



Original Article

Electrophysiological and Behavioral Programming Parameters in Patients with Facial Nerve Stimulation Post-Cochlear Implantation

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BACKGROUND: The aim of this study is to compare patients who develop facial nerve stimulation (FNS) after cochlear implantation (CI) and are managed with a triphasic stimulation pulse pattern (TPP) to those who do not develop FNS regarding the behavioral mapping parameters including the most comfortable loudness level (MCL) charge and amplitude, and the threshold level (THR), as well as the electrophysiological mapping parameters including phase duration (PD) and impedance level.

METHODS: A retrospective chart review of the patients who developed FNS at any point after device activation and were managed with TPP was carried out. Electrophysiological and behavioral mapping parameters were retrieved from the programming software database at 3 time points: the time of implantation, the time of shift to TPP, and the last programming session. A control group with no FNS was matched randomly to evaluate any difference in the mapping parameters that could be attributed to FNS.

RESULTS: Sixteen ears with FNS were found to be eligible for inclusion in this study. These cases were matched to 16 ears in the control group. The programming was changed from biphasic pulse pattern (BPP) to TPP (time point -1) after a period of 22.37 ± 14.62 months. Resolution of FNS was achieved in 14 ears (87.5%) by using TPP alone.

CONCLUSION: The TPP mapping strategy, in addition to decreased phase duration, showed successful results in managing facial nerve stimulation while allowing an increase in the hearing level in the form of increased MCL amplitude.

KEYWORDS: Otology, cochlear implant, facial nerve stimulation, mapping, impedance, amplitude, phase duration

INTRODUCTION

Facial nerve stimulation (FNS) is a known complication of cochlear implantation (CI) with a reported incidence of 0.9%-15%.¹⁻⁵ A patient's symptoms can range from simple awareness and discomfort to severe facial spasm.⁶ It has been hypothesized that CI can lead to increased excitability of the facial nerve nucleus and decreased inhibitory control on the nucleus even in patients with no overt FNS.⁷ Possible explanations for overt FNS can be either a decreased impedance to the stimulating current produced by the CI, through abnormal osteosclerotic bone, a temporal bone fracture line, or the close proximity of the upper basal turn of the cochlea to the labyrinthine segment of the facial nerve; or an increased stimulation level that can be needed in cases of a hypoplastic acoustic nerve or prolonged hearing deprivation.^{5,8-13}

Managing the FNS can be achieved by decreasing the stimulation level, switching off the facial nerve stimulating electrode, or changing the mapping program. These management options can impose some inconvenience to the patient by limiting the

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dynamic range of loudness or by preventing the full audiological benefit when some electrodes are deactivated. A recent management option for FNS is the use of triphasic stimulation pulse pattern (TPP), which showed promising resolution of symptoms and, at the same time, comparable audiological and speech outcomes.¹⁴⁻¹⁶

In current practice, CI programming is carried out through a time-consuming, trial-and-error process.^{17,18} This process can be further complicated due to the presence of FNS. We aim to illustrate our experience in programming patients with FNS through TPP and elaborate on the electrophysiological and behavioral mapping parameters. The findings of this study can be suggestive for CI programmers to direct them on what parameters would better fit patients with FNS.

METHODS

A retrospective study was conducted on patients who underwent cochlear implantation after being accepted by the Cochlear Implant Committee in King Abdullah Ear Specialist Center of King Saud University (a tertiary referral university hospital). The Institutional Review Board in King Saud University with reference number: 20/0589/IRB, on 13.07.2020. Informed consent was obtained from all participants before the initiation of this study.

Group Selection

The study group was chosen from patients who developed facial nerve stimulation, defined as a repeatable electromyographic response of the facial muscles that are clinically appreciable and detectable by the physician, audiologist, or the patient, occurring after activation of the CI for any duration at a stimulation level at or below the maximum comfortable level of any electrode. A comprehensive medical file review was performed to identify all patients with FNS who were shifted to a TPP for the management of FNS.

