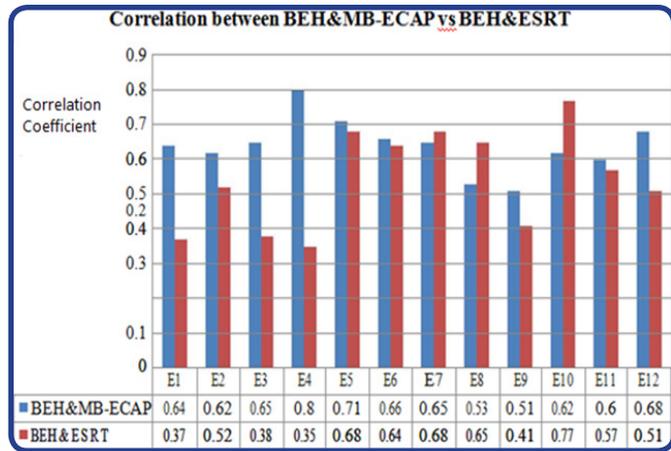

Figure 29: Correlation between Behavioral & MB-ECAP vs Behavioral & ESRT in all channels.
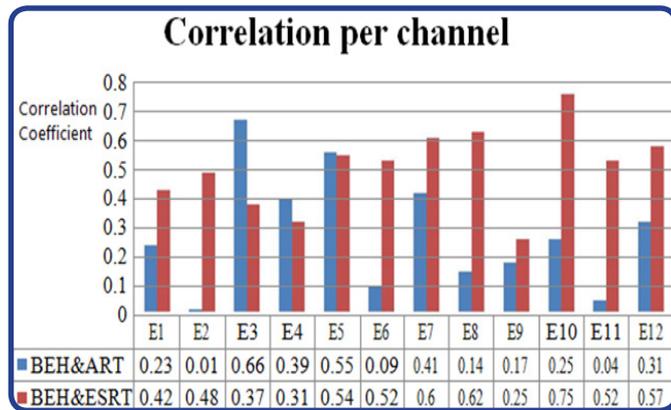

Figure 30: Correlation between Behavioral levels & ECAP THR vs Behavioral levels & ESRT THR per channel for all subjects.

ART and ESRT thresholds correlation with the MCLs levels in Behavioral: As showed in Figure 30 most channels has higher correlation between behavioral and ESRT Thresholds when comparing with the correlation between behavioral and ART Thresholds.

Session time between the 3 approaches: As shown in Figure 31, Behavioral approach is the shortest session time among the others with average 27 min comparing to a 33 min for ESRT and 41 min for ECAP but there is no significant difference between the 3 approach session time (P > 0.10).

Patient Performance between using the three Approaches

Speech Recognition Thresholds (SRT): Figure 32 is showing each subject and their SRT using the 3 approaches with

average of:
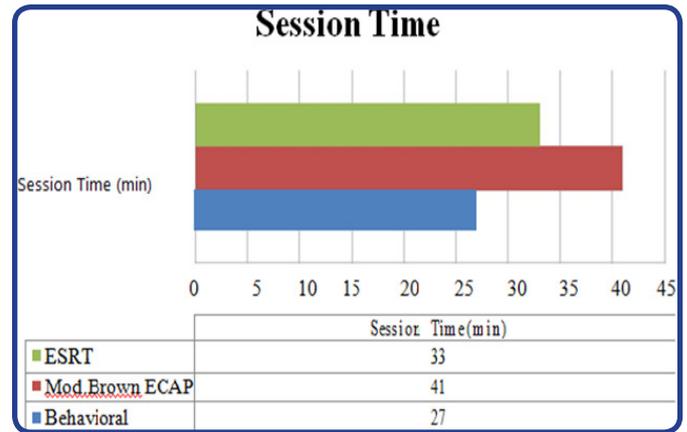
Figure 31: Session time for all 3 approaches.
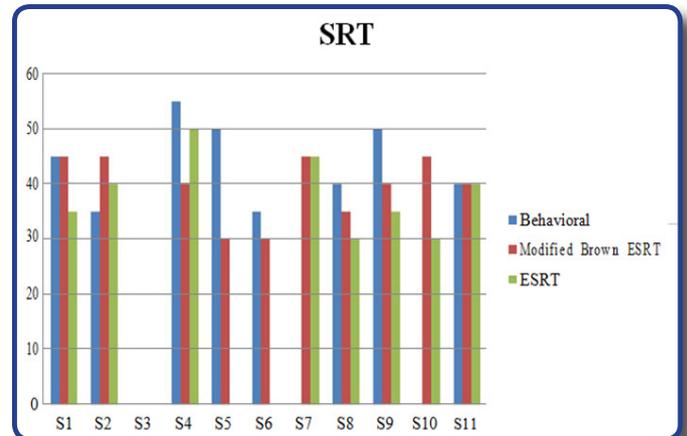
Figure 32: SRT of each subject for all approaches.

