

Equations to establish a regression between current units with respect to patient's age and the use time of cochlear implants

Ecuaciones para establecer una regresión entre las unidades de corriente con respecto a la edad del paciente y el tiempo de uso de los implantes cocleares

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Abstract

Objective: Propose a system of multivariate multiple regression equations in order to establish a mathematical association that allows estimating the current units needed during the adjustment phase with respect to age and time that were used the implants. **Method:** Descriptive cross-sectional study. A total of 41 pediatric patients with a unilateral cochlear implant participated. Three groups were formed and multivariable multiple regression equations were constructed. **Results:** For Group 1, in electrode Groups 3 and 4, there is a lower standard deviation and a similar index of asymmetry of the current units; in Group 2, the groups of electrodes with similar index of asymmetry were 2 and 4, while group of electrodes 3 presented average of 21.54 and dispersion smaller (16.25); in Group 3, groups of electrodes 3 and 4 presented similar standard deviation and average and smaller standard deviation. With respect to the standard estimation error, the lowest variability of current units was obtained in Group 2 for electrode Group 3. **Conclusion:** The proposed equations could be used in the clinical area by knowing the units current needed with respect to age and time of use the implant.

Key words: Electrode group. Cochlear implant. Current units.

Resumen

Objetivo: Proponer un sistema de ecuaciones de regresión múltiple multivariable para establecer una asociación matemática que permita estimar las unidades de corriente necesarias durante la fase de ajuste con respecto a la edad y el tiempo de uso del implante coclear. **Método:** Estudio transversal descriptivo. Participaron 41 pacientes pediátricos con implante coclear unilateral. Se conformaron tres grupos y se construyeron ecuaciones de regresión múltiple multivariable. **Resultados:** Para el grupo 1 se observa en los grupos de electrodos 3 y 4 menor desviación estándar y similar índice de asimetría de las unidades de corriente; en el grupo 2, los grupos de electrodos con similar índice de asimetría fueron el 2 y el 4, y el grupo de electrodos 3 presentó un promedio de 21.54 y una dispersión más pequeña (16,25); en el grupo 3, los grupos de electrodos 3 y 4 presentaron similar desviación estándar y promedio y desviación estándar más pequeños. Con respecto al error estándar

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de estimación, se obtuvo una menor variabilidad de unidades de corriente en el grupo 2 para el grupo de electrodos 3. **Conclusión:** Las ecuaciones propuestas son de utilidad clínica al conocer las unidades de corriente necesarias considerando la edad y el tiempo de uso del implante coclear.

Palabras clave: Grupo de electrodos. Implante coclear. Unidades de corriente.

Introduction

The World Health Organization reported in 2018 a prevalence of 466 million people with hearing disability in the world, out of which 34 million are pediatric population¹. In Mexico, the 2010 Population and Housing Census reported that 12.1% of Mexicans with disabilities suffered from hearing problems², and, in 2014, the General Directorate of Analysis and Prospective, with data from the National Household Income and Expenditure Survey, indicated that the population of individuals with some type of hearing disability who wanted to be admitted to some public program was 1.4 million (18.3%), of a potential population of 7.7 million³.

Cochlear implant is a small and complex electronic device that facilitates the perception of sound to people with profound or severe sensorineural hearing loss. In recent years, these devices have become quite popular and, by December 2012, approximately 324,200 devices had been implanted worldwide. Cochlear implant adaptation requires a surgical procedure and audiological follow-up to guarantee its coupling and optimal functioning⁴, which is achieved by programming the device based on periodic adjustments of psychophysical and neurophysiological⁵ parameters related to stimulation and signal processing⁶.

Determination of thresholds

In the cochlear implant programming process, the generation of hearing maps is fundamental, where the electric field required by each patient is recorded in order to establish the amount of microvolts necessary to generate the hearing sensation⁷⁻¹⁰. They are determined by the electrical stimulation threshold or T-threshold (TT), which corresponds to the lowest amount of current that produces a hearing sensation, and the comfort threshold or C/M threshold (C/MT), corresponding to the highest level of electrical stimulation the patient refers to as a comfortable sound^{5,6,11,12}. TT and C/MT determination is based on sound psychophysical judgments measured in clinical units of

electric current, often referred to as current units (CU) or charge units^{7-10,13,14}.

