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ORIGINAL ARTICLE

Study of the relationship of stapedial reflex thresholds induced during cochlear implant surgery and the highest hearing comfort of paediatric patients

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Cochlear implant;
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Abstract
Introduction and goals: We have studied the relationship between the minimum stapedial reflex thresholds induced by means of the intra-operative stimulation of the cochlear implant and the post-operative thresholds of highest auditory comfort level.
Methods: We have assessed the maximum auditory comfort at the end of the first and second quarters following activation of the cochlear implant, by which time the strategy for codification of the stimuli and the programming map are considered to be already stable. The study was carried out at our cochlear implants unit. All the patients in the study had bilateral sensorineural deafness of varying aetiology and, following our standardized battery of diagnostic tests, were considered to be good candidates for cochlear implant. All aspects of the surgical technique were kept the same in order to be able to compare the results better. All members of the study were fitted with at least one Nucleus Freedom implant with Contour Advance Electrode.
Results: This study has been carried out on 24 cochlear implants placed in 22 patients younger than 14 years old.
Conclusions: After assessing our experience, we can conclude that, in the Nucleus Freedom with Contour Advance Electrode cochlear implant, there is a positive statistical relationship between the levels of acoustic reflex induction obtained at the peri-operative stage and the levels of maximum auditory comfort, as determined by behavioural observation techniques for each of the different electrodes, in children up to 14 years old.

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PALABRAS CLAVE
Implante coclear;
Programación;
Reflejo estapedial

Estudio de la correlación entre los umbrales del reflejo estapedial inducido durante la cirugía del implante coclear y la máxima comodidad auditiva del paciente pediátrico

Resumen
Introducción y objetivos: Hemos estudiado la relación entre los umbrales mínimos del reflejo estapedial, inducidos mediante la estimulación intraoperatoria del implante coclear, y los umbrales postoperatorios de máxima confortabilidad auditiva.
Métodos: Hemos valorado dicha confortabilidad auditiva al final del primero y el segundo trimestre, tras la activación del implante coclear, momento en el que se considera que la estrategia de codificación de los estímulos y el mapa de programación utilizados ya son estables. El estudio ha sido realizado en nuestra unidad de implantes cocleares. Todos los pacientes en estudio, afectos de hipoacusia neurosensorial bilateral plurietiológica, tras la realización de nuestra sistemática protocolizada de pruebas diagnósticas, fueron considerados como buenos candidatos para la implantación coclear. La técnica quirúrgica se ha uniformizado al máximo en todos sus aspectos, a fin de poder comparar mejor sus resultados. Todos los integrantes del estudio eran portadores de, al menos, un implante Nucleus Freedom con Contour Advance Electrode.
Resultados: Este estudio se ha realizado sobre 24 implantaciones cocleares realizadas en 22 pacientes menores de 14 años.
Conclusiones: Tras la valoración de nuestra experiencia, podemos concluir que, en el modelo Cochlear Freedom con Contour Advance Electrode, hay una relación estadística positiva entre los grados de inducción del reflejo estapedial obtenidos peroperatoriamente y los grados de máximo confort auditivo determinados mediante técnicas de observación del comportamiento, para cada uno de los diferentes electrodos, en niños de hasta 14 años de edad.

Introduction

At present, cochlear implantation is considered the treatment of choice for all patients suffering from severe or profound bilateral sensorineural hypoacusis, and whose maximum rate of intelligibility does not exceed 50% of understanding, in an open field determination using the most powerful hearing aids suitable for each case.[1] At present, some authors even indicate a cochlear implant for situations with intelligibility rates below 70%, obtained under the conditions expressed above.[2]

However, cochlear implantation requires, at a time after surgery, the programming of each of the electrodes, according to different stimulation strategies, to achieve optimal hearing results.

The activation process of the cochlear implant is performed with a processor using so-called units of current ranging from 1 to 225, which correspond to units of measurement of intensity ranging between 0.01 mA and 1.75 mA, respectively.

One of the most important aspects of the operation of the cochlear implant is the degree of hearing comfort, also known as degree of maximum comfort. This refers to the maximum intensity the user of the cochlear implant can receive without it causing unpleasant or annoying auditory sensations.

The hearing comfort of the patient and, consequently, the functional success of the cochlear implantation depend on both the implantation surgery and the appropriateness of the programming of the cochlear implant.

Indeed, the degrees of stimulation of each electrode in the stimulation strategy chosen, ie, what is known as the "stimulation map" must be appropriately established during the first months of hearing rehabilitation and will optimize the auditory comfort level (C) and the hearing threshold level (T) of the child.

Thus, the choice of the previously mentioned degrees of stimulation for the electrodes, in each of the strategies used, is a meticulous process, in which the adult patient must collaborate in order to achieve the best auditory performance of the implanted device.

