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REVIEW ARTICLE

# The importance of electrically evoked stapedial reflex in cochlear implant☆

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**KEYWORDS**
Cochlear implants;
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**Abstract**
*Introduction:* The most important stage in fitting a cochlear implant is the identification of its dynamic range. The use of objective measures, in particular the electrically elicited stapedius reflex, may provide suitable assistence for initial fitting of cochlear implant, especially in children or adult with multiple disorders, because they provide specific values that serve as the basis of early cochlear implant programming.
*Objective:* Verify through a review the use of the electrically elicited stapedius reflex threshold during the activation and mapping process of cochlear implant.
*Methods:* Bibliographical search on the Pubmed and Bireme plataforms, and also on Medline, LILACS and SciELO databases, with standard searches until September 2012, using specific keywords. For the selection and evaluation of scientific studies found in the search, criterias have been established, considering the following aspects: author, year/location, grade of recommendation/level of evidence, purpose, sample, age, mean age in years, evaluative testing, results and conclusion.
*Results:* Among 7,304 articles found, 7,080 were excluded from the title, 152 from the abstract, 17 from the article reading, 43 were repeated and 12 were selected for the study.
*Conclusion:* The electrically elicited stapedius reflex may support when programming the cochlear implant, especially in patients with inconsistent responses.



**PALAVRAS-CHAVE**
Implante coclear;
Perda auditiva;
Reflexo acústico

**A importância do reflexo estapédico evocado eletricamente no implante coclear**

**Resumo**
*Introdução:* A determinação da área dinâmica do implante coclear é um dos procedimentos mais importantes em sua programação. O uso de medidas objetivas, em especial a do limiar do reflexo estapédico evocado eletricamente, pode contribuir para a definição deste campo, principalmente em crianças ou em indivíduos com múltiplos comprometimentos, pois fornecem valores específicos que

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servem como base no início da programação do implante coclear.
*Objetivo:* Verificar por meio de uma revisão a utilização do limiar do reflexo estapédico evocado eletricamente durante o processo de ativação e de mapeamento do implante coclear.
*Métodos:* Levantamento bibliográfico nas plataformas Pubmed e Bireme e nas bases de dados MedLine, LILACS e SciELO, com buscas padronizadas até setembro de 2012, utilizando-se palavras-chave. Para a seleção e avaliação dos estudos científicos levantados, foram estabelecidos critérios, contemplando os seguintes aspectos: autor, ano/local, grau de recomendação/nível de evidência científica, objetivo, amostra, faixa etária, média de idade em anos, testes avaliativos, resultados e conclusão.
*Resultados:* Dos 7.304 artigos encontrados, 7.080 foram excluídos pelo título, 152 pelo resumo, 17 pela leitura do artigo, 43 eram repetidos e 12 foram selecionados para o estudo.
*Conclusão:* O reflexo estapédico evocado eletricamente é capaz de auxiliar na programação do implante coclear, principalmente em pacientes que apresentam respostas inconsistentes.


## Introduction

The cochlear implant (CI) is acknowledged worldwide as the treatment of choice for severe and profound bilateral sensorineural hearing loss (SHL).[1] This device consists of external and internal components. The external components are the microphone, speech processor, and transmitter antenna. Among the internal components is the stimulatory receptor, which includes the internal antenna, which is surgically placed adjacent to the skull. The CI is a device that partially replaces the functions of the cochlea, transforming sound energy into electrical signals.[2]

In this type of device, each electrode directly stimulates the auditory nerve, and the amount of electric current necessary to elicit an auditory sensation is different for each individual and for each stimulation channel. For this reason, the speech processor of each user must be individually adjusted in a process called programming or mapping. The dynamic area is the region between the amount of current that primarily induces an auditory sensation, i.e., the threshold for electrical stimulation (T level) and the level of sensation of maximum intensity that the patient will accept for electrical stimulation without discomfort (C level).