C/MT can be obtained by subjective tests (behavior observation), objective tests (neurophysiological response) or a combination of both^{11,13}. Threshold detection is carried out on all cochlear implant electrodes, which are tonotopically located in the cochlea representing the different frequency bands (low, medium and high pitch); other important parameters that are considered during adjustment are speed, signal coding strategy, pulse width and stimulation mode^{13,14}.

Deficiencies in C/MT calibration or activation generate inadequate reception of acoustic signals representative of the spectral band associated with the electrodes, thus altering voice recognition, hindering sound quality and limiting patient voice self-control abilities; on the other hand, under-stimulation or over-stimulation has been reported to generate weak or highly intense sounds, which causes an uncomfortable perception of acoustic signals and makes voice recognition difficult, affects sound quality or causes implant aversion^{5,15}. Thresholds and the amount of electrical current required to trigger the hearing sensation are different in each patient and, therefore, programming of the speech processor must be individualized for each channel^{5,16}.

Current units

Current units (CUs) are numerical values used to designate the amount of current released to the electrodes⁷ in order to determine the electrical stimulation threshold (least amount of electrical stimulation) required by the patient. The name assigned to both parameters varies depending on the manufacturer of the cochlear implant (clinical unit, current level, current unit or charge unit)^{5,17,18}.

Cochlear implant adjustment with subjective assessment methods

Audiometry as a psychoacoustic measurement technique can be a subjective method given that it generates difficulty in reliably obtaining the audiological

threshold during cochlear implant calibration, due to factors such as patient age (early age), neurological, behavioral or cognitive comorbidity associated with the hearing impairment¹⁹.

Cochlear implant adjustment with objective assessment methods

Electrically evoked stapedial reflex (ESR)²⁰, neural response telemetry, brainstem auditory evoked potentials (BAEPs), cognitive evoked potentials, neural response imaging, and action potentials with electrical component (APEC) are some of the objective clinical tools that allow determining the CU required during adjustment process^{10,16,20-22}.

APECs are the most commonly used in the evaluation of auditory nerve activity, which corresponds to wave I in BAEPs in cochlear implant users²³. The threshold for these potentials is generally between the TT and C/MT levels (sometimes measured by behavioral reactions observed in patients), and this is why APEC, BAEP and ESR are used during the generation of auditory maps as objective assessment methods to obtain these thresholds, mainly in pediatric patients^{16,24-27}. In the case of BAEPs, V-wave amplitude increases when stimulation levels are augmented²⁸. Walkowiak et al.²⁷ and Kama¹⁷ reported that there is a strong correlation between ESR and C/MT for each electrode. The correlation coefficient between C/MT and ESR is significantly higher ($r = 0.75$); conversely, in the correlation between C/MT and APEC, the value was $r = 0.39$.

ESR in cochlear implant adjustment

Various studies report that ESR is an electrophysiological test that should be considered in cochlear implant activation process and for the generation of auditory maps, as it positively influences aspects of time, quality and patient well-being^{7,9,11,16,29}. Furthermore, it has been possible to establish that this study allows determining the correct functioning of the cochlear implant, as well as of the auditory pathway and its connection with the ipsilateral and contralateral motor nuclei of the 8th cranial nerve at the level of the brainstem^{20,30}. Lorens et al.³¹ demonstrated that programming of the cochlear implant based on ESR response to obtain C/MT produces better results than programming carried out with behavioral tests.

Raghunandhan et al.¹⁰ analyzed the electrode thresholds to obtain ESR and observed a gradual

ascending increase, from those arranged in the apical region (low frequencies) to those located in the basal region (high frequencies); consequently, the same was observed in C/MT values, with an average of 36.3 CU (± 7 standard deviations) between both regions (apical and basal) in patients with 1-year experience of cochlear implant use. The highest C/MTs were located in the cochlear basal region, which implied the need for stronger impulses for the electrodes in this region, which is characterized for having a high density of spiral ganglia that code for auditory stimulation high frequencies. Moreover, an increasing trend in C/MT over time has been reported to exist, with a gradual increase that starts with an average of 155 CU in the first month of use and reaches up to 272 CU by the end of the first year of implantation. When establishing an initial auditory map based on ESR in an uncooperative pediatric patient, care must be taken to avoid any level of mapping above the thresholds, since it can induce an uncomfortable response due to acoustic overstimulation¹⁰.