However, in the case of children, this activation process and organization of the strategy and of the degrees of stimulation of the cochlear implant will result much more laborious and will require greater collaboration from the family of the patient.

Especially in the case of an infant or young child, the changes in behaviour and involuntary reflexes that may take place are the considerations which must be used in the creation of individual activation maps.

This difficulty is accentuated in situations where the patient, child or adult, in addition to age limitations, suffers multiple deficit syndrome, which may, in addition, produce communicative or cognitive defects.

Therefore, at this point in the investigation of cochlear implantology, it is very important to establish objective parameters which facilitate, in children or in patients unable to cooperate, the identification of appropriate stimulation thresholds.

In this regard, the current technological development allows us, intra-operatively during implantation, to perform a series of determinations, including measurement of the impedance of the electrodes, the evaluation of the stapedius reflex threshold and the obtention of neural response to

stimulation, which can be measured to obtain data allowing better post-operative performance of the cochlear implant, especially in the situations mentioned above.

These peri-operative determinations do not result uncomfortable for the patient, as they are carried out whilst under the effects of general anaesthesia and analgesia, despite taking place in extreme stimulation conditions and continuing for as long as necessary.

Of all the possible determinations of the hearing function which may be performed peri-operatively, we have chosen for this study only the intra-operative induction of stapedial reflex.

The stapedial reflex is defined as a protective stapedial reflex response of the auditory system against high intensity sounds, through a contraction of the stapes muscle fundamentally, although there is also a contraction of the hammer muscle.

In daily clinical practice, it is possible to evaluate the threshold of this reflex using tympanometers, which can assess changes in impedance of the eardrum-ossicular system. Under these study conditions, the threshold for triggering the stapedial reflex is approximately 70 dB above the hearing threshold of the subject, for stimulations verified with 50-4000 Hz tones. With contralateral stimuli, in children, the reflex threshold is slightly higher.

The nerve pathway that triggers the stapedial reflex is polysynaptic, as it uses four neural stations: the first, the organ of Corti; the second in the ventral cochlear nucleus; the third, the interneurons of the medial, ipsilateral and contralateral superior olive; and the fourth, the medial neurons of the motor nucleus of the facial nerve.

In certain cases of transmission hearing loss, this reflex can be abolished; in cochlear hearing loss it may be present with hearing loss of 60 dB, and in retrocochlear hearing loss it can be abolished, even with mild hearing loss.

The purpose of our study is to verify whether the stapedius reflex threshold, established through peri-operative stimulation of different electrodes, can be used as a reference value for the subsequent calculation of the maximum degree of hearing comfort in the implanted child.

Methods

In the study described below we have included 24 cases of cochlear implantation in 22 patients, between 1 and 14 years of age, operated on at our cochlear implant unit.

Each of the subjects included in the study underwent a surgical technique of cochlear implantation for the treatment of bilateral sensorineural hearing loss.

Implantations were carried out during the period between July 2005, and June 2007.

All our patients were fitted with a Freedom type Nucleus implant (Cochlear Corporation®) with Contour Advance Electrode.

The stapedial reflex was induced in all of them during surgery for cochlear implantation, in the same 5 electrodes of the beam, composed of 22 electrodes, and successfully introduced into the cochlea at a comparable depth of insertion.

The electrodes selected for this measurement are those occupying positions 22, 16, 11, 6, and 1 (from the apex to the basal spiral).

The complete study population were 22 patients, since 2 of our cases included bilateral implantation, of which 8 (36.36%) were male and 14 (63.7%) were female.

The aetiology of hearing loss is shown in Table.

Logically, we have excluded from the study those patients with stapedial fixation syndrome, auditory malformation, auditory neuropathy, and those in whom the surgical technique or some other illness made it impossible to obtain a stapedial reflex that could be evaluated.

The following were used for the different electrophysiological determinations: the Custom Sound EP v1.2.5 electrophysiology software for Freedom implant model and the Custom Sound v1.2.6 programming software for Freedom implants and Freedom processor.

Cochlear implantation was performed in the otolaryngology service of the hospital, a referral centre for the early diagnosis and treatment of profound hearing loss in our region.

This implant centre has been working in the framework of the Program for Diagnosis and Treatment of Profound Deafness since 1995, when the first cochlear implantation was carried out.

All the different aspects of our activity are protocolized in action guidelines subject to constant review.

The procedure for general anaesthesia is always performed by the same specialist in anaesthesiology, who carries out his activity in such a way that it cannot influence the intra-operative neurophysiologic determinations under study.[3,4]

The same surgeons always perform the surgery, and verify that the introduction of the device is comparable in all cases.

Thus, after the introduction of the beam of electrodes through the orifice of the cochleostomy, and prior to its sealing, the stapedial reflex is measured using the software and hardware provided by Cochlear Corporation, as specified earlier.

