Article

Triphasic Pulse Stimulation Pattern in Cochlear Implant Users Assessed with Ecap Measure

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Abstract: The rationale for the use of three-phase stimulation for programming the processor of the cochlear implantation system (CI) in patients with deafness is presented. To study the possibilities of using a new type of stimulation, we selected patients after cochlear implantation, with signs of facial nerve stimulation (FNS) in postoperative period. All subjects were previously fitted with an audio processor with individual fitting maps based on traditional biphasic stimulation. The use of three-phase stimulation to prevent FNS is caused by the geometry of the electric current pulses, which allows to reduce the penetrating power of the charge in the tissues and eliminate the effect on the facial nerve, without resorting to reducing the levels of stimulation necessary to create a dynamic range of sound perception. Comparative data of the parameters and the results of audiological testing in 21 patients with symptoms of FNS with traditional (two-phase) and three-phase electrical pulses in the stimulation algorithm of the CI system are presented. The positive effect of three-phase stimulation has been established. The results of the study show a significant increase in sound perception indicators when switching to a three-phase stimulation algorithm.

Keywords: cochlear implantation, hearing and speech rehabilitation, sensorineural hearing loss, cochlear implant processor fitting.

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1. Introduction

Facial nerve stimulation (FNS) is one of the possible complications of cochlear implantation (CI). According to the literature, this condition occurs in 1-15% of patients in the postoperative period [2, 3]. FNS can be mild, affecting only individual facial muscles (e.g., eye, mouth, or forehead), or severe, when contractions affect all facial muscles and cause pain [4].

FNS can manifest immediately after CI activation or with a delay; a case with FNS onset 10 years post-activation has been described. Initial symptoms may not be obvious but worsen over time and depending on audio processor settings, leading to patient complaints and clinical manifestation [5]. Moreover, the evaluation of initial FNS symptoms is largely subjective, therefore It is important not to miss the initial manifestation of FNS in young children and people with neurological comorbidities.

The causes of FNS include: a) proximity of the facial nerve to the outer wall of the cochlea, b) excessively high stimulation levels in combination with auditory nerve hypoplasia or after a long period of deafness, and c) decreased bone impedance due to otosclerosis, meningitis, or temporal bone fracture [6, 7].

Traditionally, CI audio processors use biphasic pulse stimulation. Two common ways of reducing FNS when using the biphasic mode are: a) switching off individual electrode channels and b) reducing the maximum comfortable loudness (MCL) level. However, these interventions harm speech perception and limit the duration of CI use. An alternative solution that does not have these limitations is triphasic pulse stimulation [8].

Biphasic pulse stimulation has two phases with opposite polarities but with the same duration and amplitude - one negative (cathode) and one positive (anode) [5]. Triphasic pulse stimulation has two phases with the same polarity, duration, and amplitude (cathode) and one phase with the opposite polarity, double the duration, and the same amplitude (anode), resulting in a balanced charge [5]. It is suggested that triphasic stimulation prevents current spread into neighbouring tissues and thus reduces FNS, even though it requires higher stimulation levels than the biphasic mode to achieve the same MCL levels [5].

Problem: hearing is compromised if FNS is treated with conventional methods. Triphasic stimulation provides an alternative solution. Need evidence that speech understanding improves (no change in Braun 2019 paper).

Aims: The aim of the study was to evaluate the effectiveness of this method in treating FNS and effect of changing the stimulation type from biphasic to triphasic on speech intelligibility in quiet and noise.

2. Patients and Methods

Participants were recruited from CI users treated at the Research Institute of Pediatrics and Child Health of the Central Clinical Hospital of the Russian Academy of Sciences and at the Research Institute of Ear, Throat, Nose, and Speech in St Petersburg. All participants had a CI system from MED-EL (Austria) that allowed to choose between two stimulation types: a biphasic and triphasic pulse. Participants were excluded if they had neurological comorbidities or congenital anatomical anomalies of the cochlea. The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of the Central Clinical Hospital of the Russian Academy of Sciences.

Fitting:Prior to the study, all participants had speech processors fitted with the biphasic pulse stimulation and had clinical manifestations of FNS (contraction of 1 or more facial muscles) during fitting or speech testing. Their FNS-related discomfort was initially managed by lowering the MCL level and adjusting the microphone gain. The participants demonstrated unsatisfactory auditory performance when tested by a speech therapist despite regular speech rehabilitation sessions.

