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Mathematical model of calculating the minimum stimulation current based on neural response telemetry data in cochlear implantation systems

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The aim of the research is to develop the alternative model based on the experimental data in the course of the cochlear implantation, to calculate the minimum stimulation current that generates an electrically evoked action potential of auditory nerve in cochlear implantation systems. The experimental data (the current and action potential) were received from 69 patients. The core of the mathematical model is power function approximation as well as construction of tangents to the midpoint, introduction of correction factors. Due to the additional algorithm, during the implant testing the minimum „visual" current which was used as the true one when estimating the model application proposed by the authors was determined. Additionally, the minimum current within the linear approximation model was calculated. Statistical data processing was conducted in MS Excel, Spearman's rank correlation method for correlation assessment was used. The alternative model may be used in case of computer-assisted algorithm malfunction for various reasons both in intra- and postoperative period.

Keywords: cochlear implantation, distortion of signals, approximation, extrapolation, correlation.

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Introduction

Currently, cochlear implantation (CI) is a second to none unique high-tech method of restoring hearing in patients with severe and profound sensorineural hearing loss, which is based on using a cutting-edge device — the CI system [1–3]. This method has been used in the world for over 40 years and over 30 years so far in Russia. According to a report on hearing problems presented by WHO in 2021 [4], more than 430 million people in the world need rehabilitation assistance due to hearing impairment, and by 2050 this number will increase to at least 700 million. Therefore, CI will continue to be relevant in the future, certainly being a socially significant area in our days [5]. In Russia, CI is included in the „High-Tech Medical Care" program and is implemented in specialized medical institutions in accordance with the clinical guidelines of the Russian Health Ministry on sensorineural hearing loss. The CI systems of four foreign manufacturers are used: Cochlear®(Australia), Advanced Bionics®(USA), MED-EL®(Austria) and Nurotron®(China).

The CI system consists of two parts: internal and external. The first part is a cochlear (auditory) implant that is installed during surgery. The second part — permanently wearable speech processor (SP). Depending on its modification, the SP may be of two types [6].

CI surgery involves two consecutive stages: surgical and audiological. The latter is related to testing of the newly installed implant, which is carried out using software (SW) of a particular manufacturer. For Cochlear implants® — Custom Sound®EP v. 6.0 (CSEP) is used, Nucleus®SmartNav system is also used abroad. A mandatory testing procedure should include calculating the impedances of the twenty-two isolated intra-cochlear electrodes of the implant, as well as detecting the electrically induced auditory nerve action potential (eCAP), which is itself a total response from the auditory nerve fibers to stimulation of a specific intra-cochlear electrode [7]. Intra-operational eCAP detection [8] allows checking the correct placement of the implant electrode array in the cochlea. The scala tympani is the optimal location, since it is this part of the cochlea that allows the electrode array to be placed as close as possible to the nerve fibers for their subsequent electrical stimulation. For Cochlear®implants (in particular, CI 512 and CI 612 models) it is needed to find the equivalent stimulation current amplitude allowing to find the minimal arithmetic difference (in μV) between eCAP values in points of maxima P_1 and minima N_1 (further in the text - amplitude N_1P_1), while the peak value N_1 occurs on eCAP plot after $200-400\,\mu$s from the start of stimulation, peak P_1 — after $400-800\,\mu$s [6] respectively, and $N_1P_1 = \mathrm{eCAP}_{P1} - \mathrm{eCAP}_{N1} > 0$.