Along with this determination, an impedance test and a test for determining neural response are also systematically carried out.

The intra-operative measurement of the stapedial reflex is carried out only on 5 electrodes of the total making up the implant, distributed in a permanent way, from 1 to 22, always taking as reference the same electrodes in all patients in the study: electrodes 1, 6, 11, 16, and 22. Thus, we obtain measurements of electrodes from the apex to the cochlear basal spiral.

The evaluation of the triggering of the stapedial reflex is always carried out by the same surgeon, using the surgical microscope and a monitor image which greatly amplifies the presence of muscle contraction, enabling highly reliable data; any minimal contraction of the stapes muscle occurring after adequate stimulation is considered as a positive reflex.

Similarly, data have been collected at the patients' activation sessions, 3 and 6 months after implantation, when a programming session takes place with the audiologist from Cochlear and an activation map is created, from which the patients' hearing comfort threshold has been obtained (C level).

Table 1 Aetiopathogenic and epidemiological data on our study group

Patient	Gender	Age, y	Aetiology	Date of implant	Insertion	Type of implant
1	Female	4	Genetic	20-7-2005	T	Contour advanced
2	Male	3	Genetic	21-9-2005	T	Contour advanced
3	Female		Genetic	14-12-2005	T	Contour advanced
4	Male	3	Premature	25-1-2006	T	Contour advanced
5	Female	3	Connexin 26	15-2-2006	T	Contour advanced
6	Female	2	After meningitis	8-3-2006	T	Contour advanced
7	Male	4	Blood relationship	23-3-2006	T	Contour advanced
8	Male	2	Blood relationship	29-3-2006	T	Contour advanced
9	Female	4	Premature	21-4-2006	T	Contour advanced
10	Male	7	Ototoxicity	24-5-2006	T	Contour advanced
11	Female	6	Ototoxicity (?)	31-5-2006	T	Contour advanced
12	Female	3	Genetic	28-6-2006	T	Contour advanced
13	Male	2	Genetic	30-6-2006	T	Contour advanced
14	Female	1	Premature	28-7-2006	T	Contour advanced
15	Female	2	Blood relationship	6-9-2006	T	Contour advanced
16	Female	8	Genetic	17-11-2006	T	Contour advanced
17	Female	5	Premature	10-1-2007	T	Contour advanced
18	Male	2	Genetic	28-2-2007	T	Contour advanced
19	Female	2	Genetic	23-5-2007	T	Contour advanced
20	Female	6	Genetic	6-6-2007	T	Contour advanced
21	Female	1	After meningitis	13-6-2007	T	Contour advanced
22	Male	1	Blood relationship	20-6-2007	T	Contour advanced

P indicates partial; T, total.