The control groups were matched to the study group regarding their age, gender, type of electrode, and duration of CI use, without developing postoperative FNS. All subjects in the control group had smooth, full insertion of their electrode arrays with no surgical complications. Patients were excluded if they had a history of meningitis, cochlear ossifications, anomalous basal turn of the cochlea, anomalous facial nerve course, cochlear nerve aplasia/hypoplasia or internal auditory canal narrowing, otosclerosis, electrode migration, device failure, explantation, incomplete records, or loss of follow-up.

Data Collection Time Points

Most comfortable loudness level (MCL) charge and amplitude, threshold level, phase duration (PD), and impedance of the study group were obtained at 3 time points as follows: Time point -0 is defined as the time of cochlear implantation, with only impedance

is measured at this time point. Time point -1 is defined as the time of shift from BPP to TPP. All readings were obtained for both BPP and TPP at this time point. Time point -2 is defined as the last programming session at the time of study for the study group, where they had reached an FNS symptom-free status. For the control group, since there was no shift to TPP at time point -1, only one reading of the same parameters with BPP was available. Time point -1 and time point -2 were matched to that of the study group (Figure 1).

MEASUREMENTS

Behavioral Mapping Parameters

The behavioral mapping parameters included the THR and MCL. Both were measured in charge units (qu). Electrical stimulation levels were determined using subjective responses in adults, play audiometry in children, and behavioral observation in younger children. The THR was defined as the lowest current level that elicits an auditory perception and was measured by presenting a stimulus in a descending current level until the patient stops hearing the stimulus. The MCL was defined as the highest current level that does not induce an uncomfortable level of auditory sensation.

The MCL was performed in an ascending fashion to the level where the patient perceived it as "uncomfortably loud." The encounter of a non-auditory perception, such as facial nerve stimulation, was not assessed when setting MCL.¹⁹ The THR for younger children was set approximately 10 below a change in behavior due to the possibility of late or decreased responses.

The amplitude, measured in current units, refers to the magnitude of the electrical signal in the MCL and was determined by the behavioral programming.

Electrophysiological Mapping Parameters

Phase Duration (Microseconds/Phase)

Phase duration is the duration that the stimulus is in each of the opposite polarities, either a positive or a negative phase, allowing

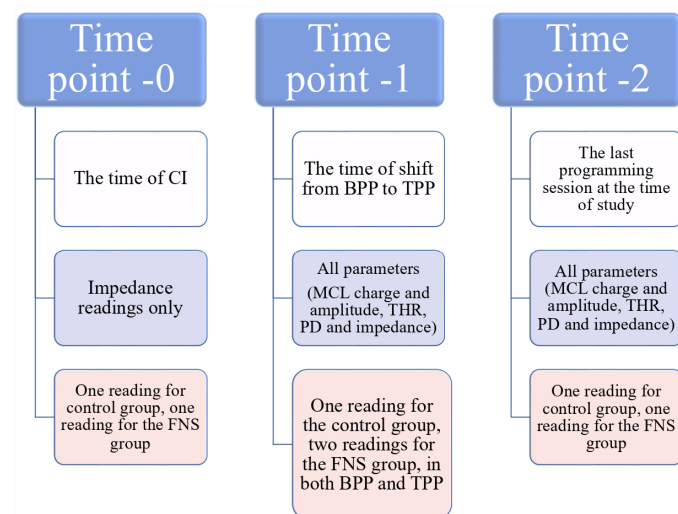


Figure 1. The mean of the behavioral and the electrophysiological mapping parameters in the facial nerve stimulation (FNS) and the control group in all time points.

MAIN POINTS

- It is possible that an inherited high threshold level in patients with post-cochlear implantation FNS is the underlying cause for setting a high MCL that leads to FNS.
- TPP is a promising programming strategy for managing FNS.
- Using the TPP, it was found that the patient tolerated higher levels of amplitude without the development of FNS symptoms.

the nerve to charge to reach an action potential upon reaching the threshold. The total electrical charge by the electrical stimulus is determined by the pulse duration and the amplitude of the stimulus. Total charge per phase = amplitude \times phase duration.

The phase duration was set based on each electrode's impedance to avoid a maximum total load of 40 μ cu. In MAESTRO fitting, the phase duration is automatically adjusted to deliver the required charge for MCL to avoid compliance (clipping of the pulse amplitude). An inter-phase of 2.1 μ s was set.

