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Original Article

The Relationship between Electrical Stapedius Reflex Thresholds and Behaviorally Most Comfortable Levels in Experienced Cochlear Implant Users

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OBJECTIVES: Programming the cochlear implant's speech processor with subjective methods in young, uncooperative children is difficult. Since young children cannot provide adequate feedback to the clinician, objective methods which do not require patient's response were often used. Electrical Stapedius Reflex Test is one of the most common procedures used. The goal of this study was to investigate the relationship between electricalstapedius reflex thresholds and behaviorally most comfortable levels in experienced cochlear implant users.

MATERIALS and METHODS: The patients implanted with two brands of cochlear implants were compared in terms of electrical stapedius reflex thresholds versus most comfortable levels. Speech tests results were also compared between the two groups. 46 cochlear implanted patients who had at least 1 year of cochlear implant experience were included in the study. 28 patients were implanted with Nucleus, 18 patients with Med-El devices.

RESULTS: Moderate correlations were obtained between Electrical Stapedius Reflex (ESR) thresholds and the comfort (C) levels in Nucleus users; higher correlations were obtained for Med-El patients. ESR thresholds were present at higher levels than the most comfortable and the comfort (MCL/C) levels in both Nucleus and Med-El users. No significant difference was obtained between the two groups in terms of speech tests.

CONCLUSION: ESR test can be very informative for programming young and uncooperative patients.

KEYWORDS: Electrical Stapedius Reflex Test, cochlear implant, MCL, comfort level

INTRODUCTION

Speech processor of the cochlear implant (CI) requires individual programming of the electrical dynamic range, which is different for each patient. The threshold level and the comfort (C) level or the most comfortable level (MCL) are determined for each electrode. The setting of these map levels is performed by performing behavioral testing in most patients. Accurate programming of these map levels is required for a good map. A good map gives access to hearing and speech perception with the implant, thus, enabling better speech understanding in postlingually deafened adults and better speech and language development in prelingual young CI users. In adult CI users, even after making small changes in electrical levels for programming the speech processor, significant deterioration in speech understanding has been observed [1]. The behavioral measurements of map levels can easily lead to over- or underestimation of map parameters. An appropriately set map is necessary, as it will give access to sounds and speech, thus, enabling the development of speech and language in the implanted child.

Programming the CI's speech processor using subjective methods in young, uncooperative children is difficult and challenging. Because young children cannot provide adequate feedback to the clinician, objective methods that do not require a patient's response are often used. Electrical Stapedius Reflex Test (ESRT), as an objective measurement method, may be helpful in determining C levels or MCLs in programming young children who do not have enough auditory experience and who exhibit lack of cooperation for appropriate programming. With the implementation of the newborn hearing screening, children with hearing loss can be diag-

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nosed earlier than ever, and they can get access to cochlear implantation at a very young age. Because the age of children undergoing implantation is decreasing and the candidacy criteria is expanding to include babies at a young age as well as multiple handicapped children, the need for objective tools to program these children has increased.

Electrical Stapedius Reflex Test can be used as an objective method to program both adult and pediatric implant patients. The relationship between ESRT thresholds and C levels has been reported as early as late 80s [2]. Recent studies have shown postoperative ESRT thresholds to have a high correlation with the map MCLs [3-8]. Recording postoperative ESRT thresholds can help predict map C/MCLs.

Opie et al. [9] have evaluated intraoperative ESRT levels measured through three different CI systems. ESRT thresholds were found to be higher than MCLs in Med-El and Clarion implant users and both higher and lower than C levels in Nucleus patients. To our knowledge, few studies have been conducted to compare the relationship between postoperative ESRT levels and electrical map parameters among different CI brands.

The goal of this study was to investigate the relationship between electrical stapedius reflex thresholds and behaviorally MCLs in experienced CI patients.

Patients implanted with two different brands of CIs were compared in terms of ESRT thresholds versus C/MCLs and speech tests results.