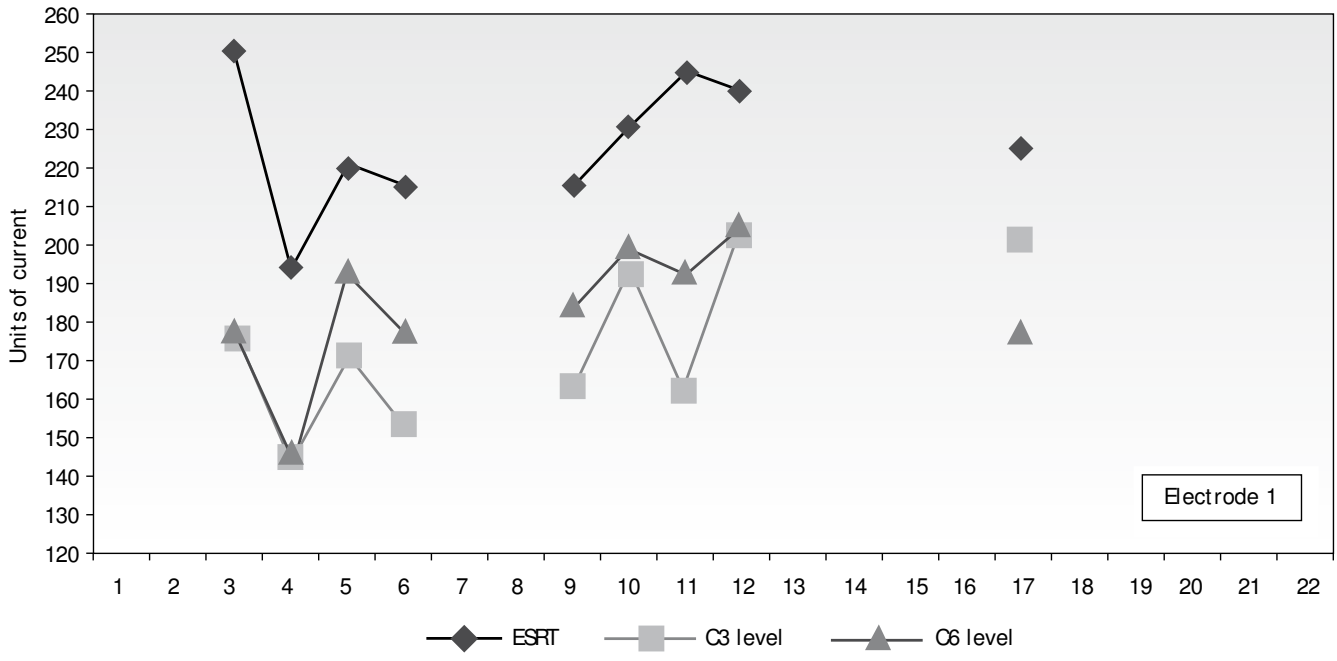

Figure 1 Representation of the ESRT values from electrode 1 during peri-operative stimulation, as well as the comfort values obtained at the end of the first and second quarters, after the activation of the cochlear implant, in all cases studied.

For analysis of the data obtained we used the SPSS statistical program, and a study of linear correlation through the Pearson correlation coefficient was performed to measure the linear relationship between quantitative variables.

Results

Figures 1-5 present the results obtained by determining the stapedius reflex threshold in the electrodes indicated.

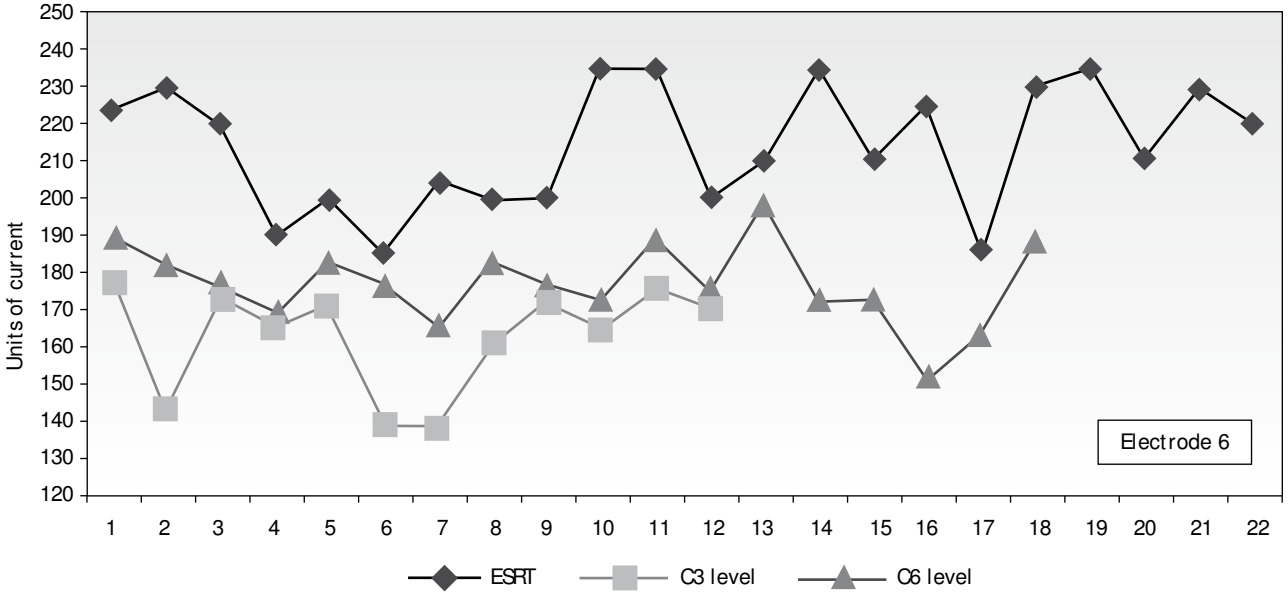

Figure 2 Representation of the ESRT values from electrode 6 during peri-operative stimulation as well as the comfort values obtained at the end of the first and second quarters, after the activation of the cochlear implant, in all cases studied.