The purpose of this work is to propose a multivariate multiple regression equations system with the purpose to establish a mathematical association that allows estimating the necessary CUs during the adjustment phase with respect to patient age and cochlear implant usage time.

Method

Descriptive, cross-sectional study carried out at the pediatric audiology department of a high specialty hospital based in Mexico City. Forty-one patients with ages ranging between 2 years and 1 month and 7 years and 6 months with an Advanced Bionics® unilateral cochlear implant and a minimum usage time of 6 months participated. The protocol was approved by the Research and Ethics Committee. All parents or legal guardians, after being explained the interventions, signed an informed consent in accordance with the Declaration of Helsinki, informed consent was obtained from each one of the patients.

ESR obtainment

The Advanced Bionics Sound Wave® software, version 2.2, was used. Speech Burst stimulation was used to obtain the ESR of the ear contralateral to the implanted one, evaluating the 16 electrodes of the cochlear implant divided into four groups: the first group (EG1) includes electrodes 1 to 4; the second

group (EG2), electrodes 5 to 8; the third group (EG3), electrodes 9 to 12; and the fourth group (EG4), electrodes 13 to 16.

C/MT was the reference parameter to estimate the necessary CU to reach an ESR; when there was no response, CUs were gradually increased in units of 5 until it was identified (in case of discomfort, the CU increase was made 1 by 1 dB). During the test, the cochlear implant remained turned on to clinically test tolerance to live speech. The obtained ESR was corroborated on three occasions.

Statistical analysis

For the analysis, three groups were formed: group 1, made up of the entire sample ($n = 41$), 16 boys (39%) and 25 girls (61%), with an age of 2 years and 1 month to 7 years and 6 months; group 2, with 13 patients, 4 boys (30.8%) and 9 girls (69.2%), with an age of 2 years and 1 month to 3 years and 11 months; and group 3, with 28 patients, 12 boys (42.9%) and 16 girls (57.1%), with an age of 4 years to 7 years and 6 months.

For data analysis, descriptive statistics tests were used in order to know data behavior with regard to the mean and standard deviations of age, aid usage time, group of electrodes and current units variables.

Multiple regression equations were constructed to assess the necessary CU in the calibration of the cochlear implant in order to establish a possible association between CUs, age, and implant usage time.

The multiple regression model used was:

$$\hat{y} = b_0 + b_1x_1 + b_2x_2$$

where:

$\hat{y}$ = dependent variable estimated value (UC).

x_1, x_2 = predictor variables (x_1 = usage time and x_2 = age).

$b_0, b_1, b_2 = \beta_0, \beta_1, \beta_2$ sample estimates.

To calculate the equations the least squares method was used:

$$\sum y = b_0n + b_1 \sum x_1 + b_2 \sum x_2$$

$$\sum yx_1 = b_0 \sum x_1 + b_1 \sum (x_1)^2 + b_2 \sum x_1x_2$$

$$\sum yx_2 = b_0 \sum x_2 + b_1 \sum x_1x_2 + b_2 \sum (x_2)^2$$

To calculate the estimate standard error, the following formula was resorted to:

$$S_{yxs} = \sqrt{\frac{\sum (y - \hat{y})^2}{n - k}}$$

where:

S_{yxs} = estimate standard error.

y = (UC) sample values.

$\hat{y}$ = values calculated from the regression plane.

k = number of linearly independent parameters to be estimated (it is the number of b , in the equation $k = 3$).

n = sample size ($n_1 = 41, n_2 = 13, n_3 = 28$).