In adults, the determination of the energy levels is accomplished through psychophysical measures (behavioral method). In infants, small children, or individuals with multiple disorders, this procedure requires techniques that can generate inconsistent and asystematic responses due to the child's hearing inexperience or age. Thus, using only the behavioral method to program the speech processor can prolong the process of adaptation to the CI due to the difficulty of establishing appropriate levels of stimulation.[3-5]

The use of objective measures in the CI process has greatly contributed to the definition of the dynamic field, as they provide specific values that serve as the basis for the start of the mapping process, especially in cases of infants and young children. Some examples of these measures are electrically evoked stapedius reflex threshold (ESRT), neural response telemetry (NRT), brainstem auditory evoked potential (BAEP), and P300, among others.[6-9]

The stapedius reflex is defined as a contraction of the middle ear muscles induced by an intense acoustic stimulus. This has become a valuable clinical and research tool of human hearing.[10-12] The acoustic reflex, considered the lowest intensity of sound that makes the minimum measurable change in the middle ear, is normal between 70 and 90 dBSPL.[13]

The correlation between the values obtained objectively and values assessed by the behavioral method has been extensively studied. However, in clinical practice, there is no consensus and standardization regarding the use of these measures in the treatment of CI users.[14] ESRT appears to be a promising finding, as several studies have indicated an association between these thresholds and the assessment of maximum comfort level in adults and children with cochlear implants.[15] Through further studies, this measure may be included in the standard procedures, because its contributions are evident and the gains for the patient and for the professional are undeniable.

The objective of the study was to verify, through an integrative review, the use of ESRT during the CI activation and mapping process, as well as its value associated with behavioral assessment.

## Methods

The methodological process characterized the present study as an integrative review, conducted from electronic searches in the PubMed, BIREME, MEDLINE, LILACS, and SciELO Regional databases. The search was performed in the months of August and September of 2012. Studies published in English, Spanish, or Portuguese were selected for the analysis. There was no restriction regarding the year of publication, i.e., studies published until October 2012 were analyzed and the articles were subsequently selected according to the inclusion and exclusion criteria.

A specific strategy for the crossing of the descriptors (DeCS and MeSH) was created for each of these databases, as well as for free terms that are not found among DeCS and MeSH terms, but that are relevant to the research. The descriptors used to locate the studies were cochlear implants/cochlear implantation, acoustic reflex, and hearing loss.

### Search strategy

The search strategy was the syntax of the strategy, used for the bibliographic search in the databases. This was directed by a specific question: "What is the importance and applicability of ESRT during the activation and mapping process of the CI?". To identify relevant articles with the proposed question, a search strategy was developed using the descriptors in groups, with at least two keywords. In PubMed, the crossings were: cochlear implantation/cochlear implants AND hearing loss and cochlear implantation/cochlear implants AND acoustic reflex. In Bireme, the crossings were cochlear implant AND hearing loss, cochlear implant AND hearing impairment, cochlear implant AND hearing loss, and cochlear implant AND acoustic reflex. The free terms used were: hearing loss and hearing impairment.

### Selection criteria

The inclusion criteria were: original articles; with research subjects undergoing CI surgery; with procedures such as ESRT in the CI process (surgery and/or programming and/or rehabilitation), and published in Portuguese, English, or Spanish. Studies that were not original articles and those that did not mention CI in the title of the manuscript were excluded.

### Study identification, selection and inclusion

The search was independently performed by two researchers, and points of conflict were discussed during specific meetings. After applying the search strategy containing the defined descriptors, the selection of articles was performed in three steps:

- Identification and reading of titles in different electronic databases, and exclusion of those that did not meet inclusion criteria.
- Reading the abstracts of the studies selected in the first step, and further exclusion of those that did not meet the inclusion criteria.
- Reading in full of all studies not excluded by the first two steps.

All the studies considered met the criteria of inclusion defined at the beginning of the present study's methodological protocol, responding to the question guiding this integrative review.

The main data of each article were collected and entered into a database using Microsoft Office Excel 2011® software.