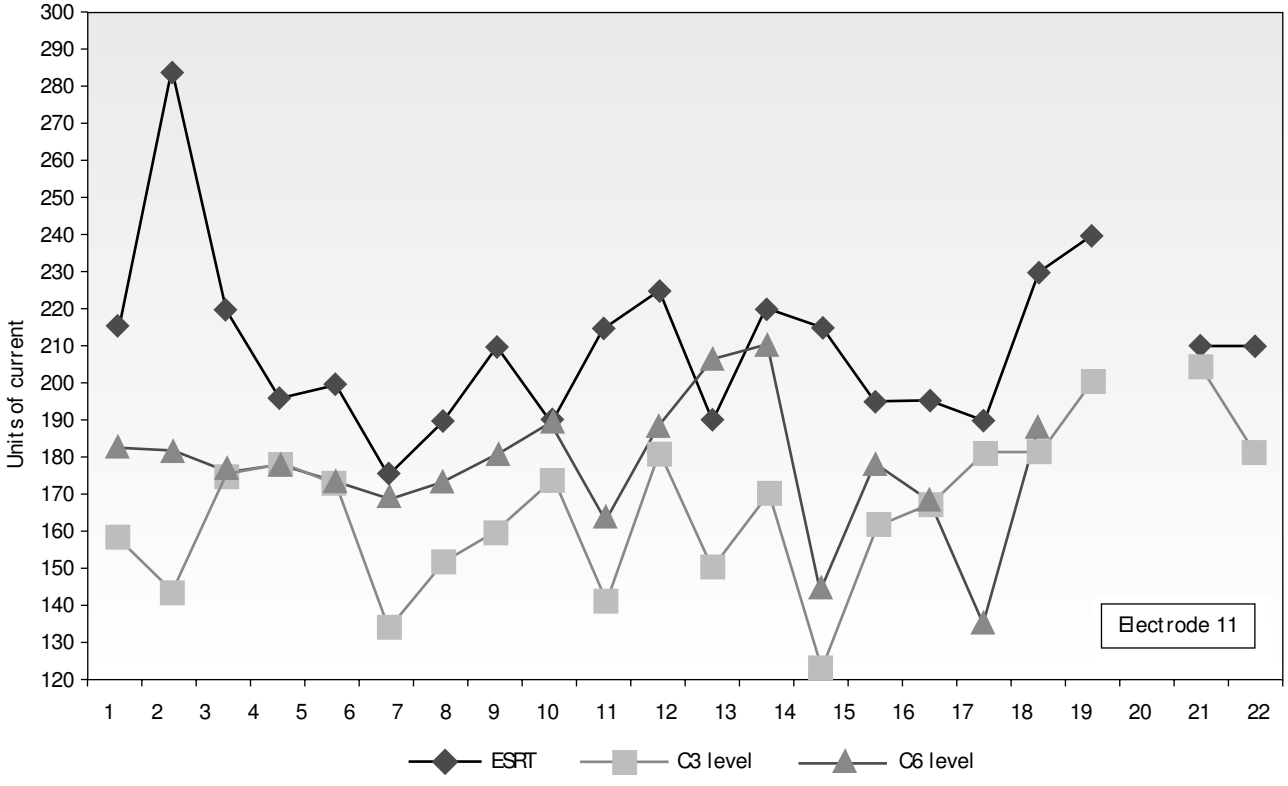

Figure 3 Representation of the ESRT values from electrode 11 during peri-operative stimulation as well as the comfort values obtained at the end of the first and second quarters, after the activation of the cochlear implant, in all cases studied.

The graphs are linear, showing the values obtained by stimulating the stapedial reflex intra-operatively, in each of the electrodes considered in the study, in all cases included. These results are presented as a group in Figure 6. In electrode 1, the values of ESRT exceed an average of 52 units of current, at level C, at the end of first term, and an average of 45 units of current at the end of the semester, as shown in Figure 1.

In the case of electrode 6, we found an average of 42 and 37 units of current, in ESRT stimulation, above the hearing