i. Behavioral Approach: 43.75 dB

ii. Modified Brown ECAP Approach: 39.5 dB

iii. ESRT Approach: 38 dB

No significant difference between SRT in the 3 approached (P > 0.10). Obviously the chart shows that the ESRT approach enhance the SRT in most subjects comparing to other approaches.
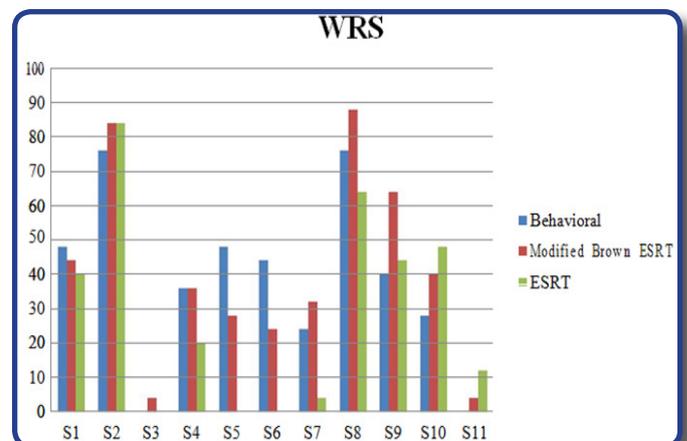
Figure 33: WRS of each subject for all approaches.

Word Recognition Score (WRS): Figure 33 is showing each subject and their WRS (at 65dB) using the 3 approaches with average of:

a)   Behavioral Approach: 47%

b)   Modified Brown ECAP Approach: 41%

c)   ESRT Approach: 40%

In some subjects, the MB- ECAP approach had a significant effect on the performance as far as the WRS is concerned (P<0.05), in other subjects the behavioral had better score comparing to others.

Validation of the Modified Brown ECAP Approach
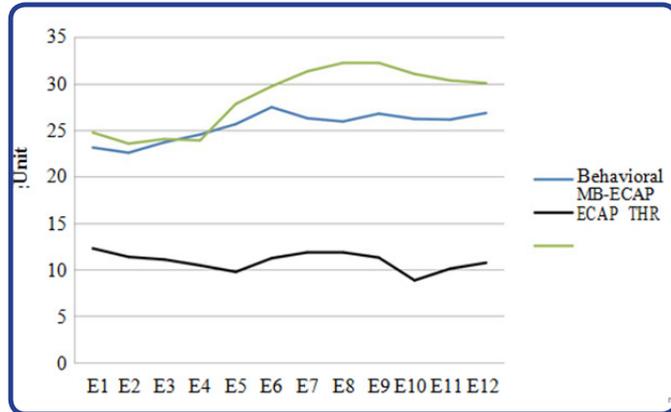
Figure 34: Behavioral, MB-ECAP and ECAP THR levels.