MATERIALS AND METHODS

Subjects

The subjects in this prospective study included a subset of adult patients from the CI program at a tertiary referral hospital. Overall, 46 adult unilateral CI patients with a mean age of 22.9 years (19-55 years) who had at least 1 year of CI experience and had normal middle ear function participated in the study. All CI patients were postlingually deafened. The mean duration of CI use was 6.5 years (1-13 years). Exclusion criteria included presence of middle ear pathology, inconsistency in CI use, and presence of inner ear malformation.

In total, 28 patients were implanted with Nucleus (Cochlear Corporation, Melbourne, Australia) CI24M, CI24R, or CI 24RE devices and 18 patients with Med-El (Med-El Corporation Innsbruck Austria) Sonata or Pulsar devices. Full insertion of the electrode array was achieved in all patients.

There was no significant difference between the two groups of patients ($p<0.05$) in terms of age and duration of CI use.

The study was approved by the Marmara University Clinical Studies Ethical Committee (21.03.2012-8) and was conducted according to the ethical standards of Helsinki Declaration. Written informed consent was obtained from the subjects.

Procedure

All subjects were tested while they were attending the clinic for their routine programming. The measurements were performed after at

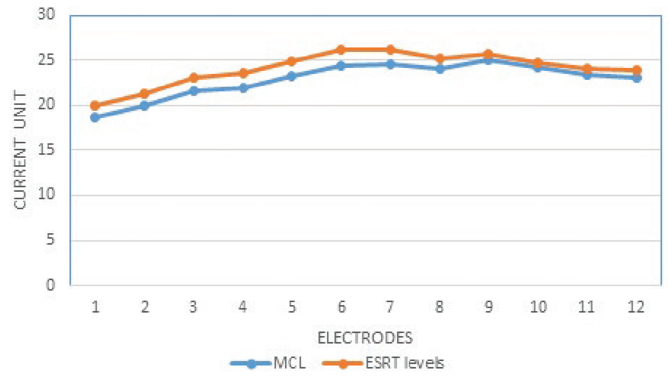

Figure 1. Mean MCLs and ESRT thresholds for patients implanted with Med-El devices.

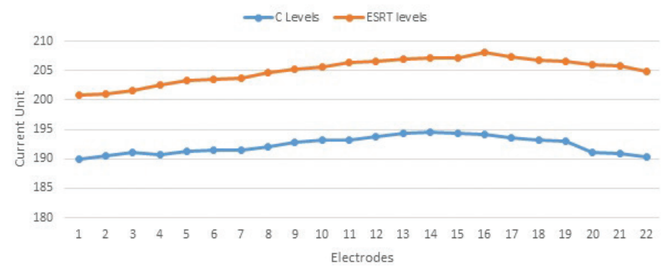

Figure 2. Mean C levels and ESRT thresholds for patients implanted with Nucleus devices.

least 1 year of CI use with a mean of 6.5 years. Of all, 11 subjects had normal middle ear function as evidenced by normal type A tympanograms. The behavioral map T and C/MCLs were set, and a behavioral map was generated using these behavioral measurements. The patients were tested with the behavioral map using an open-set sentence test and trisyllabic and monosyllabic word identification tests.

The open-set speech tests were performed in a sound-treated test booth. The speech materials were delivered in live mode at a normal conversational level (at 65 dB SPL) with 0° azimuth.

For ESRT measurements, standard programming software were used to stimulate each electrode. For Cochlear users, Custom Sound Suite 3.0 software (Cochlear Corporation, Melbourne, Australia) was used for programming and for ESRT testing. For Med-El users, Med-El fitting software 4.02 (Med-El Corporation Innsbruck Austria) was used to program the speech processor and to perform the ESRT testing.