For a better result presentation, the following variables of the selected articles were considered: author, year/location, grade of recommendation/level of evidence, objective, sample, age range, mean age in years, assessment testing, results, and conclusion. The Oxford Centre for Evidence-Based Medicine Classification was used to measure the level of scientific evidence.[16]

## Results

A total of 7,304 articles were retrieved in the electronic searches in the PubMed, BIREME, MEDLINE, LILACS, and SciELO Regional databases. A total of 12 articles were selected according to the inclusion and exclusion criteria defined in Methods, and after removing the references listed in more than one database.

In the MEDLINE database via PubMed, when crossing the keywords and free terms, 7,106 articles were retrieved, of which 6,893 were excluded by the title, 213 abstracts were read, and 69 articles were selected for full reading. Of these 69, 43 were repeated and 14 articles were excluded. In the LILACS database, 183 articles were retrieved, of which 172 were excluded by the title, and three abstracts were read and were excluded. In the SciELO database, 15 articles were retrieved and 15 were excluded by the title. Fig. 1 provides an overview of the process for obtaining the articles selected for the integrative review.

## Discussion

Among the 12 selected articles, one study had level of evidence B (2B)[17] and 11 had level of evidence C (4).[18-28] No publications were found with level of evidence A. Among the study designs analyzed in the review, one was a cohort study and the others were case reports (Table 1).

Due to the recent increase in the number of studies in the area of CI, this review highlights researches between 1988 and 2011. All selected articles had ESRT and other