Effect of using this approach in having MCLs level and compare it with the behavioral levels: As shown in Figure 34 the MB- ECAP Approach raise the levels and decrease the charge unit's difference between pure ECAP THR and the Behavioral levels which increase the correlation and enhance patient performance with only 3 behavioral points and ECAP thresholds.

Effect of using MB- ECAP Approach to enhance correlation with behavioral approach: As shown in Figure 35 the MB- ECAP enhanced the correlation with behavioral levels comparing to pure ECAP thresholds which give more reliable map profile comparing to pure ECAP thresholds.

	E1	E2	E3	E4	E5	E6	E7	E8	E9	E10	E11	E12
ECAP Modified Brown corr	0.64	0.62	0.65	0.8	0.71	0.66	0.65	0.53	0.51	0.62	0.6	0.68
ECAP THR corr	0.23	0.01	0.66	0.39	0.55	0.09	0.41	0.14	0.17	0.25	0.04	0.31
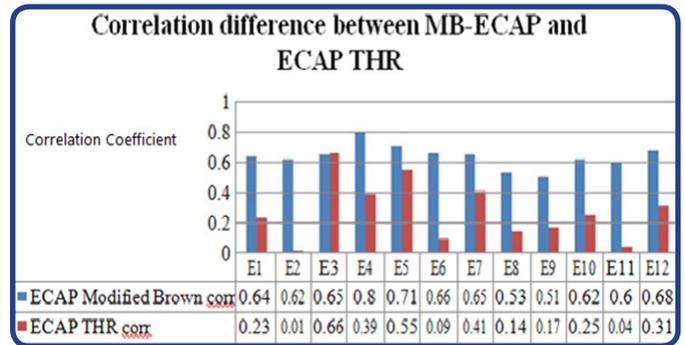
Figure 35: Correlation of behavioral &MB-ECAP vs behavioral &ECAP THR.

Effect of using MB-ECAP Approach in patient performance: As shown in Figure 36 some patients had better WRS comparing to behavioral approach, also SRT in average showed better thresholds comparing to behavioral approach.

Questionnaire: As shown in Figure 36, questionnaire has been filled every session for each patient taking in considerations all implants.

	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11
Behavioral	81	85	65	51	74	75	61	72	80	85	68
MB-ECAP	68	97	65	50	77	81	65	75	71	90	74
ESRT	71	98	0	55	0	0	64	81	77	87	75
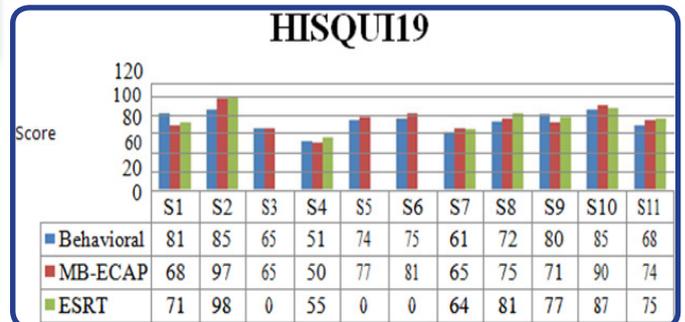
Figure 36: HISQUI19 score of all patients for 3 approaches.

a)   Average score for behavioral Approach: 72.

b)   Average score for MB-ECAP Approach: 74.

c)   Average score for ESRT Approach: 76.

Discussion

This study mainly focus on the concept of having several approaches for CI adult fitting, and through the goals and results, it is obvious that it has 2 main goals to achieve. First is the comparison of 3 important approaches including 1 subjective and 2 objective approach? Second is the validation of new approach which considered as a modification to the current Brown ECAP approach.

Comparison between the 3 approaches

Many studies showed the strong correlation between the ESRT and the behavioral MCLs comparing to the correlation of the ECAP and here in this study it was also proved the same correlation Figure 31 in most of the channels, Correlation coefficient in this study is lower than what was proved by Kosaner J [24] this may due to number of subjects in both studies and usage duration of each program. It appears that all three approaches have upper and lower points comparing to each other's and there is no dominant approach that has an upper hand on others and this can prove the variability of cochlear implant fitting and it is not only a one side process. It depends also on the patients factors (history, deafness duration, etiology, psychological and social) etc.