A standard middle ear analyzer (Interacoustics AZ 7, Denmark) was used to perform tympanometry and to record electrical stapedius reflexes. The compliance changes were monitored in the contralateral ear at the reflex decay mode. The default recording parameters suggested by each company were used to record ESRTs as shown in Table 1. Stimulation began at 20 programming units below the behaviorally obtained C/MCLs.

If an ESRT response was present, the stimulation level was decreased until a clear response was obtained at least at two measurements. The reflex was accepted to be present when there was a definite and reliable deflection of at least 0.5 mL. If the stimulation caused any

Table 1. Recording parameters for ESRT threshold

	Med-El	Nucleus
Pulse Rate	1515 pps	50 pps
Burst length	500 ms	500 ms at 900 Hz
Pulse duration	26.7 µs	500 µs

discomfort to the patient, the test was abandoned. ESRT thresholds were measured for each active electrode.

Table 2. Comparison of speech test results with behavioral maps for Nucleus and Med-El users

	Nucleus		Med-EL			
	Mean	SD	Mean	SD	t	p
3 syllabic words	93.71%	6.83	91.37%	12.89	0.789	0.434
Monosyllabic words	60.96%	24.49	61.5%	23.36	−0.071	0.944
Sentences	84.64%	17.14	90.87%	9.23	−1.566	0.125

SD: Standard Deviation

Table 3. Comparison of speech test results with ESRT-based maps for Nucleus and Med-El users

	Nucleus		Med-EL			
	Mean	SD	Mean	SD	t	p
3 syllabic words	81.94%	12.40	82.28%	10.28	−0.083	0.934
Monosyllabic words	47.29%	20.35	36.28%	12.49	1.765	0.088
Sentences	74.94%	25.49	72.57%	20.14	0.282	0.780

SD: Standard Deviation

ESRT thresholds were set at C/MCLs, and a new map was generated. The patients were tested with the new generated map using an open-set sentence test and trisyllabic and monosyllabic word identification tests. The speech test results were compared with those obtained with patient's latest behavioral map.

Statistical Analysis

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, USA) version 17. A $p<0.05$ was considered statistically significant. Mann-Whitney U test was used to compare the age and duration of CI use between Med-El and Cochlear device users.

Spearman correlation coefficients were calculated to compare ESRT levels and map C/MCLs, and Wilcoxon test was used to compare speech test scores obtained for ESRT-based and behavioral maps for Med-El and Nucleus users. To predict subjective map levels using ESRT thresholds, a regression analysis was used.

RESULTS

The behavioral T levels and C/MCLs and ESRT thresholds were obtained for each active electrode in 46 CI users. Figure 1 compares the behaviorally measured MCLs and ESRT thresholds for Med-El CI users. Mean ESRT thresholds were found to be 1-2 units higher than the behavioral MCLs in these patients. The difference between mean ESRT thresholds and MCLs was not statistically significant ($t=0.049$; $p=0.961$).

Spearman correlation coefficients were calculated between behavioral MCLs and ESRT thresholds. A strong positive correlation was obtained between ESRTs and MCLs in Med-El CI users ($r=0.74$, $p<0.05$). To predict subjective levels using objective thresholds, a regression analysis was used. Regression analysis for all electrodes combined indicated that MCL levels were significantly affected by ESRT thresholds ($F=21.817$; $p=0.000$). Among the factors affecting behavioral MCLs, ESRT thresholds were found to affect MCL's by a ratio of 0.565 ($R=0.565$). For a 1 unit increase in, ESRT, MCL threshold increased by 0.657 unit (ss=0.657; $t=4.671$; $p=0.000$).

Figure 2 compares the behaviorally measured MCLs and ESRT thresholds for Nucleus CI users. Mean ESRT thresholds were found to be 10-15 current units higher than the behavioral C levels in these users. The difference between ESRT thresholds and C levels was found to be statistically significant ($t=-4.387$; $p=0.002$).

Spearman correlation coefficients were calculated between behavioral C levels and ESRT thresholds. Moderate correlations were observed between ESRT thresholds and C levels in Nucleus CI users ($r=0.554$; $p=0.002$).