Table 1. Forward Masking for suppression of artefacts

Condition	Stimulation of the studied of electrode	Detection eCAP (c near-located electrode)	Result of detection eCAP
A	„Trial“ pulse	Curve containing the required eCAP (provided there's sufficient electrical charge transmitted through the nerve fibers), artefact from the pulse „Trial“, artefact from the stimulator-receiver	eCAP (A)
B	„Masking“ pulse, „Trial“ pulse	Curve containing artefacts from pulses „Trial“, „Masking“, artefact from the stimulator-receiver	eCAP (B)
C	„Masking“ pulse	Curve containing artefact from the pulse „Masking“, artefact from the stimulator-receiver	eCAP (C)
D	No	Curve containing artefact from the stimulator-receiver	eCAP (D)

In practice, for Cochlear®implants the relative measurement units (the so-called Current Level, CL) are used which are equivalent to the electrical stimulation current I. The transition formula is written as [9]:

$$I = \begin{cases} 0, & \mathrm{CL} = 0, \\ 17.5 \cdot 100^{\mathrm{CL}/255}, & 1 \leq \mathrm{CL} \leq 255, \end{cases}$$

where I are given in μA, CL values are given as integer numbers without dimension.

In the postoperative period, during connection and periodic adjustments of the speech processor, eCAP detection with a minimum amplitude N_1P_1 corresponding to the equivalent current in CL allows forming a profile of the patient's auditory tuning chart for each intra-cochlear electrode: adequately set (in CL) the so-called „Comfort“ level (comfortable perception of loud sounds) and „Threshold“ audibility (perception of quiet sounds barely audible to the user). Thanks to the neural response telemetry function, which is implemented in Cochlear®hearing implants, it is possible to record eCAPs. The Neural Response Telemetry (NRT) occurs when a stimulus (an electrical pulse with certain parameters) is applied to the intra-cochlear electrode, followed by excitation of nerve fibers and further eCAP detection from another nearby intra-cochlear electrode (for implants of CI 512 and CI 612 models — this is through one or two in the direction of the apical part of the cochlea). This feature of eCAP detection from another electrode is related, among other things, to signal distortions (artifacts) resulting from the supply of a stimulus and activation of a receiver-stimulator for eCAP detection, namely, an amplifier built into it, which is a technological feature, generally speaking, of any hearing implant. In the amplifier saturation mode, it is impossible to detect eCAP until the active mode of the amplifier is restored in order to minimize distortion of the amplified signal. This causes difficulties in eCAP detection because of its short latency. Also, the inability to detect eCAP should include an insufficient amount of charge transferred from the intra-cochlear electrode to the nerve fibers, which requires additional correction of the stimulation parameters. Since the dependence of eCAP on time has relatively small minima and maxima in its morphology in comparison with the observed artifact, the Cochlear®manufacturer uses the following basic techniques to identify eCAP: Alternating Polarity, Subtraction Template, Forward Masking. As seen from practice (including by the authors), the latest technology can also be used to search for eCAPs in implant users with auditory nerve hypoplasia [10] and to evaluate the interaction of the intra-cochlear electrodes[11,12]. Forward Masking technology, where the refractory properties of the auditory nerve are used, is applied by default to study Cochlear®implants. The purpose is to stimulate the same intra-cochlear electrode with different pulses „Trial“ and „Masking“ (with relatively short time intervals between them); signals for subsequent eCAP identification are recorded under four conditions (A, B, C and D, (Table 1)). It is important to note that when detecting eCAP, there is always an artifact from the stimulator receiver when it is turned on for detection. Table 1 provides description of the process to identify eCAP using Forward Masking to suppress the artefacts.

The required eCAP is determined as

$$\mathrm{eCAP} = \mathrm{eCAP(A)} - \mathrm{eCAP(B)} + \mathrm{eCAP(C)} - \mathrm{eCAP(D)}.$$

CSEP software uses Auto Neural Response Telemetry algorithm (Auto$^{\mathrm{TM}}$NRT, which allows embedded expert

Table 2. Demography and CI-related data about patients

Characteristic	Numerical indicators
Number of patients	69
Gender (male / female)	30/39
Implantation side (left / right)	32 / 37
Number of patients with a second implant (left side / right side)	7 / 4
Range of age at the date of CI, year	1−5
Average age (± standard deviation) at the date of CI, year	2.7(±1.2)
Installed hearing implant (CI 512 / CI 612)	46 / 23

systems to automatically determine the so-called Visual T-NRT in CL (the average value of two equivalent stimulation currents: the current values at which the minimum value N_1P_1 is detected, and the maximum current values at which N_1P_1 is not detected) by iterating through the values of equivalent stimulation currents and their corresponding amplitudes N_1P_1 during measurements. Experience has proven that, in some cases (for example, hypoplasia of the auditory nerve, saturation of the amplifier, insufficiency of the transmitted electric charge), Auto^{TM}NRT algorithm may not work, and, consequently, Visual T-NRT cannot be determined.