One of the most important points in this study is that it actually compares 3 different ways of having the MCLs and ending with a little difference in the patient's performance. The first approach which is the behavioral is purely subjective way needs the influence and feedback of the patient. According to the current study, it is the fastest approach to configure the fitting map with the best word recognition score of 47%, however, patients experience should be considered as they have used the behavioral approach more than using the other approaches which may be the reason for having better WRS.

Regarding the MB-ECAP approach it can be considered as combined subjective and objective approach. It uses a base of objective measurements (ECAP THR) and 3 subjective points. This approach reaches nearly some profile looks like the one generated by the behavioral approach but differs in the overall loudness level or charge units [35]. The difference is due to the fact that it is not a channel by channel measurement approach but it has many interpolations and approximations which will affect the accuracy of the profile itself. On the other hand, it can be used with uncooperative and difficult adults in addition to pediatric CI recipients as it only needs 3 subjective points and the ECAP thresholds. One more advantage in this approach is that it doesn't need any additional devices or equipment, not like the ESRT approach which needs some setup and tympanometer with some features.

The incidence of having ECAP signal according to this study is higher than the incidence of having ESR which increases the feasibility of using this approach on other approaches. The fact of manual adjustment of the P and N to determine the ECAP threshold may depend on the experience of the clinician, while the ESRT approach which is objective, reliable and independent on the clinician.

Patient Performance between 3 approaches

As mentioned before, there is no dominant approach regarding patient performance but it can be better if the following is applied:

a)   A recorded list is used in the speech audiometry rather than live speaker.

b)   One clinician is doing the speech audiometry having the same dialect as the subjects.

c)   Same usage duration for all programs. And this was not possible as all patients were using already the behavioral approach map before applying any other approaches.

Validation of MB-ECAP Approach

In this study, the results of a new approach were compared to two other well-known validated approaches and as per the study proved. No significant difference between the three approaches was found. However it showed upper hands on some points like the correlation between MB-ECAP and Behavioral levels comparing to the ESRT levels with the same behavioral levels, it was also found that patient performance with this approach is within the same values regarding SRT and WRS of the other approaches which can validate using this way for CI patients. This study can open the way to have more studies to validate this approach by having more subjects and automatic N and P measurements which will reduce the human factor of calculating the ECAP thresholds [36].

Questionnaire

The overall scores show increase in the hearing quality score from one session to other. Most patients showed improvement in the hearing quality when changing the approach from behavioral to MB-ECAP or ESRT. The reliability of this questionnaire can be improved if the questionnaire is modified as some questions are not suitable with the Saudi Culture as many questions are about music perception and tonal discriminations which is not applicable for most of the patients. Also, two weeks between sessions is not enough to have reliable feedback about the change in the programs, However most of the patients reported improvement in the sound quality when using ESRT over all other approaches. Only one patient prefer the MB-ECAP over all other approaches.

Conclusion

For fitting adult CI patients, many approaches can be used from pure subjective approaches to pure objective approaches passing with the new combined approach which is the Modified Brown ECAP Approach (MB-ECAP). MB-ECAP can have MCLs profile with good correlation with behavioral approach (r=0.64) comparing to the correlation of ESRT map with behavioral approach (r=0.54) in all 12 channels. No map has upper hand on another and therefore it depends on the patient preference and ability whether to use subjective or objective or use the MB-ECAP approach. With more subjects both MB-ECAP and ESRT correlation can be more accurate and better validated. MB-ECAP can be used with pediatric as it only needs 3 subjective feedbacks from the patient and their ECAP thresholds. Finally using MB-ECAP by automatic measured ECAP thresholds will enhance the correlation and give more reliable levels compared to manual measured thresholds.

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