To predict subjective levels using objective ESRT thresholds, a regression analysis was used. Regression analysis for all electrodes combined indicated that C levels were significantly affected by ESRT levels ($F=14.527$; $p=0.001$). Among the factors affecting behavioral C levels ESRT thresholds were found to explain the behavioral C levels by a ratio of 0.326 ($R^2=0.326$). For a 1 unit increase in ESRT threshold, C level, increase by 0.444 unit (ss=0.444; $t=3.811$; $p=0.001$).

All patients were tested using open-set speech tests with their behavioral map. On testing with behavioral maps we did not find any significant difference between Med-El and Nucleus CI users (Table 2).

ESRT-based maps were generated for all patients; four patients implanted with Med-El device and eight patients with Cochlear device found the ESRT-based map too loud and refused to use it. Speech perception performance was assessed in 34 patients with the new ESRT-generated maps. Patients tested with ESRT-based maps found these maps generally louder than their behavioral maps. None of them accepted to use it after the study.

When tested with ESRT-based maps, no significant difference was found between Med-El and Nucleus CI users (Table 3).

Speech tests results obtained with ESRT-based maps were compared with those obtained with behavioral maps; open-set sentence and trisyllabic and monosyllabic word test scores were significantly higher when obtained with the behavioral maps than those obtained with ESRT-based maps for both Med-El and Nucleus CI users ($p<0.05$).

Tables 4 and 5 show Wilcoxon test comparing speech tests scores obtained for ESRT-based and behavioral maps for Med-El and Nucleus users, respectively.

Table 4. Difference between speech test results obtained with behavioral and ESRT-based maps for Med-El users

	Behaviorally set map		ESRT-based map		
	Mean	SD	Mean	SD	p
3 syllabic words	91.37%	12.89	82.28%	10.28	0.03
Monosyllabic words	61.5%	23.36	36.36%	12.49	0.002
Sentences	90.87%	9.32	72.57%	20.14	0.006

SD: Standard Deviation

Table 5. Difference between speech test results obtained with behavioral and ESRT-based maps for Nucleus users

	Behaviorally set map		ESRT-based map		
	Mean	SD	Mean	SD	p
3 syllabic words	93.71%	6.83	81.94%	12.40	0.002
Monosyllabic words	60.96%	24.49	47.29%	20.35	0.028
Sentences	84.64%	17.14	74.94%	25.49	0.021

SD: Standard Deviation

DISCUSSION

Prelingually deafened young cochlear implantees or children with multiple handicaps exhibit lack of cooperation for behavioral setting of the map parameters. These CI recipients are difficult-to-map patients even for experienced audiologists. Objective tests including ESRTs are helpful to set the optimal map for these children in order to gain access to speech sounds. ESRT is one of the frequently used objective methods to program the speech processor.

Literature review shows positive correlations between ESRT thresholds and behavioral C levels in Nucleus CI users [5, 10, 11]. On the other hand, the results of this study revealed medium positive correlations between C levels and ESRT thresholds in patients using Nucleus device, which are lower than those reported by other studies performed with Nucleus device. The reason for much lower correlation values obtained in this study might be the diversity of Nucleus electrodes and speech processors used by our patients. These results are further supported by Gordin et al. [12] who found that ESRT threshold levels were significantly affected by the CI device type. ESRT threshold values were found to be higher in patients using Nucleus 24RE device than in those using 24M and 24RCS devices. Polak et al. [11] have reported that ESRT levels were not different between the 24M and 24RCS electrode arrays; on the other hand, in our study, 3 of 28 patients with Nucleus device were implanted with N24RE device and the rest with N24M and N24R devices.