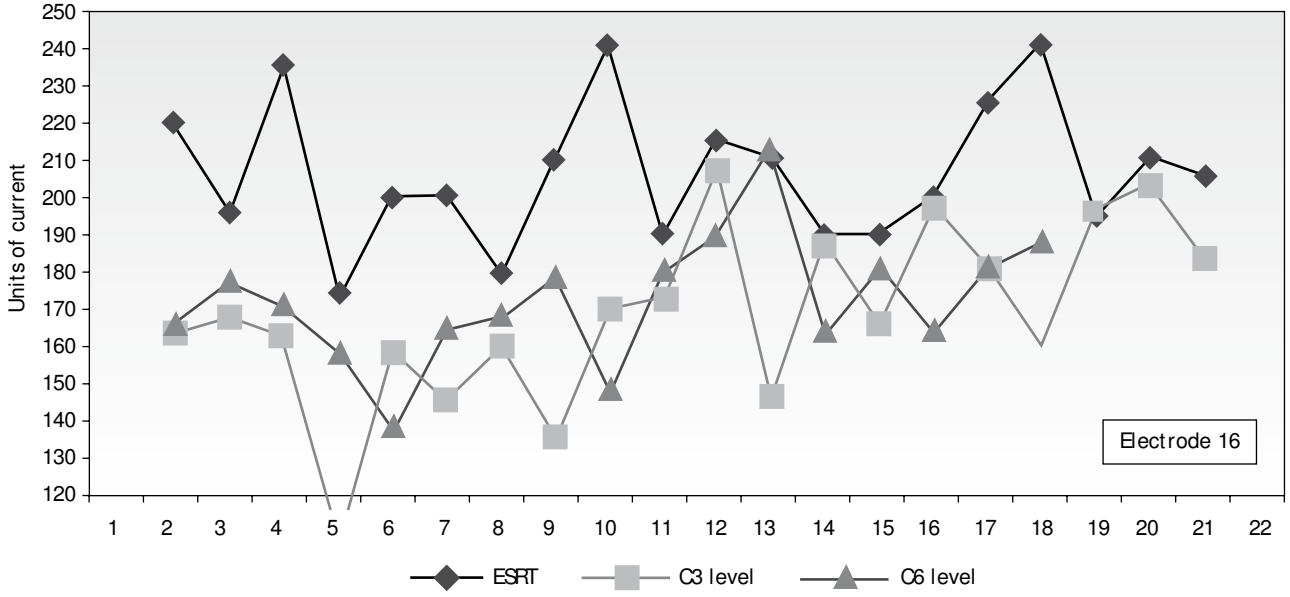

Figure 4 Representation of the ESRT values from electrode 16 during peri-operative stimulation as well as the comfort values obtained at the end of the first and second quarters, after activation of the cochlear implant, in all cases studied.

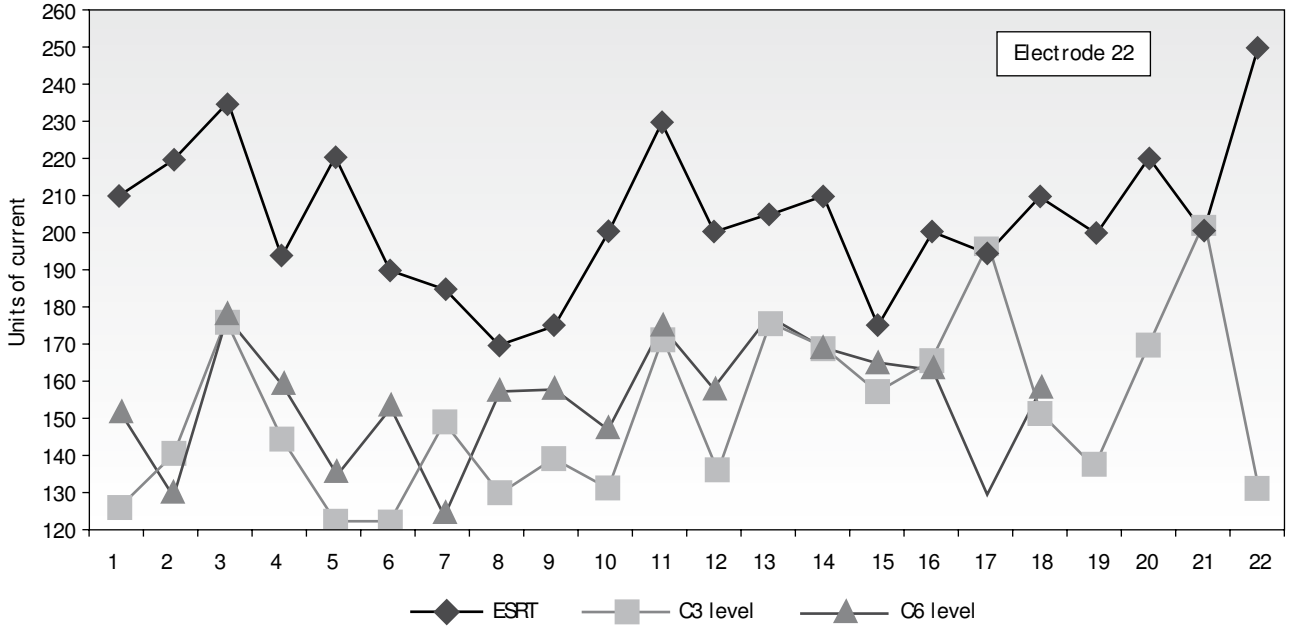

Figure 5 Representation of the ESRT values from electrode 22 during peri-operative stimulation as well as the comfort values obtained at the end of the first and second quarters, after activation of the cochlear implant, in all cases studied.

comfort level at the end of the first and second quarters, respectively, as presented in Figure 2.

In the case of electrode 11, the difference between ESRT and the C level, after 3 months, was shown to be 44 units of current, decreasing to 32 when studying the same electrode in the sixth month after activation, as shown in Figure 3.

In the case electrode 16, the result is an average of 37 units of current above the comfort level (C level) after 3 months; the difference is reduced to 33 units of current, in the sixth month, as is shown in Figure 4.

Finally, in the case of electrode 22, ESRT exceeds the level of hearing comfort by 52 units of current, after 3 months of activation, and by 46 units of current after 6 months, as shown in Figure 5.