The purpose of this study is to develop an alternative mathematical model that makes it possible, based on experimental data obtained during telemetry, to determine the equivalent stimulation current (New T-NRT in CL) for the intra-cochlear electrode with a minimum value of N_1P_1 on eCAP curve.

1. Material and research techniques

The research included the intra-operational data of 69 patients (children) in the age from 1 to 5 years old that got operated for the purpose of CI in FGBI North-Western District Clinical Research Centre named after L.G. Sokolov FMBA of Russia and had a hearing implant Cochlear®(Australia) installed. All patients had no history of contraindications to CI related to complete aplasia of the inner ear, complete obliteration of the cochlea, and the presence of severe somatic, neurological, and mental illnesses that prevent surgery under general anesthesia and postoperative hearing and speech rehabilitation. At the preoperative stage, patients also had no pathology of the auditory nerve. The electrode array was placed into the cochlea mainly through the round window, and also in a smaller number of cases through the cochleostomy. In all cases, an experienced surgeon visually observed the complete insertion of an array of 22 electrodes into the cochlea. The hearing implants of CI 512 and CI 612 models have the same structure, including the electrode array inserted into the cochlea, except for the fixation magnet embedded in the implant coil. Table 2 provides demography and CI-related data about the patients.

Intraoperative measurements of each newly installed hearing implant were performed on a laptop using CSEP SW right during the CI operation. To connect to the implant, a software module was used, the test CP 910 speech processor with a coil and a strong magnet built into it, which made it possible to establish physical contact and a stable radio signal with the implant coil. The automatically calculated impedances in the four stimulation modes („MP 1", „MP 2", „MP $1+2$" and „Common Ground") showed no any short-circuit and open circuit in all 22 intra-cochlear electrodes [13]. Therefore, in order to reduce the time of testing the implant and, as a result, the time spent by the patient (child) under general anesthesia, Visual T-NRT was searched using Auto^{TM}NRT algorithm on each of the five intra-cochlear electrodes (numbered „22", „16", „11", „6" and „1"), selected with almost equal steps relative to each other in the cochlea. Table 3 shows the parameters of Auto^{TM}NRT algorithm, adapted for our study and used to detect eCAPs with their corresponding equivalent stimulation currents for the subsequent calculation of VisualT-NRT.

New T-NRT calculation model proposed by the authors on the selected intra-cochlea electrode includes the following steps:

1. Application of n points obtained from measurements on the Cartesian coordinate system, where the X-coordinate of the point — value of current in equivalent clinical units in CL (furtherx_i, $i=1,\ldots,n$), Y-coordinate — value of N_1P_1 (further y_i). At the same time, the following conditions shall be met when selecting points: if $x_{i+1}>x_i$, then $y_{i+1}>y_i$. This condition is a consequence of the fact that, in general, the dependence of the current in equivalent clinical units on the values of N_1P_1 is a sigmoidal function [14].

2. Approximation of the obtained points by a power function $f(x)=b\cdot x^a$, where the coefficients b, a are uniquely determined using the least squares method.

3. Determination of point $M(x_M,y_M)$ on the graph of approximated function, where $x_M=(x_1+x_n)/2$, $y_M=f(x_M)$. In case of a fraction value x_M the value is rounded up to an integer.

4. Plotting of tangential line $g(x)$ to the graph of function $f(x)$ in point$M$. 5. Determination of point $N(x_N,y_N)$ as an intersection of curves of functions $g(x)$ and $h(x)=y_1$.