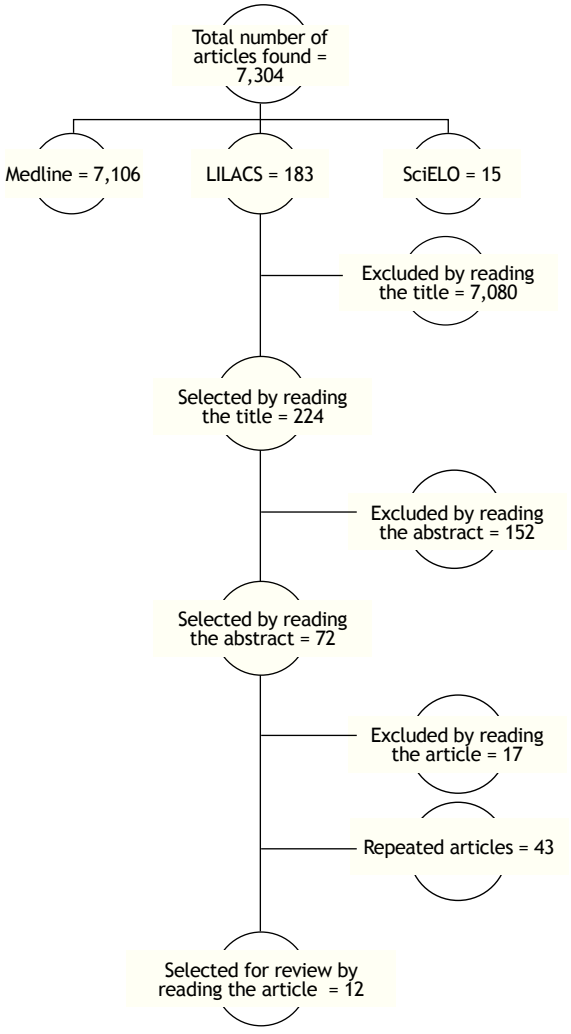


**Figure 1** Flowchart of articles included in the review.

**Table1** Characteristics of the studies included in the integrative review.

| | Author | Year/ Country | Study type | Grade of recommendation/ Level of scientific evidence | Objective | Sample | Age range in years | Mean age in years | Assessment | Results | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. | Stephan et al.[18] | 1988/ Austria | Case report | C/4 | To develop a method that provides information on the dynamic area for electrical stimulation | 12 users of CI | Not reported | Not reported | ESRT and C level | ESRT was observed, mostly above the dynamic range of electrical stimulation of the electrodes. | ESRT can provide appropriate assistance in adjusting the speech processor of the CI in inconsistent patients. |
| 2. | Battmer et al.[19] | 1990/ Germany | Case report | C/4 | To assess the use of ESRT for the definition of objective data in the speech processor | 25 users of CI | 19 to 68 | 42.8 | ESRT | 76% showed ESRT and a reflex amplitude saturation was observed in 56% of the sample. | ESRT can be used in the initial C level programming of the speech processor of CI. |
| 3. | Stephan et al.[20] | 1991/ Austria | Case report | C/4 | To analyze the usefulness and ESRT threshold values in the CI process | 21 users of CI | Not reported | Not reported | ESRT, and C and T levels | ESRT was observed in 11 patients, and there was no correlation between the reflex threshold and the sensitivity threshold. | ESRT can estimate the upper limit of the dynamic range of the CI. |
| 4. | Spivak et al.[21] | 1994/USA | Case report | C/4 | To assess the association between C levels and ESRT in adults and children using CI | 35 users of CI | 5 to 70 | Not reported | ESRT and C level | ESRT differed from C levels in behavioral tests by an average of 19.4 units of stimulus level for adults and 9.6 units of stimulus level for children. | Data from the ESRT can be very useful in programming the CI of adults and children with inconsistent responses |

**Table1** Characteristics of the studies included in the integrative review (cont.).

| | Author | Year/ Country | Study type | Grade of recommendation/ Level of scientific evidence | Objective | Sample | Age range in years | Mean age in years | Assessment | Results | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 5. | Van den Borne et al.[22] | 1996/ the Netherlands | Case report | C/4 | To compare the ESRT in the intraoperative and postoperative periods, as well as the C level | 19 users of CI | Not reported | Not reported | ESRT and C level | The ESRTs in the intraoperative period were higher than those in the postoperative period and higher than C levels. | ESRT, especially for children with meningitis etiology, in the intraoperative period, is a poor predictor of C levels. |
| 6. | Bresnihan et al.[23] | 2001/ Ireland | Case report | C/4 | To assess the use of ESRT to measure C levels in children with CI and compare these results with behavioral methods | 26 users of CI | 2 to 9 | 4.9 | ESRT, tympanometry, and behavioral measures | The C levels obtained from ESRT were considered lower than those obtained with behavioral techniques. | The estimation of C level through ESRT is reliable and objective, and therefore a valuable programming tool in the pediatric population |
| 7. | Gordon et al.[24] | 2004/ Canada | Case report | C/4 | To report behavioral and electrophysiological responses in child candidates for CI | 68 candidates for CI | 0.7 to 17 | 4.6 | ESRT, BAEP, ECAP, and C levels | BAEP and ECAP thresholds did not significantly change from the 1st to the 12th month of CI use, while ESRT and C levels increased | Nonbehavioral, intra- or postoperative measures may assist in determining levels of stimulation in the CI, particularly in young children |
| 8. | Mason[25] | 2004/ United Kingdom | Case report | C/4 | To perform a retrospective study on the implementation of the electrophysiological and objective measures and their value when managing children with a CI | 29 users of CI | Not reported | Not reported | BAEP, ECAP, and ESRT | ESRT was observed in 28 patients, BAEP in 27, and ECAP in 29. | Objective electrophysiological measures not only assist in the initial installation of the CI, but also provide valuable data for future device programming. |

**Table1** Characteristics of the studies included in the integrative review (cont.).

| | Author | Year/ Country | Study type | Grade of recommendation/ Level of scientific evidence | Objective | Sample | Age range in years | Mean age in years | Assessment | Results | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 9 | Caner et al.[26] | 2007/ Turkey | Case report | C/4 | To investigate the association between NRT, ESRT, and behavioral outcomes | 16 users of CI | Not reported | Not reported | ESRT, NRT, and behavioral measures | NRT was obtained in 91.7% of patients intraoperatively and 94.2% postoperatively. ESRT in 80% intraoperatively. ESRT levels were higher than NRT levels. | The two objective measures, together with the behavioral responses, should be included in the CI programming process to avoid setting C levels too high. |
| 10. | Pau et al.[27] | 2011/ Germany | Case report | C/4 | To compare the intraoperative and postoperative ESRT and tympanometry results | Six users of CI | Not reported | Not reported | Visual observation and tympanometry | There are no major differences between the two techniques used in the intraoperative period, but there are differences when comparing the intra- and postoperative periods. | ESRT valuesobtained intraoperatively are not suitable for exact definitions used for programming the speech processor of the CI. |
| 11. | Cinar et al.[17] | 2011/ Turkey | Cohort | B/2B | To investigate the effectiveness of objective techniques in the programming of speech processors for cochlear implant users with cochlear malformations | 35 users of CI | Not reported | Not reported | BAEP, ECAP, and ESRT | ECAP, BAEP, and ESRT thresholds differ from one another in both groups | BAEP is a more reliable measure than ECAP or ESRT |