Impedance (Kilo Ohms)

The resistance of current flow through a medium is defined as impedance. The clinical electrode impedance is measured by delivering a low-level current pulse through an active intracochlear stimulating electrode at the trailing edge of the pulse and then measuring the resulting voltage across the associated electrodes at the end of the anodic phase. Finally, the impedance value is calculated through Ohm's law. These clinical impedance levels were imported from the telemetry software (Maestro 9, MED-EL).

Analysis

Data collection and management were performed using Microsoft Excel version 16.3 (Microsoft; Seattle, WA, USA). This Excel file was saved in an encrypted Google Drive. Statistical analysis was performed using IBM SPSS 23.0 software for Mac (IBM SPSS Corp.; Armonk, NY, USA). A two-sided significance level of 0.05 and a 2-sided 95% CI were set. The mean value of all the electrodes was used for further analysis.

RESULTS

This study included 16 ears in the study group with FNS managed by TPP, with a matched control group of 16 ears who did not develop FNS. The study and the control groups each consisted of 10 females and 6 males (16 ears), with the age at implantation ranging from 2 to 60 years (mean 27.68 ± 21.06 years). Three of the study group subjects had Mondini deformity, in which the basal turn of the cochlea has normal anatomy and hence they were not excluded. The rest of the study group and all the control group participants had normal inner ear anatomy. Of the study group, 7 ears were implanted with FLEX 28 electrodes, 7 ears with FORM 24, and 1 ear with FLEX 24. Looking at the etiology of the study group, 8 ears had progressive hearing loss, 1 ears were associated with congenital hearing loss, 2 ears had sudden sensorineural hearing loss (SSNHL), and 2 ears had post-meningitis hearing loss. Regarding the radiological findings, we observed the following: enlarged vestibular aqueduct (EVA) in 3 cases, diminished fluid signal intensity, especially in the basal and middle turns, in one case, a temporal bone fracture in one case, and normal radiological findings in the remaining 11 cases.

The onset of FNS presentation was at the first activation session postoperatively in 4 patients, and the latest presentation was 6 months postoperatively in 1 patient (mean 1.68 ± 1.85 months). The programming was changed from BPP to TPP (time point -1) after a period ranging from 1 to 52 months (mean 22.37 ± 14.62). A close match of this time point was chosen in the programming sessions of the control group, with a range from 6 to 64 months (mean 24.12 ± 12.34). The duration of follow-up postoperatively (time point -2) ranged from 2 to 77 months (mean 38.75 ± 20.36 months) in the FNS

group and from 6 to 94 months (mean 43.12 ± 16.03 months) in the control group.

Before shifting the patients into TPP, multiple strategies were undertaken to control the symptoms, including decreasing the MCLs, adjusting the level of THR, increasing the phase duration, changing the compression, changing the sensitivity, and even switching off the most facial nerve-stimulating channels. However, these measures could not control the symptoms with satisfactory hearing levels. The successful resolution of FNS was achieved in 14 ears (87.5%) by using TPP alone, whereas deactivation of 1 channel was needed in the other 2 ears to control the symptoms in addition to the TPP. Triphasic stimulation pulse pattern alone successfully resolved FNS in 14 ears (87.5%). In the remaining 2 ears, TPP was applied after deactivating 1 channel in each case to control FNS. Six channels (5 through 10) were responsible for FNS in one case, and only channel 8 was deactivated with TPP. Eight basal channels were initially involved in the second case, but TPP allowed the deactivation of just one (channel 12). In the first case, a FORM 24 electrode was used for the unresolved cases. The distance between the facial nerve's labyrinthine segment and the cochlea's upper basal turn was 0.52 mm, and the angular depth of insertion was approximately 430° . The etiology was sudden sensorineural hearing loss (SSNHL); with radiological findings, diminished fluid signal intensity was noted, especially in the basal and middle turns. In this case, the channel that required deactivation was channel 8; the facial nerve's proximity to the cochlea's basal turn and the radiological findings may have contributed to the persistent FNS in this case.¹³ In the second case, the etiology was SNHL. FLEX 28 electrode was used, and the distance between the facial nerve's labyrinthine segment and the cochlea's upper basal turn was 0.61 mm, with an angular insertion depth of around 390° . Imaging revealed a bilateral enlarged vestibular aqueduct. In this case, channel 12 was deactivated; however, we could not correlate its relation to the facial nerve, which may be attributed to the apparent pathway or current leakage.