Table 3. Algorithm parameters Auto™NRT

Description	Parameter / characteristic
Artefacts suppression technology	Forward Masking
Form of electric pulses „Trial“, „Masking“	Square bi-phase double-sided
Shape of electric pulse to decrease the artefact from „Trial“, „Masking“ pulses (connected automatically to minimize the artefact)	Mono-phase square (duration 10 μs, amplitude doesn't exceed the amplitude of pulse „Trial“ in CL)
Difference of amplitudes of „Masking“ and „Trial“, CL	10
Initial amplitude of „Trial“ pulse for electrical „22“, CL	150
Amplitude increment rate of „Trial“ pulse in equivalent clinical units to obtain two credible curves eCAP, CL	6
Amplitude decrease rate of „Trial“, CL	3
Electrodes measurement priority	„22“, „1“, „11“, „16“, „6“
Initial amplitude of „Trial“ for electrode „1“, CL	pulse Calculated value Visual T-NRT electrode „22“
Initial amplitude of pulse „Trial“ for electrodes „11“, „16“ and „6“, CL	Calculated as average value Visual T-NRT between two measured electrodes
Duration of one phase of pulses „Trial“, „Masking“, μs	25
Inter-phase delay for pulses „Trial“, „Masking“, μs	7
Stimulation frequency of „Trial“, Hz	250
Stimulation frequency of „Masking“, pulse Hz	100
Number of measurements to get one resulting curve eCAP, pcs.	A: 35, B: 35, C: 35, D: 35
Number of „Masking“ pulses per one „Trial“ pulse to identify eCAP in condition „B“, pcs.	1
The interval between pulses „Masking“, „Trial“, μs	400
Delay between the end of stimulation and start of detection eCAP, μs	122
Detection and fixation on curve eCAP the minimum N_1 and maximum P_1	Expert system based on experimental data, built in the algorithm
Duration of curves recording to further identify eCAP in them when activating the amplifier of receiver-stimulator, μs	1600
Gain factor of amplifier of the receiver-stimulator, dB	50

Table 3. (*Continued*)

Description	Parameter / characteristic
Out-of-cochlea electrode involved in stimulation	MP 1
Out-of-cochlea electrode involved in curves recording to identify the potential	MP 2
Sequential number of the intra-cochlea electrode, where recording occurs of curves for further identification of eCAP	„+2“ in respect to the sequential number stimulated electrode Exclusion: for the stimulated electrode „22“ recording electrode „20“

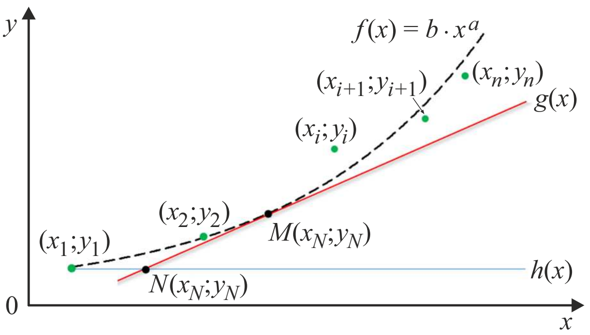

Figure 1. Graphic representation of mathematical model.

The abscissa of the x_N point N represents the New T-NRT in CL.

6. The introduction of a correction factor k_N for each of the patient's five intra-cochlear electrodes, representing the ratio of Visual T-NRT to New T-NRT.

Fig. 1 shows graphic representation of the mathematical model.

X-coordinate of point M, to which the tangent line to the approximating function is plotted, as the average value of equivalent amplitudes of the stimulation currents of successful first and last measurements was selected accounting for the peculiarities of Visual T-NRT calculations in Auto$^{\text{TM}}$NRT algorithm (as the average value of two equivalent amplitudes of currents stimulations: the values of the current at which the minimum value N_1P_1 and the maximum current value are detected, when N_1P_1 is not detected) and the starting value of the equivalent stimulation current for the start of measurements on the intra-cochlear electrode (which is also defined as the average value of two Visual T-NRT electrodes between which the measured electrode is placed).