**Table1** Characteristics of the studies included in the integrative review (cont.).

| | Autor | Ano/local | Tipo de estudo | Grau de recomendação/ Nível de evidência científica | Objetivo | Amostra | Faixa etária em anos | Média de idade em anos | Testes avaliativos | Resultados | Conclusão |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 12. | Walkowiak et al.[28] | 2011/ Poland | Case report | C/4 | To assess the viability of using ESRT and ECAP in the speech processor programming of a Medel CI | 30 users of CI | 18 to 66 | 45 | ESRT, ECAP, and C level | In the adult population, the correlation between the ESRT and C level was better for apical, medial, and basal electrodes than between ECAP and C level. There was no significant difference in the mean values obtained for ECAP and ESRT in children and adults in any of the tested electrodes | Although ESRT has a better association with C levels, both ESRT and ECAP are useful in creating CI maps for children |

ESRT, electrically evoked stapedius reflex threshold; ECAP, electrically evoked compound action potential of the auditory nerve; BAEP, brainstem auditory electrically evoked potential; NRT, neural response telemetry; CI, cochlear implant; C level, level of maximum sensation intensity that the patient will accept for electrical stimulation without discomfort; T level, threshold for electrical stimulation.

objective tests, whether performed intraoperatively or postoperatively, for the purpose of comparison with behavioral tests, widely used in the definition of the dynamic range in the CI process.

It was at the same time of the first selected article,[12] between the 1980s and 1990s, that there was a great revolution in the area of CIs, due to increased investment in research. At the beginning of CI procedures in the 1980s, patients referred for CI surgery were those classified as having profound bilateral sensorineural hearing loss. However, over the years, with the observation of results and technological advancements, the indications were expanded and started to have broader criteria.

Currently, not only individuals with profound bilateral hearing loss are considered as possible candidates for the CI, but also those with severe and profound hearing loss with no benefit from a hearing aid, as well as other less classic indications such as for hybrid implants (acoustic electric stimulation).[15] This greater coverage led to a significant increase in potential candidates for CI surgery, and as a consequence, results of researches involving the subject have increased considerably.

The evolution of and faster diagnosis of hearing loss is also an illuminating point regarding the increase in the number of surgeries, especially in young children. According to the protocol of neonatal hearing screening, suggested by the Joint Committee on Infant Hearing in 2000,[29] the diagnosis should be made by 3 months of age, and intervention initiated by 6 months of age.

This change in profile of candidates for CI, exemplified by articles containing the pediatric range in their samples,[23,24] explains the growing need to include objective testing in the activation and mapping procedures of the CI. Unlike adults, who have the determination of energy levels of each of the CI electrodes performed through psychophysiological measurements, infants need more specific procedures, which require techniques that can be inconsistent and unsystematic due to the child's hearing inexperience or age. The process is characterized as much more arduous, and requires greater collaboration from the patient's family.

Especially for those children with pre-lingual hearing loss, as they do not have any hearing experience, changes in behavior and reflexes should be used to create individual activation maps.[5]

Knowing that an appropriate definition of the dynamic area (the region between the amount of current that first induces an auditory sensation [T level] and the level of maximum intensity of sensation that the patient will accept for electrical stimulation without discomfort [C level])[4,24] is the key to the success of the CI, most of the articles had ESRT and behavioral measures as single assessment tests.[18-23] These studies demonstrated that ESRT can very efficiently help in mapping the CI, especially when the goal is to safely define the C level.