The MCL levels were measured during the fitting with the biphasic and triphasic mode on all electrode contacts. Electrically evoked compound potentials (ECAPs) were measured on all electrode contacts using the AutoART tool of the MAESTRO software (version 7), MED-EL, Austria).

Audiological testing:Speech intelligibility was assessed using the standardized Russian pediatric multisyllabic speech test at three time points: before the triphasic mode activation (using the biphasic mode), 1 hour post-activation, and 48 hours post-activation. The speech intelligibility in quiet test was administered at 65 dB SPL in free field from zero degrees azimuth. The speech intelligibility in noise test was administered under the same conditions at 6 dB SNR, with both the signal and the noise sources located at zero degrees azimuth (S0N0).

The whispered voice test was conducted at two time points: before the triphasic mode activation (using the biphasic mode) and 1/48 hours post-activation. Each participant was seated while the examiner stood behind them to prevent lip reading. The examiner whispered words at different distances from the participant and the participant repeated them. The maximum distance at which the participant correctly repeated 50% of whispered words was recorded.

Data analysis:Descriptive statistics (mean, standard deviation, and range) were calculated for the demographic and audiological data. The Kolmogorov-Smirnov test and the Shapiro-Wilk test were used to check if the data were normally distributed. The Friedman test was used to assess the change in speech intelligibility across all three conditions (biphasic, triphasic 1 h post-activation, triphasic 48 h post-activation). Pairwise comparisons were done using the Wilcoxon signed-rank test. A p-value ≤ 0.05 indicated statistical significance. For the speech intelligibility tests, the p-value was adjusted to ≤ 0.017 using the Bonferroni correction for multiple comparisons. Statistical analysis was done in IBM SPSS Statistics (version 25, IBM, Armonk, New York, USA).

3. Results

Demographics:21 CI users included in the study were 3 to 12 years old (mean age: 6.0 ± 1.98 years old). The mean age at implantation was 10.0 ±16.34 months old (range: 6 – 75 months old). The mean time of CI use with biphasic pulse stimulation was 36.0 ± 21.02 months (range: 1 – 112 months).

Fitting:The electrode array insertion was complete and all electrode contacts were activated in all participants.

Speech Intelligibility:Participants' speech intelligibility in quiet improved significantly after the triphasic mode activation (Friedman test: Chi-square = 29.585, df = 2, $p < 0.001$). Individual pairwise comparisons using the Wilcoxon signed-rank test confirmed the statistically significant improvement. The mean score increased from 41.9% (SD = ±25.3%) pre-activation to 51.1% (SD = ±21.5%) 1 h post-activation ($z = -2.447$, $p = 0.014$) and to 76.0% (SD = ±19.3%) 48 h post-activation (vs biphasic: $z = -3.884$, $p < 0.001$; vs 1 h post-activation: $z = -4.016$, $p < 0.001$). The distribution of scores is presented in Figure 1.

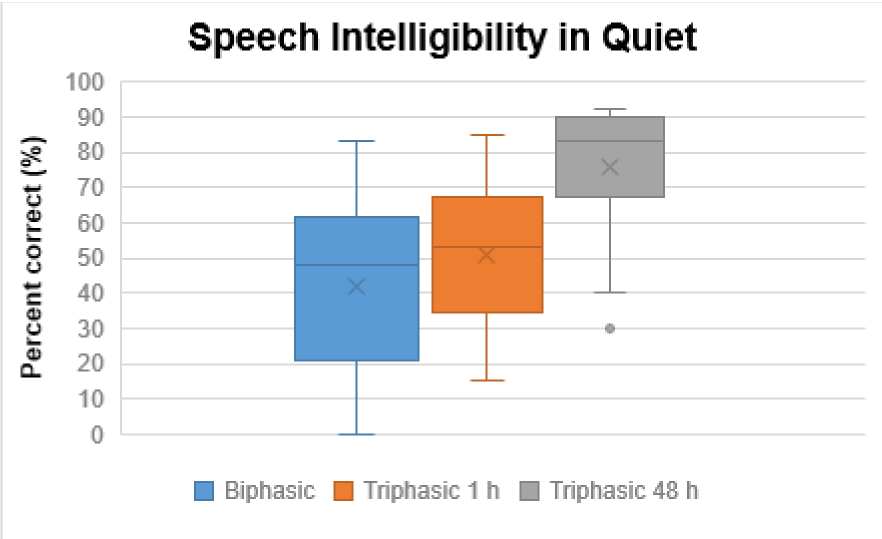

Figure 1. Speech intelligibility in quiet (% of correct responses) was assessed with the biphasic mode (blue) and with the triphasic mode 1 hour (orange) and 48 hours post-activation (gray) across 21 participants.