Results

In group 1, average age was 4.54 ± 1.36 years (mean $\pm$ standard deviation), α_3 asymmetry index was 0.511, indicating a distribution slightly skewed to the right due to the age range obtained by the study subjects (range = 5.4), and mean cochlear implant usage time was 1.82 ± 1.24 years. Analyzing the CU values that were used for the calibration of the implants of the patients in this group, the average obtained for EG1 was 22.39 ± 33.42 CU, with an asymmetry index of 1.94, indicating a distribution skewed to the right, defined by the 125 CU range; in EG2, the average was 24.85 ± 29.87 CU, with an asymmetry index of 1.651, distribution skewed to the right and a range of 115 CU; in EG3, the mean was 19.32 ± 21.6 CU, with an asymmetry index of 1.304, indicating a distribution skewed to the right and a range of 82 CU; and in EG4, the mean was 20.2 ± 22.21 CU, with an asymmetry index of 1.21, distribution skewed to the right and a range of 90 CU. EG3 and EG4 are observed to have a similar asymmetry index, with 1.304 and 1.21 CU respectively, with a difference between both of 0.094 CU; in addition, they show similar behavior in the average and standard deviation for being smaller in comparison with EG1 and EG2 (Table 1 and Fig. 1).

When group 2 ($n = 13$) descriptive statistics are analyzed, average age is observed to be 3.12 ± 0.48 years and α_3 asymmetry index -0.564, indicating a distribution slightly skewed to the left due to the age range obtained by the study subjects (range = 1.83), while mean usage time was 0.57 ± 0.48 years. When the CUs that were used to calibrate the implants of the patients in this group were analyzed, average for EG1 was found to be 19 ± 21.24 CU, with an asymmetry index of 1.014, indicating a distribution skewed to the right, defined by the 60-CU range; in EG2, average was 24.62 ± 18.08 CU, with an asymmetry index of 0.187, distribution slightly skewed to the right and a range of 55 CU; in EG3, the mean was 21.54 ± 16.25 CU, with an asymmetry index of 0.457, indicating a distribution skewed to the right and a range of 50 CU; and in EG4, the mean was 25.46 ± 18.03 CU, with an asymmetry index of 0.62, distribution skewed to the

Table 1. Group 1 descriptive statistics

	n	Range	Minimum	Maximum	Mean	SD	Variance	Asymmetry	Kurtosis
Age	41	5.4167	2.0833	7.5000	4.544685	1.364496	1.862	0.511	-0.415
Usage time	41	5.1667	0.0833	5.2500	1.827202	1.241694	1.542	0.597	0.289
EG1 CU	41	125	0	125	22.39	33.426	1117.294	1.940	3.114
EG2 CU	41	115	0	115	24.85	29.878	892.678	1.651	2.526
EG3 CU	41	82	0	82	19.32	21.605	466.772	1.304	1.114
EG4 CU	41	90	0	90	20.20	22.213	493.411	1.210	0.994

CU: current units; EG: electrode group; SD: standard deviation.

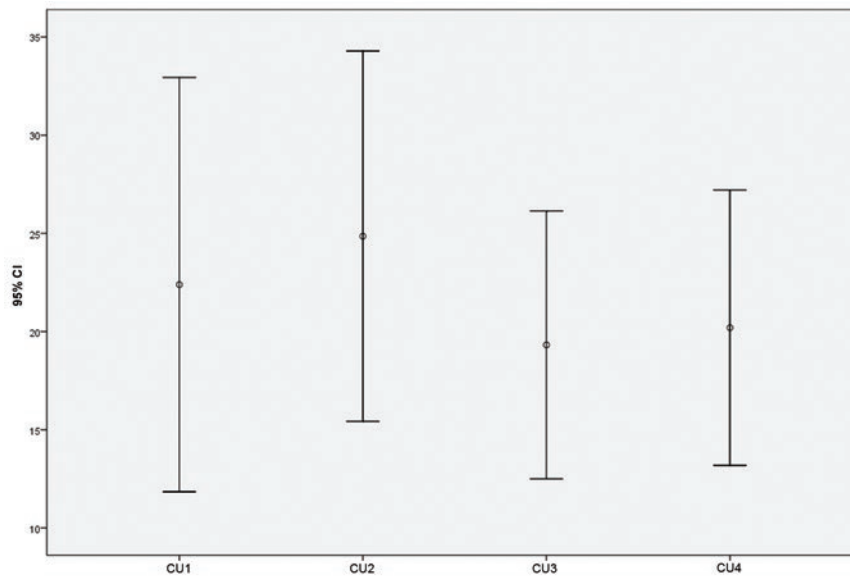


Figure 1. Group 1 four-electrode groups error plot. EG3 and EG4 are observed to have required a lower number of current units (CU) for cochlear implant calibration. CI: confidence interval.