Table 1 summarizes the behavioral and the electrophysiological mapping parameters in the study and control groups at all time points. The MCL charge and amplitude, THR, and PD were found to be nonparametric data with a Kolmogorov-Smirnov test value ranging from 0.125 to 0.184 and a P -value $<.001$, while the impedance was normally distributed with a Kolmogorov-Smirnov test value of 0.0092 and P value = .2.

Generally, during all time points and with all stimulation modes, the FNS group showed higher MCL, THR, PD, and impedance, while showing lower amplitude compared to the control group (Table 1, Figure 1). While these differences were significant in amplitude and PD (Kruskal-Wallis test P value $<.001$), no significance could be detected in the MCL, THR, and impedance (Kruskal-Wallis test P value $>.2$). (Table 2).

The MCLs were found to be higher, with no statistical significance, in the FNS group compared to the control group (mean 29.25 ± 10.91 qu compared to 25.23 ± 9.78 qu, Mann-Whitney U -test P value .07). There was no difference found in the MCLs between the BPP and TPP in the FNS group (Mann-Whitney U -test P value .48) (Figure 2).

The PD of the FNS group was higher at time point -1 in compared to the control group and decreased to be comparable to the control

Table 1. Mean and the Standard Deviation of the Behavioral and the Electrophysiological Mapping Parameters in the Facial Nerve Stimulation (FNS) and the Control Group in All Time-Points

Group		MCL (qu)	Amplitude (cu)	THR (qu)	PD (sec)	Impedance (kΩ)
FNS group time point -0	Mean					5.12
	SD					1.59
Control group time point -0	Mean					4.79
	SD					1.39
FNS group time point -1 BPP	Mean	28.51	521.63	3.36	75.74	5.71
	SD	8.47	292.86	2.07	41.70	0.86
FNS group time point -1 TPP	Mean	33.06	611.29	3.40	70.77	5.77
	SD	14.19	353.78	1.47	36.18	1.01
Control group time point -1	Mean	24.20	938.55	2.30	25.9	5.30
	SD	8.83	113.74	1.23	9.30	1.26
FNS group time point -2	Mean	27.38	609.54	3.98	60.40	5.31
	SD	10.164	344.42	3.54	41.29	0.38
Control group time point -2	Mean	26.27	897.88	2.05	29.71	5.15
	SD	10.83	166.11	1.07	15.82	1.22
Total	Mean	27.39	738.93	2.96	49.24	5.26
	SD	10.52	305.91	2.20	36.16	1.25

BPP, biphasic pulse pattern; FNS, facial nerve stimulation; MCL, the most comfortable loudness level; PD, phase duration; THR, threshold level; TPP, triphasic pulse pattern.

group at time point -2. It is possible that the PD was increased on purpose to manage FNS with BPP. It seems that the longer-than-needed PD was also maintained for the TPP map at time point -1 where the symptoms were still not controlled.

DISCUSSION

In this study, 16 ears of patients with FNS were compared to a matched control group of 16 ears without FNS. Patients with FNS

were found to have a higher THR level that may have contributed to the increased stimulation level, with a compensatory increase in the MCL to achieve an acceptable dynamic range for hearing. This increased MCL setting can be a contributor to their extra-auditory stimulation in the form of facial nerve stimulation.

Since the MCL is set to the level that causes auditory discomfort, the FNS was probably overlooked as an uncomfortable encounter. It would be expected that the electrical stimulus will cause discomfort to the auditory nerve which is closer to the stimulus before causing the discomfort in the more distal facial nerve. However, it is not uncommon for patients to have a FNS thresholds that are lower than the MCL. The underlying cause for finding is poorly understood but can be due to the phase sensitivity.