Participants' speech intelligibility in noise improved significantly, too (Friedman test: Chi-square = 28.617, df = 2, $p < 0.001$). Pairwise comparisons were also statistically significant. The mean score increased from 37.4% (SD = ±25.2%) pre-activation to 51.8% (SD = ±22.9%) 1 h post-activation ($z = -3.583$, $p < 0.001$) and to 68.0% (SD = ±20.8%) 48 h post-activation (vs biphasic: $z = -3.911$, $p < 0.001$; vs 1 h post-activation: $z = -3.924$, $p < 0.001$). The distribution of scores is presented in Figure 2.

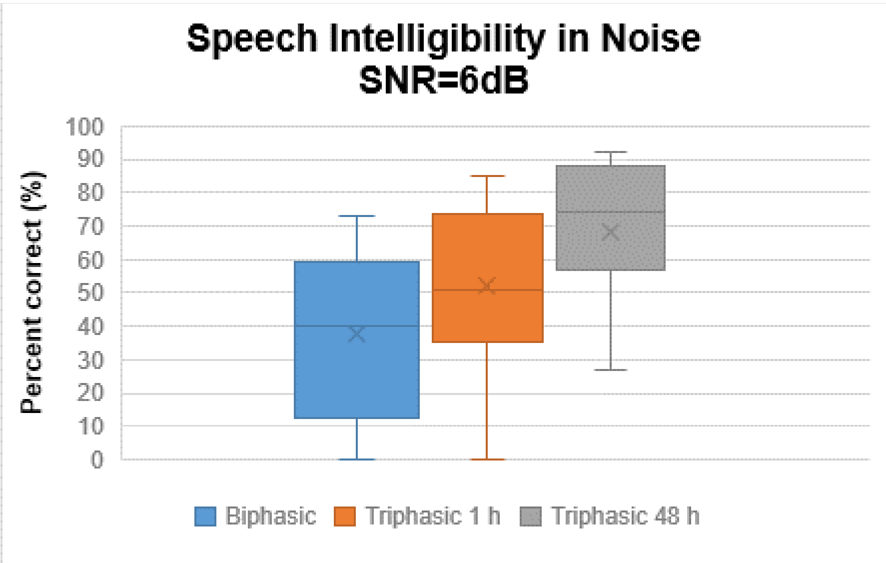

Figure 2. Speech intelligibility in noise (% of correct responses, signal-to-noise ratio = 6 dB) was assessed with the biphasic mode (blue) and with the triphasic mode 1 hour (orange) and 48 hours post-activation (gray) across 21 participants.

Whispered Voice Test:The average performance in the whispered voice test improved across participants from the average distance of 3.6 m (SD = ±0.9 m) to 5.6 m (SD = ±0.5 m) and this change was statistically significant (Wilcoxon signed-rank test: $z = -3.912$, $p < 0.001$). Individual performance improved in all but two participants (P7 and P15, Fig. 3).