right and a range of 55 CU. EG2 and EG4 are observed to exhibit a similar asymmetry index, with 0.187 and 0.062 CU respectively, with a difference between both of 0.125 CU; in addition, with regard to the average, EG1 is observed to have the lowest (19) and the widest standard deviation (21.24), while EG3 has the second lowest average (21.54) and the smallest dispersion (16.25). (Table 2 and Fig. 2).

When group 3 ($n = 28$) descriptive statistics were analyzed, average age was observed to be 5.2 ± 1.11 years, with α_3 asymmetry index being 0.721, indicating a distribution skewed to the right due to the age range obtained by the study subjects (range = 3.5), while mean usage time was 2.4 ± 1.03 years. Analyzing the CUs that were used for the calibration of the cochlear implants of the patients in this group, EG1

average was found to be 23.96 ± 38.03 CU, with an asymmetry index of 1.834, thus indicating a distribution skewed to the right, as defined by the 125-CU range; in EG2, average was 24.96 ± 34.31 CU, with an asymmetry index of 1.636, distribution skewed to the right and a range of 115 CU; in EG3, the mean was 18.29 ± 23.88 CU, with an asymmetry index of 1.484, indicating a distribution skewed to the right and a range of 82 CU; and in EG4, the mean was 17.75 ± 23.8 CU, with an asymmetry index of 1.625, distribution skewed to the right and a range of 90 CU. EG3 and EG4 are observed to exhibit similar standard deviations, 23.887 and 23.809 CU respectively, with a difference of 0.078 CU between both; in addition, they show similar behavior in the average and standard

Table 2. Group 2 descriptive statistics

	n	Range	Minimum	Maximum	Mean	SD	Variance	Asymmetry	Kurtosis
Age	13	1.833	2.083	3.917	3.12817	0.484256	0.235	-0.564	0.742
Usage time	13	1.3333	0.0833	1.4166	0.576892	0.4828767	0.233	0.0447	-1.082
EG1 CU	13	60	0	60	19	21.241	451.167	1.014	-0.216
EG2 CU	13	55	0	55	24.62	18.081	326.923	0.187	-0.399
EG3 CU	13	50	0	50	21.54	16.256	264.269	0.457	-0.813
EG4 CU	13	55	0	55	25.4615	18.03522	325.269	0.062	-1.207

CU: current units; EG: electrode group; SD: standard deviation.

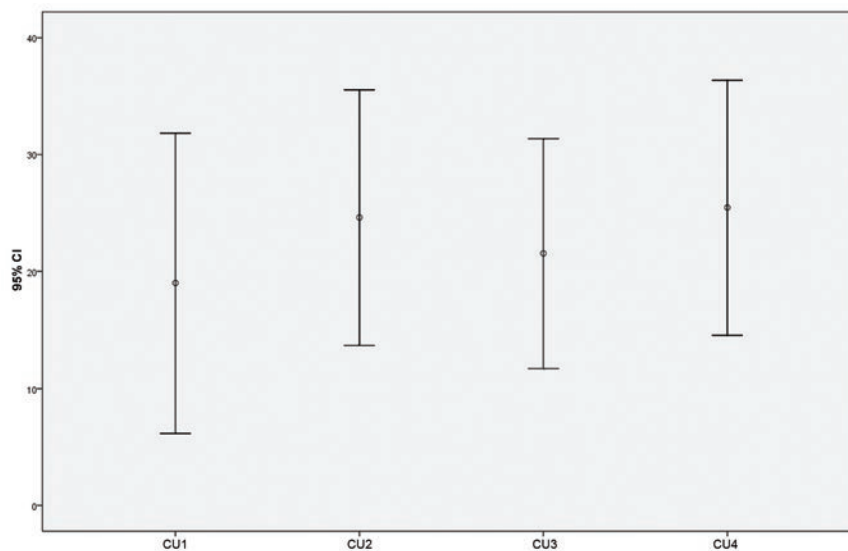


Figure 2. Group 2 four-electrode groups error plot. EG1 and EG3 are observed to have lower values than those in EG2 and EG4. CI: confidence interval; CU: current units.

deviation for being smaller in comparison with EG1 and EG2 (Table 3 and Fig. 3).