Another important point concerns the other evaluation tests studied in addition to ESRT, especially ECAP, which consists of the action potential of the distal portion of the auditory nerve, which can be recorded during the intraoperative period directly in the cochlea, using the CI electrodes as stimulus generators and response recorders using specific software.[30] The comparison between ESRT and ECAP, observed in one study,[28] was performed precisely because ECAP is the measure of auditory nerve activity most commonly used in CI users, since ECAP's thresholds can be useful to predict minimum and maximum levels that should be used to program the speech processor,[31] and ESRT can be useful to assess the maximum comfort level in adults and children using CI.[15]

Three other studies[17,24,25] used, in addition to ESRT and ECAP, the BAEP, an objective measure of great assistance in CI procedures, but with higher susceptibility to electrical noise artifacts.[32] According to one study,[17] the BAEP was shown to be a more reliable measure than the ECAP and the ESRT. However, since this study aimed to analyze the effectiveness of such objective techniques in the speech processor programming of CI users in a total sample of 35 individuals (20 in the study group, with cochlear malformations, and 15 in the control group) the conclusion which showed BAEP as the most reliable measure is justified by the sample, which was different from the other studies.

Another assessment test used in one study,[26] NRT, is used in clinical routine for programming the CI in order to predict the best levels of electrical stimulation.[9,23,32,33] Including this measure in studies is important because virtually all programming methods available and recommended by the manufacturers currently use NRT measures for mapping the CI. This is possibly due to the fact that NRT can be adjusted or combined with fully objective methods, such as programming by a correction factor, by preset progressive maps, or by adjusting the speaker. The programming software allows for the importing of thresholds obtained by the NRT and automatically combines them with the psychoacoustic levels obtained through the behavioral test in at least one of the electrodes.

Some scholars argue that NRT can be reliably used as a starting point to define initial levels of connection, as it is found between the T and C levels.[34] Indeed, clinical experience suggests that NRT in the postoperative period is more easily found than ESRT. However, when possible, the combination of NRT and ESRT, as well as other objective measures, tend to add valuable information for the team responsible for the CI speech processor programming, since the measures of comfort may be too high or too low in children when determining the dynamic field based solely on behavioral responses.

Some studies have significant methodological limitations, since important data such as age and mean age of the studied sample were not identified.[17,18,20,21,25-27] Considering that some auditory responses are typical in certain age groups, the lack of such data weakens these studies and limits some inferences, as the procedures used during the mapping of the CI differ mainly regarding the patient's age and the time of hearing deprivation to the device activation.

The evaluation methods described in the studies included in this review used intraoperative techniques, postoperative techniques, or both.[22,27] Intraoperative visual assessment of the stapedius reflex is subject to difficulties, as bleeding and scar tissue in the middle ear tend to cause inaccuracy in the observation of muscle contractions. In one study,[27] despite the visual aspects and tympanometry that showed nearly identical intraoperative thresholds, the ESRT was higher intraoperatively than postoperatively, a fact that can be explained by the action of anesthetics, which may weaken the stapedius reflex during surgery.[35-37]

The results of the 12 articles selected for the present review suggest that the objective tests, especially ESRT, whether performed intra- or postoperatively, significantly help the team responsible for surgery and rehabilitation of patients submitted to CI. The comparison of methods of measurement allows the team to be more confident regarding the results; thus, the process becomes faster and safer, as the behavioral assessment will be assisted by objective measures.

Based on these data, it is observed that ESRT can be included as valid information to be used as a parameter in the standard procedures of the CI process, since its contributions are positive to both activation and mapping of this device.

## Conclusion

Based on the studies included in this literature review, it can be concluded that:

- ESRT, whether measured intra- or postoperatively, is an objective measure that can help in programming the CI device, especially in patients with inconsistent responses.
- The combination of objective and behavioral tests during the programming of the speech processor of the CI should be used to avoid setting very high-intensity maximum levels of sensation.
- This combination makes the process faster and safe, even for infants, small children, or individuals with multiple disorders.

## Conflicts of interest

The authors declare no conflicts of interest.

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