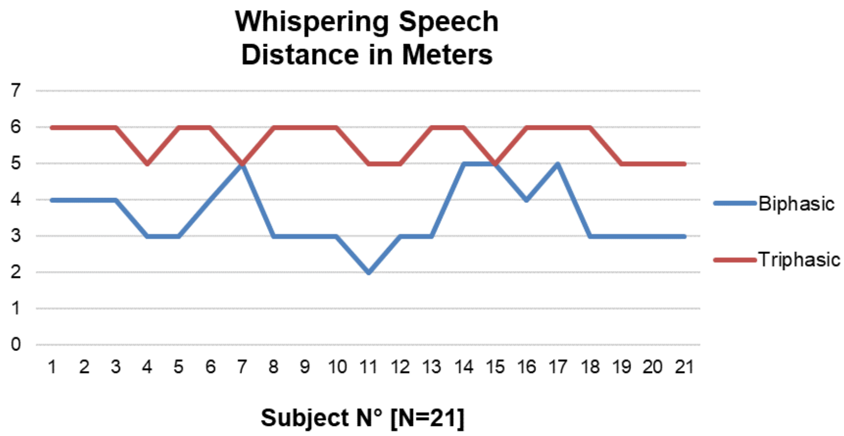

Figure 3. Individual results of the whispered voice test across 21 participants using the biphasic mode (blue) and the triphasic mode (orange).

ECAPs and Maximum Comfortable Loudness Levels:MCL levels were measured with the biphasic and triphasic modes on. The average MCL levels correlated with the ECAP values across electrode channels both in biphasic (stats) and triphasic mode (stats) (Fig. 4).

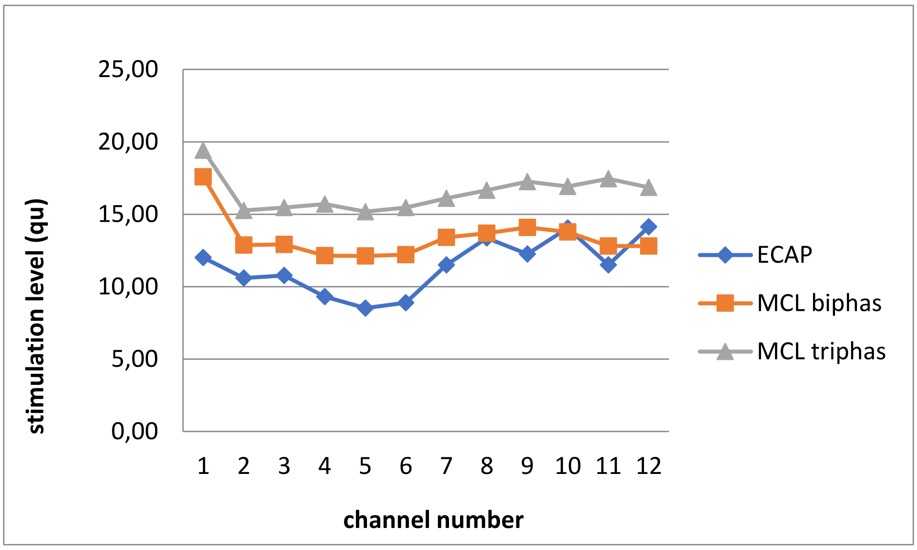

Figure 4. ECAP values (blue) and MCL levels across electrode channels in biphasic (orange) and triphasic mode (grey).

4. Discussion

The use of three-phase stimulation positively affects the rehabilitation of patients after CI having manifestations of stimulation of the auditory nerve due to a relatively larger dynamic range of sound perception. The relationship of MCL values in both biphasic and three-phase stimulation with ECAP registration thresholds was statistically significant, suggesting the potential of this solution, regardless of the type of stimulation chosen, since ECAP thresholds correlate with MCL [9]. The increase in MCL values required to create an effective dynamic range, with three-phase stimulation, can prevent the occurrence of FNS manifestations, as previously shown [8] in a study using electromyography in patients under general anesthesia. Our study shows the positive effect of three-phase stimulation while simultaneously increasing MCL levels on the results of speech testing or speech audiometry (in two patients with advanced speech skills). Three-phase pulses reduce the manifestations of FNS by distributing the charge between two negative phases of the same duration and one positive phase with twice the duration. The results of speech testing and speech audiometry (in children with developed speech skills) showed a significant increase in sound perception when switching to a three-phase stimulation algorithm.

5. Conclusions

The use of three-phase CI stimulation is a promising tool to prevent facial nerve stimulation after cochlear implantation while maintaining an effective dynamic range and, therefore, a relatively large sound perception potential compared to the traditional biphasic stimulation algorithm. In case of clinical manifestations of FNS, it is recommended to use a three-phase type of stimulation to create fitting maps for patients with CI.

Application of artificial intelligence :

The article is written without the use of artificial intelligence technologies.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.
Conflicts of Interest: The authors declare no conflict of interest.

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