Multiple regression equations were constructed taking usage time (x_1) and age (x_2) as variables, in order to determine the CUs that were required in the calibration of the cochlear implant (y). Similarly, the estimate standard error ($Syxs$) was calculated in order to know the deviations obtained in the equations.

The equations calculated for group 1 were:

$$EG1 \hat{y} = 2.617 - 10.161x_1 + 8.436x_2$$

$$EG2 \hat{y} = 18.505 - 7.535x_1 + 4.426x_2$$

$$EG3 \hat{y} = 13.617 - 8.297x_1 + 4.590x_2$$

$$EG4 \hat{y} = 12.727 - 7.510x_1 + 4.663x_2$$

The equations calculated for group 2 were:

$$EG1 \hat{y} = 67.296 + 4.427x_1 - 16.256x_2$$

$$EG2 \hat{y} = 70.401 + 1.599x_1 - 14.931x_2$$

$$EG3 \hat{y} = 83.329 - 8.894x_1 - 18.113x_2$$

$$EG4 \hat{y} = 53.088 - 10.280x_1 - 6.936x_2$$

And the equations calculated for group 3 were:

$$EG1 \hat{y} = -0.371 - 18.8x_1 + 13.379x_2$$

$$EG2 \hat{y} = 17.354 - 13.827x_1 + 7.862x_2$$

$$EG3 \hat{y} = 5.657 - 12.244x_1 + 8.094x_2$$

$$EG4 \hat{y} = -4.452 - 7.772x_1 + 7.865x_2$$

Where $\hat{y}$ is CU predictive value according to usage time (x_1) and age (x_2).

Finally, usage time and age variables original values were substituted to calculate the error by group of patients and by group of electrodes. This way, in group 1, CU lower variability was obtained in EG3 and EG4, with a standard error of ± 21.361 and ± 22.22 , respectively; in group 2, the lowest standard error was obtained in EG3, with ± 13.761 ; and in group 3, the

Table 3. Group 3 descriptive statistics

	n	Range	Minimum	Maximum	Mean	SD	Variance	Asymmetry	Kurtosis
Age	28	3.5	4	7.5	5.202354	1.1132955	1.239	0.721	-0.730
Usage time	28	4.5834	0.6666	5.25	2.407704	1.0384472	1.078	.0807	1.309
EG1 CU	28	125	0	125	23.96	38.035	1446.628	1.834	2.207
EG2 CU	28	115	0	115	24.96	34.310	1177.147	1.636	1.8
EG3 CU	28	82	0	82	18.29	23.887	570.582	1.484	1.296
EG4 CU	28	90	0	90	17.75	23.809	566.861	1.625	2.032

CU: current units; EG: electrode group; SD: standard deviation.