In the general consideration of all the electrodes, it can be observed that during the first quarter after the initial programming, the difference between the ESRT and the level of hearing comfort is 45.4 units of current and at the end of the first semester the difference between both values is 39 units of current.

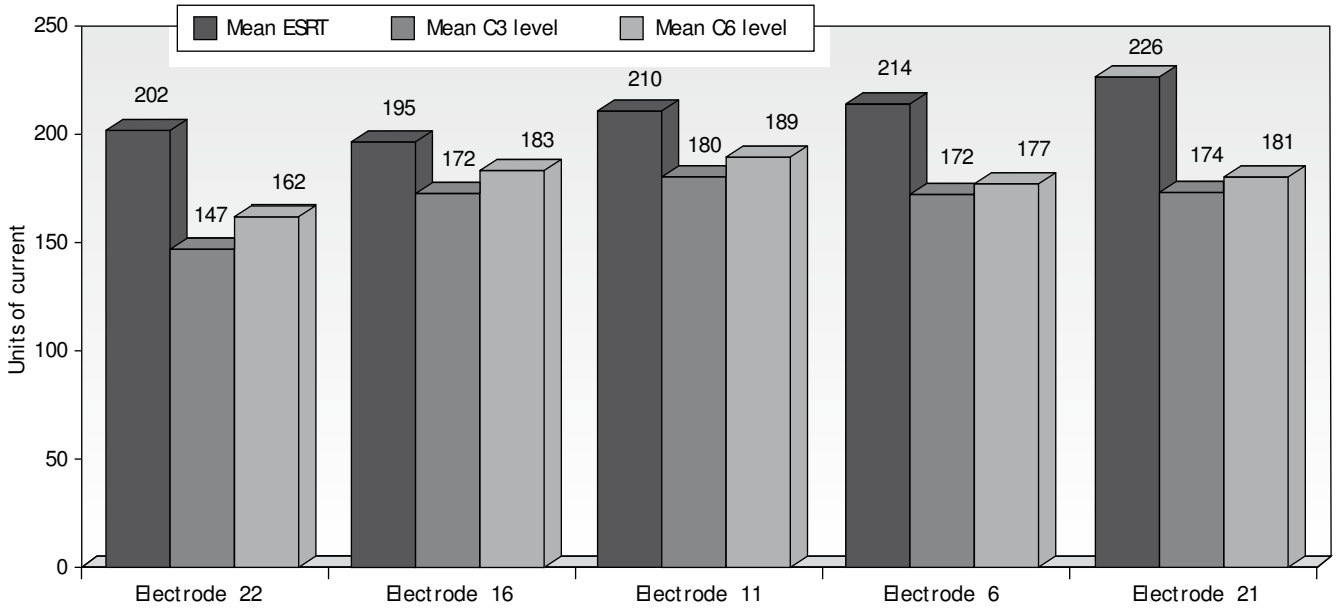

Figure 6 Representation of the ESRT values obtained intra-operatively and the degrees of hearing comfort established at the end of the first and second quarter, after activation of the cochlear implant, for the different electrodes considered in the study.

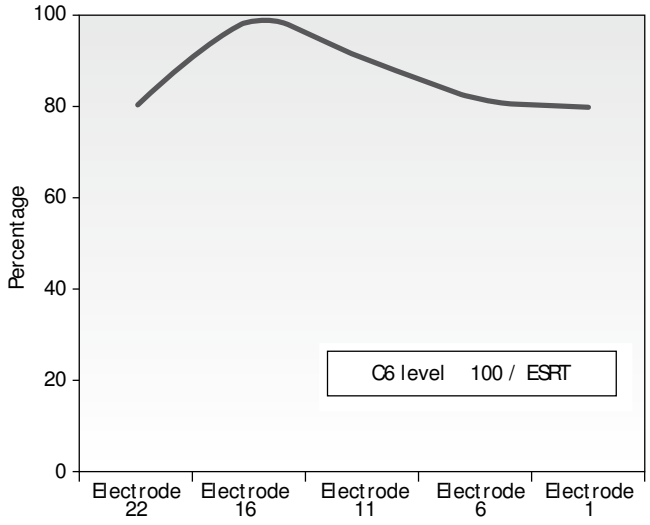

Figure 7 Expression of the percentage relationship between the values of the stapedius reflex threshold, established through peri-operative stimulation of the different electrodes, and the subsequent calculation of the maximum hearing comfort, 6 months after cochlear implant activation, in each of the electrodes studied.

Regarding the statistical treatment of data using the Pearson test, the results show that, for all electrodes studied, the degree of comfort at 3 and 6 months presents a positive correlation regarding the degree of intra-operative stapedial reflex.

The correlation in the levels at 6 months shows a range of 0.142-0.656, and is greater than the interval of the levels at 3 months, which varies between 0.07 and 0.537.