The routine CI programming largely uses a biphasic pulse stimulation, in which the cathodic phase is proceeding and similar in amplitude to the anodic phase. This method of stimulation, although widely used, may not be the most efficient due to the canceling effect of the opposing polarity phases that occur in a short duration close to each other. Furthermore, it has been shown that the auditory nerve is more sensitive to the anodic phase rather than the cathodic phase. Therefore, an anodic phase leading stimulus is supposed to be more significantly perceived than a cathodic phase leading stimulus.²⁰⁻²⁴

In opposition to the auditory nerve, the facial nerve has been assumed to be more sensitive to the cathodic phase of stimulation. Due to this sensitivity difference, an anodic-phase-leading triphasic stimulation has been suggested by some studies to overcome FNS.¹⁷⁻²⁵

The patients needed a decrease in their MCL setting and a decrease in the PD to control the FNS symptoms. This decrease in PD allowed an increase in the amplitude to achieve an appropriate total charge (PD × amplitude) Which in turn allowed a decrease the MCL to get rid of the FNS.

It has been suggested that FNS happens with a leak of electrical charge to the facial nerve.^{16,26}

Therefore, the other theory for the mechanism by which TPP reduces FNS is by reducing the current spread. This theory is supported by showing a decreased electrical artifact when recording electrically evoked action potentials upon the use of TPP.^{27,28}

Table 2. Comparing the Behavioral and the Electrophysiological Mapping Parameters of the Control and the FNS Groups in Different Combinations

Grouping Variables		MCL (qu)	Amplitude (cu)	THR (qu)	PD (msec)	Impedance (kΩ)
Kruskal–Wallis test: 6 groups of FNS and Controls in 3 time points	Chi-square	4.24	20.30	5.11	26.53	8.17
	Asymp. sig.	0.37	0.000	0.27	0.000	0.22
Kruskal–Wallis test: The 3 time points	Chi-square	0.19	0.10	0.45	0.78	5.99
	Asymp. sig.	0.66	0.74	0.50	0.37	0.05
Comparing FNS to control	Mann–Whitney <i>U</i>	444.00	229.00	415.50	182.50	723
	Asymp. sig. (2-tailed)	0.07	0.000	0.034	0.000	0.11
Comparing TPP to BPP in FNS group: time point -1	Mann–Whitney <i>U</i>	45.00	44.00	51.00	51.00	54.5
	Asymp. sig. (2-tailed)	0.48	0.43	0.77	0.77	0.97

BPP, biphasic pulse pattern; FNS, facial nerve stimulation; MCL, the most comfortable loudness level; PD, phase duration; THR, threshold level; TPP, triphasic pulse pattern.

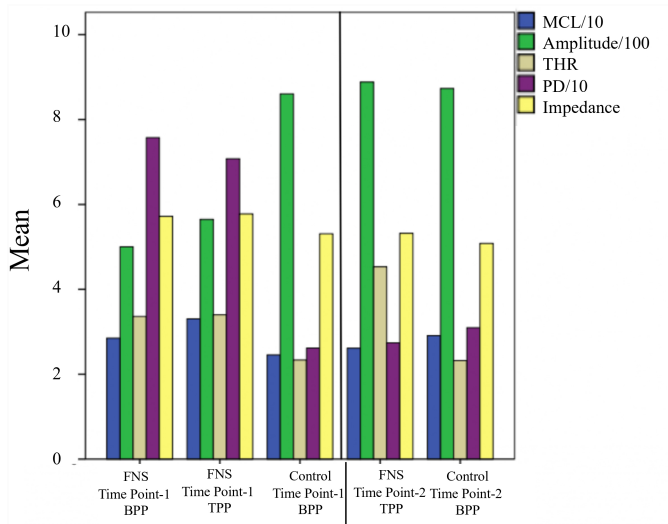


Figure 2. Illustrating the mean of the behavioral and the electrophysiological mapping parameters in the facial nerve stimulation (FNS) and the control group in all time points.