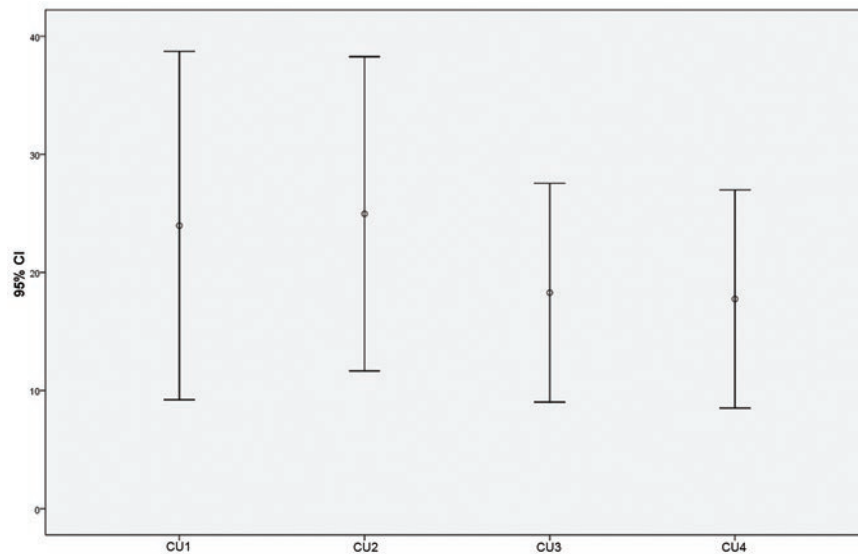


Figure 3. Group 3 four-electrode groups error plot. Averages obtained for EG1 and EG2 are observed to be higher, and EG3 and EG4 error bars are almost equal. CI: confidence interval; CU: current units.

lowest standard error was observed in EG3 and EG4, with ± 23.453 and ± 24.084 , respectively (Table 4).

Discussion

Language acquisition and development requires intervention of the cerebral cytoarchitecture specialized in the coding and decoding of sounds that belong to a linguistic system, optimal functioning of the auditory organ, structural and functional integrity of the phono-articulation apparatus, the hearing experience that involves brain plasticity and feedback of sounds from the environment, which generate each one of these different types of information, with the most important possibly being the power of human communication³².

Patients with implant require having the experience of the sounds coming from the environment, and time

and neurophysiological maturity are therefore necessary. As cited in the literature, post-implant calibrations are mostly provided by patient stimulus-response when age allows for it⁵⁻⁹.

In the present work, mathematical equations are proposed that aim at establishing a correlation between biological age and cochlear implant usage time with regard to the necessary CUs for calibration. Multivariate multiple regression analysis is a new analysis proposal that has not been previously reported in the literature.

Raghunandhan et al.¹⁰ demonstrated an increase in CUs during cochlear implant adjustment process, considering exclusively the usage time variable. They reported an average of 155 CU at first month, and at the end of first year, an average of 272 CU. In our study, the proposed equations jointly contemplate

Table 4. Estimate standard error by patient group and electrode group

	EG1 Syxs	EG2 Syxs	EG3 Syxs	EG4 Syxs
Group 1	± 30.684	± 30.207	± 21.361	± 22.220
Group 2	± 21.622	± 18.189	± 13.761	± 18.474
Group 3	± 37.535	± 34.366	± 23.453	± 24.084

EG: electron group.

patient age, usage time and electrode group, thus determining the values obtained for the estimate standard error (Table 4).

In the present work, when the standard error in each equation was assessed by group, we found that the necessary CUs vary according to patient neurological maturity and biological age. This way, in group 1 ($n = 41$), dispersions by electrode group were, for EG1, ± 30.684 ; for EG2, ± 30.207 ; for EG3, ± 21.361 ; and for EG4, ± 22.220 . As for group 2 ($n = 13$), for EG1, it was ± 21.622 ; for EG2, ± 18.189 ; for EG3, ± 13.761 ; and for EG4, ± 18.474 . Finally, in group 3 ($n = 28$), CUs for EG1 were ± 37.535 ; for EG2, ± 34.366 ; for EG3, ± 23.453 ; and for EG4, ± 24.084 . It is suggested that the use of these equations can be reliable for cochlear implant adjustment, since they are calculated by associating three variables (CU vs. age and implantation time).

Conclusions

Further works of these characteristics should be carried out, broadening the sample size in order to reduce standard errors with regard to population size.

The proposed equations can be of clinical usefulness since they allow knowing the necessary CUs for cochlear implant adjustment with regard to patient age and implant usage time.

Conflict of interests

The authors declare that there are no conflicts of interest.

Ethical disclosure

Protection of people and animals. The authors declare that the procedures followed were in agreement with the ethical standards of the responsible

human experimentation committee and in accordance with the World Medical Association and the Declaration of Helsinki.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained informed consent from the patients and/or subjects referred to in the article. This document is in the possession of the corresponding author.

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