Statistical data processing was carried out in MS Excel: the Kolmogorov-Smirnov test was used to check the distribution normality of the obtained results, Spearman rank correlation method

2. Results

In total, 345 electrodes in 69 patients were tested. The values Visual T-NRT (taken as true) were determined on 334 electrodes. The Kolmogorov-Smirnov test did not show a normal distribution of Visual TNT across the electrodes „22“, „16“, „11“, „6“ and „1“. Each Visual TNT value is set when getting amplitudes N_1P_1 with their corresponding current values in clinical units. The points where the amplitude decreased with the growth of stimulation current N_1P_1 are excluded from consideration. Visual analysis of curves on 11 electrodes in CSEP showed the availability of artefacts which couldn't allow to define Visual T-NRT.

To compare the New T-NRT values calculated using the proposed model, the minimum stimulation currents LineT-NRT (in clinical units of CL) were also calculated using the already well-known linear approximation model [15], where the argument of the linear function is the equivalent current value in CL, and its value is — the amplitude N_1P_1 in μV. The required Line T-NRT value was found as an X-coordinate of the linear function crossing the X-axis, i.e. value N_1P_1 in this point turns to zero.

As an example, Figure 2 shows neural response telemetry data (equivalent stimulation current and corresponding amplitude N_1P_1) for one of the users obtained on the intra-cochlear electrode „11“ using Auto$^{\text{TM}}$NRT algorithm, as well as graphs, approximated by power and linear functions, demonstrating significant differences between the two models.

It should be noted that the algorithm allows setting only Visual T-NRT without defining the values of minimal amplitude N_1P_1, therefore, the corresponding point on the graph is denoted as „void“.

Fig. 3 shows comparison of the values Visual T-NRT with New T-NRT and Visual T-NRT with Line T-NRT for the intermediate intra-cochlear electrode „11“, demonstrating visual degree of coincidence of these physical values. Similar graphs were observed for the other numbered electrodes. „22“, „16“ and „1“.

Table 4 shows the basic results of the study.

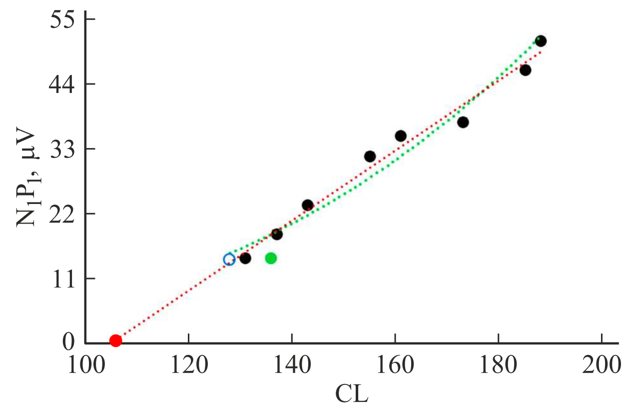

Figure 2. Graphical telemetry data of the user nervous response on the intra-cochlear electrode „11"; green curve — approximation of the obtained points by a power function, red line — approximation of the obtained points by a linear function, green circle — calculated equivalent current New T-NRT (137 CL), red circle — calculated equivalent current New T-NRT (137 CL), empty blue circle — calculated equivalent current Visual T-NRT (129 CL).