Discussion

Since the beginning, the aim has always been the use of an objective method to allow optimization of the various systems to improve hearing.

Historically, Burnett et al[5] found, in 1984, the effectiveness of stapedial reflexes to establish the appropriateness of hearing aids in animal experiments.

On the other hand, in adults, it has been attempted to compare the electrically triggered stapedial reflex, through a cochlear implant, and the acoustically triggered stapedial reflex, outside the operative period; in both cases, the triggering thresholds were similar, although the amplitude of the response and the wave form of the response were different.[6]

Jerger et al[7] and Gattaz et al[8] have made preliminary studies in previous models of cochlear implant, such as the Nucleus Contour and others. Indeed, in these models the different authors argue that the levels of electrical stimulation through the cochlear implant may be indicative of the degrees of discomfort in the later programming of the Nucleus Contour models in some patients,[9] and that these determinations can be used as guidance for the setting of the thresholds of hearing comfort, although their results should be used with caution.[10]

Subsequently, some authors pointed to the exact match between the thresholds of electrically triggered stapedial reflex and the thresholds of acoustic discomfort, both determined post-operatively.[11]

Later, the thresholds of auditory discomfort were studied, determined peri-operatively in the Nucleus Contour models, and a large coincidence was found between the 2 determinations.[12,13] However, these determinations had not been carried out, until now, in a sufficient number of patients implanted with the Freedom model with Contour

Advance Electrode, which has completely different features from previous models.

Our study determines the relationship between the stapedius reflex threshold, established by peri-operative stimulation of different electrodes, and the subsequent calculation of the maximum hearing comfort (C level) in the current Freedom models with Contour Advance Electrode.

Analyzing the data from the induction of the stapedial reflex at each electrode separately, we can conclude that, in all selected electrodes, the value obtained intra-operatively for the induced reflex is higher than the C level in the activation maps, in the conditions of our study, as shown in Figure 6. This is logical when we consider that the triggering intensity of the peri-operative stapedial reflex is an intensity of discomfort, thus the later level of comfort must inevitably be lower.

This gives additional support for the consistency of the study and informs us, moreover, of the narrow dynamic range of electrical stimulation of the cochlear implant and the need for precise programming with the aim of obtaining the best results for auditory function.

These data are consistent with the literature reviewed[4,14,15] in determinations carried out with other models of cochlear implant.

The special disposition of the Freedom model with Contour Advance Electrode makes it possible to establish a more accurate numerical relationship and with high predictive capacity with respect to the degree of patient comfort.

In fact, the graphical assessment of the results obtained 6 months after cochlear implant activation allows for an accurate relationship to be established, for each of the electrodes of the Freedom model, between the stapedius reflex threshold established by peri-operative stimulation of the different electrodes, and the subsequent calculation of the maximum hearing comfort (C level), as shown in Figure 7.

In this graph, it is clear that in the electrodes 1, 6, and 22 the percentage deviation is higher than in the central electrodes 11 and 16.

This can be explained, in the case of electrode 1, by the fact that in many patients there is a certain distance between the placement of the electrode and the area of interest, to the extent that, in some cases, there may be no stapedial reflex at that level.

In the case of electrodes 11 and 16, which have triggering intensities for the stapedial reflex, ie, hearing discomfort, generally very close to the maximum comfort level, thus reducing the range of action to 10% and 2% respectively, the result can be as follows: firstly, as a consequence of the greater proximity of these central electrodes to the area of interest, in the cochlea, probably by the special architecture and organization of the beam holding the electrodes, and secondly, we must consider that, 6 months after implantation, the concept of hearing comfort in children is controversial, because their initial sensations, whatever they may be, may in many cases seem unpleasant.

In the case of electrode 22, the greater difference between the 2 thresholds must be attributed to a greater anatomical distance between the most distal electrode and the area of stimulation in the cochlea.

In any of the cases, the values obtained at the time of surgery can be used as a prediction of what will be the approximate value of hearing comfort; in addition they will be very useful in knowing the maximum values we can achieve at the time of initiating activation in a patient with prelocutory hearing loss.

Conclusions

The values obtained for intra-operative induction of the stapedial reflex in any of the electrodes studied are above the C level of hearing comfort obtained in the activation maps over a period of 3 months.

Six months after activation, there is a *rapprochement* between the 2 values, expressed in units of current, through a statistical relationship that is different for each electrode.

This allows a prediction during surgery, by means of a peri-operative determination for each of the electrodes, of closely approximate values of hearing comfort after 6 months of activation.

All this allows us to conclude the usefulness of knowing, at the time of initiating the activation of a cochlear implant in a patient, the maximum values of auditory functionality which we can achieve later.

This possibility is especially useful in implanted children.

Conflict of interests

The authors have indicated there is no conflict of interest.

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