Some devices use a monopolar stimulation strategy where the grounding is achieved outside the cochlea in the internal receiver-stimulator body or via a ground electrode. This grounding method can result in a wide electrical field.^{29,30} In contrast, in bipolar or tripolar stimulation strategy, the electrical current is transmitted through one central electrode, and the spread of the excitation current is halted by surrounding electrodes that absorb any extra current, thereby increasing the spatial selectivity and decreasing the spread of excitation. This theory of more precise current localization aims to reduce the theory behind decreasing spread to extracochlear structures, including the facial nerve.³¹

An argument can be made that, even with using an intracochlear grounding, the site of the reference contact is horizontal to the array, halting the spread in the horizontal orientation, while the site of the maximum extracochlear stimulation by the active contact, reaching to the facial nerve, would be perpendicular to the active contact.³²

Furthermore, by limiting the spatial current spread, the stimulation received by the auditory nerve can be affected, and thus the intracochlear grounding strategy is not widely used and was not used in our study.³⁰

Additionally, FNS has been documented with all grounding methods.³³

Some manufacturers have used extracochlear grounding strategies for managing FNS to design custom-made devices for patients with FNS, where the ground electrode is located in the round window niche instead of the internal receiver-stimulator body.³⁴

In the next section of the discussion, we evaluate the effect of each parameter on its own.

Most Comfortable Loudness Level and Threshold Level

Decreasing the stimulation MCL has been suggested as a method to decrease FNS. However, the FNS might have been primarily due

to the need to increase the stimulation level to reach full loudness growth. Patients with FNS sometimes require a higher stimulation level due to fibrosis or unresponsiveness to the lower level of stimulation.⁵

In this study, the FNS group was found to have a higher THR level than the control group. The MCL level was also set at a higher level in the FNS group before managing the symptoms. This finding might support the theory that there is irresponsiveness to the auditory stimulus, especially since this higher THR level persists even after managing the FNS at time point -2. Having a higher THR can force the programmer to set a higher MCL to achieve an acceptable dynamic range, and this higher MCL in turn results in extracochlear stimulation. Since the MCL is set to the level that causes auditory discomfort, the FNS was overlooked as an uncomfortable encounter. It would be expected that the electrical stimulus will cause discomfort to the auditory nerve which is closer to the stimulus before causing the discomfort in the more distal facial nerve. However, it is not uncommon for patients to have a FNS threshold that is lower than the MCL. The underlying cause for finding is poorly understood but can be due to the phase sensitivity differences as mentioned before.^{4,6,12,14}

Amplitude

The presence of the FNS prevented the increase in stimulus amplitude. The results of this study illustrate how the amplitude could be increased in the FNS group to be comparable to the control group after managing the FNS.

Phase Duration

In this study, an increased PD was used to manage FNS. But after the resolution of FNS symptoms with TPP at time point -2, the need for increasing the PD was over, and it was returned to the usual duration similar to the control group.

Impedance

The impedances of the control group and the FNS group did not differ significantly, nor did they change significantly over time or with change in the stimulation pattern. Hence, no clear relation or association could be found between the impedances and the occurrence of facial nerve stimulation. Although, in reference to our assumption that increased intracochlear fibrosis could have led to an increased THR and consequently an increased MCL, we were expecting an increased impedance as well, but this was not found.

CONCLUSION

Use of TPP proved to be a successful strategy for treating facial nerve stimulation. It can be recommended to use the TPP stimulation with low PD for patients with expected or observed FNS. Triphasic stimulation pulse pattern allows for increasing the amplitude (hence the auditory stimulation level) and decreasing the MCL (making the stimulation more tolerable for the patient) to a level comparable to CI patients with no FNS. We recommend that audiologists consider the development of facial stimulation as an uncomfortable encounter when setting the MCL levels.

Availability of Data and Materials: The data that support the findings of this study are available on request from the corresponding author.

Ethics Committee Approval: This study was approved by the Ethics Committee of King Saud University (approval no.: 20/0589/IRB, date: 13.07.2020).

Informed Consent: Written informed consent was obtained from the patients who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – I.A., A.A.; Design – I.A., Y.A., M.Y.; Supervision – A.A., Fa.A., F.A.; Resources – A.A.; Materials – A.I.A., I.A.; Data Collection and/or Processing – A.I.A., I.A.; Analysis and/or Interpretation – I.A.; Literature Search – A.I.A., I.A., Y.A.; Writing – A.I.A., I.A.; Critical Review – A.A., Fa.A., F.A., M.Y.

Declaration of Interests: The authors have no conflicts of interest to declare.

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