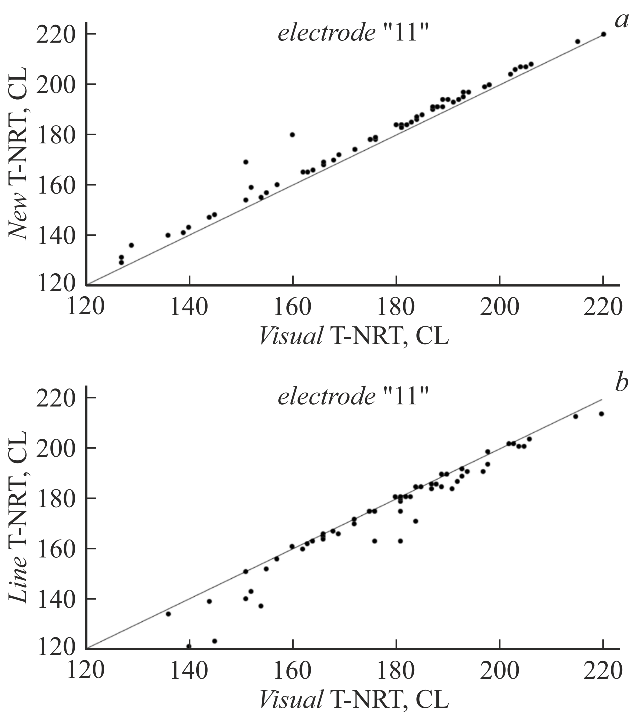

Figure 3. *a* — comparison of numerical values Visual T-NRT with New T-NRT for electrode „11"; *b* — comparison of numerical values Visual T-NRT c Line T-NRT for electrode „11".

3. Discussion

During measurements of five intra-cochlear electrodes in sixty nine patients Visual T-NRT was defined in 96.8 % cases which exceeds sensitivity (96 %) of Auto$^{\text{TM}}$NRT algorithm given in the scientific data. Inability to obtain VisualT-NRT on eleven electrodes is not related to insufficiency of the transmitted electric charge, which, apparently, proves, in general, that parameters were optimally selected from all measurements, namely sufficient stimulation current (up to 1750 μA) and the pulse phase duration (25 μs) to obtain eCAP. The automatic connection of an additional pulse during stimulation in order to reduce signal distortion was detected more in CI 612 model of the hearing implant (11 times in 23 pieces) compared to CI 512 model (4 times in 46 pieces), which can be further investigated in the development of this area.

3.1. Mathematical model

Based on measurements data obtained, the power function as an approximation was selected due to its better correspondence to experimental data in comparison with exponential, logarithmic and polynomial functions. The confidence value of the approximation for the power function turned out to be higher in comparison with the above. In addition, the graph of logarithmic and polynomial functions does not visually correspond to the obtained points as shown from the study. Due to the power function properties it is relatively easy to extrapolate towards lower values of the argument (stimulation current in equivalent clinical units of CL) relative to the obtained first measurement point, and it is also quite easy to find the power function coefficients analytically. The exclusion from consideration of points where the value N_1P_1 does not increase with the growth of stimulation current (from the mathematical standpoint — an asymptotic approximation to the upper limit of amplitudes N_1P_1 caused by the physiological features of the auditory nerve) did not show any significant difference in New T-NRT analysis. In this regard, it is allowed to include all measurement points into analysis to speed up the selection and computation process, except for those where a decrease in N_1P_1 occurs with the growth of stimulation current (which is implemented in this model). The latter is likely to be associated with the artefacts and a non-trivial mathematical approach to identify eCAP in general. The tangent to the graph at the midpoint can be considered as an approximation by an affine function that best approximates the original power function at this point. The calculated values of Spearman ratio have the best correlation strength (in all cases —„very high") in comparison with the linear approximation. If in some dimensions the form of the approximating power function is close to linear, then the tangent at the midpoint (generally speaking, and in any other points obtained during measurement) almost coincides with the linear function and New T-NRT is determined by the X-coordinate of the first measurement point, which leads to a linear extrapolation model, except for the intersection of the plotted function with the X-axis. The average correction coefficients for the studied electrodes within the framework of the proposed model have a better correlation compared to the average coefficients in case of linear approximation. Most likely, a single average coefficient of 0.9778 can be used for all intra-cochlear electrodes due to the relatively

Table 4. Basic results of the study

Characteristic	Sequential number of the intra-cochlea electrode				
	„22“	„16“	„11“	„6“	„1“
Number of measurement points (total number 1292), pcs.	228	255	217	304	288
Number of points excluded from calculations (total number 55), pcs.	6	8	14	12	15
Number of points leading to the formation of plateau on the curve of amplitudes versus equivalent currents (total number 5), pcs.	2	2	0	1	0
Number of determined Visual T-NRT	68	69	64	68	65
Number of determined Visual T-NRT at automatic adding of pulse for decreasing the artefact from pulses „Trial“, „Masking“ during stimulation (CI 512/CI 612)	1/4	0/4	0/3	1/0	2/0
Spearman ratio r_{VN} when comparing Visual T-NRT and New T-NRT	0.9979	0.9980	0.9912	0.9943	0.9941
Correlation relationship between Visual T-NRT and New T-NRT In accordance with Chaddock scale	very high	very high	very high	very high	very high
Spearman r_{VN} ratio when comparing Visual T-NRT and Line T-NRT	0.9623	0.9386	0.8937	0.8341	0.8565
Correlation relationship between Visual T-NRT and Line T-NRT In accordance with Chaddock scale	very high	very high	high	high	high
Average correction factor $\langle k_N \rangle$ for all patients within the mathematical model	0.9799	0.9788	0.9813	0.9728	0.9761
Average correction factor $\langle k_N \rangle$ for all patients within the linear approximation	1.0377	1.0346	1.1015	1.0954	1.0978

good correlation of the average correction coefficients for the five electrodes studied.

3.2. Use of the model

This model is designed to determine the minimum equivalent stimulation current during advanced telemetry using the manufacturer's software in case when a fully automated machine algorithm does not allow determining the needed values. Considering that before carrying out a new series of measurements, it will be necessary to optimize the parameters of stimulation and registration (Table. 1), which sometimes takes a long time, in practice, in order to save time (especially when working with young children), stimulation steps other than 1 CL are used (within the range set by the sign language therapist) to determine the desired minimum current in clinical units. Moreover, the obtained telemetry data allow carrying out the required computer analysis only using the linear approximation program. In this case, the proposed model is relevant and as close as possible to the results of a fully automated machine algorithm.

3.3. Limitations

The amplitude values N_1P_1 corresponding to the equivalent stimulation current should be obtained with the same stimulation and detection parameters, especially when measuring in „Extended Telemetry" mode in CSEP. We also note that New TNT cannot go to 0 and exceed 255 CL (upper limit), which is due to the technical parameters of the hearing implant. The calculated value of New TNT shall be rounded to an integer. The best empirically identified rate of stimulation (based on the data of 69 patients reviewed) is the value of 6 CL, the choice of which will reduce the time of measurements and computations.

Conclusion

The mathematical model presented in this paper for obtaining Ne T-NT can also be used for other types of Cochlear®implants (regardless of the structure of the electrode array). Apparently, the model can also be used to obtain New T-NRT in the postoperative period (at the stage of connecting and re-configuring the SP) from implant users who cannot give an adequate assessment, especially for the perception of loud sounds (young pre-linguistically deaf children, adults with comorbidities), and for which Visual T-NRT cannot be obtained in Auto^{TM}NRT mode. Most likely, the proposed model can also be used to calculate New-TNRT in Cochlear®implant users with auditory nerve hypoplasia in „Extended Telemetry" mode, where eCAP detection is characterized by instability (with an increase in the equivalent stimulation current, the amplitude values may decrease or not be determined), which will require significant variation in stimulation parameters, detection, as well as choosing the optimal technology for suppressing artifacts in each specific case. The obtained and selected points (where the eCAP amplitude increases with the growth of stimulation current) can be used in the neural response telemetry to determine the minimum equivalent stimulation currents within the framework of the proposed model.

Since the initial data in this model are currents in equivalent units (charge values may also be used, which in case of square pulses are obtained by the product of current and pulse duration) and the corresponding values N_1P_1, the model can be considered as suitable for application in the hearing implants from other manufacturers.

Compliance with ethical standards

All applicable international, national, and/or institutional guidelines for use of personal and medical data of patients were observed.

Conflict of interest

The authors declare that they have no conflict of interest.

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