The correlation obtained between ESRT thresholds and MCLs in Med-El implant users was high and consistent with that reported in the literature. Lorens et al. [7] have compared ESRT thresholds and MCLs in pediatric population and found a correlation coefficient of r=0.789. Similarly, Koşaner et al. [8], Stephan et al. [13], and Walkowiak et al. [14] have reported high r values ranging from 0.75 to 0.92 between behavioral MCLs and ESRT thresholds.

We found that ESRT thresholds were on average significantly higher than the C levels in Nucleus users; they were 10-15 current units higher than the behaviorally measured C levels. Similar results were obtained by Spivak et al. [4] who reported that ESRT thresholds were on average 19.4 current units higher than the C levels with a standard deviation of 15.5 units.

Similarly, Polak et al. [11] have compared ESRT thresholds in prelingual and postlingual Nucleus CI users; ESRT thresholds were significantly lower than C levels in the prelingual group and higher than C levels in the postlingual group. The reason for this finding was thought to be related to the long-term use of high-power hearing aids at low frequencies.

In contrast, Bresnihan et al. [15] have found that C levels obtained using the ESRT method are consistently lower than those obtained using behavioral techniques. Children using programs set with ESRT thresholds wear their implants longer and experience fewer episodes of discomfort with environmental sounds.

Jerger et al. [2] have reported that C levels were located close to the electrical reflex threshold and below reflex saturation levels in all cases. Similar results have been reported by Battmer et al. [16] in five patients using the Nucleus device.

ESRT thresholds obtained from the Med-El CI users were 1-2 programming units higher than the behavioral MCLs. Similar findings have been reported by Walkowiak et al. [14] who reported that for each electrode, tested mean values of MCL are closer to ESRT than to electrically compound action potential thresholds.

Raghunandhan et al. [17] have reported that initial ESRT thresholds tested in the first month after implantation were higher than MCLs; when the ESRT measurement was repeated 1 year after CI use, the behaviorally tested MCLs fell close to ESRT threshold levels for Advance Bionics device users. The mean average ESRT threshold and MCL difference was 3 current units.

We evaluated the speech intelligibility performance of our CI users using open-set word and sentence identification tests in two conditions: map generated with behaviorally set C/MCLs and map generated with ESRT thresholds. Four patients implanted with Med-El device and eight with Cochlear device found the ESRT-based map too loud and refused to use it. Speech perception performance was assessed with ESRT-based map in 34 patients. These maps were found to be generally louder than the behavioral maps. None of the patients accepted to use it after the study.The speech test performance was better with the behaviorally set maps than with ESRT-based maps for patients using Nucleus and Med-El devices. This result confirms the importance of appropriately set map parameters for patients' performance after implantation. Although the speech test results for behaviorally set maps and ESRT-based maps were close, the difference was found to be significant and was also felt by the patients.

Wasowski et al. [1] have reported significant deteriorations in speech comprehension test even with small changes in electrical stimulation levels. The optimal mapping of the speech processor has been stated to be of profound importance for patients' speech understanding performance afer implantation.

In contrast, Hodges et al. [18] have found that speech perception performance does not differ when adult CI users tested with ESRT-based maps or behaviorally based maps. Patients preferred using the ESRT-generated map. Spivak et al. [4] have not reported any difference in Nortwestern University Auditory Test No. 6 words and City University of New York sentences for the CI users tested with behavioral and ESRT-based maps. Koşaner et al. [8] have evaluated the performance of children with ESRT-based maps using sound-field test and speech performance scores. Average sound-field threholds with the implant for 250 to 6000 Hz were between 33 to 37 dB, allowing the children to have access to all speech sounds. The children's mean closed-set monosyllable scores were 81% and GASP scores were 7.6/10.

One of the limitations of our study was that our patients did not use ESRT-based maps for long periods; they were tested when they were at the clinic for routine mapping. They were familiar with their behaviorally set maps and had been using it for at least 1 year. They did not get the opportunity to get accustomed to the new ESRT-based maps and were tested after a short period of using these maps.

CONCLUSION

Electrical Stapedius Reflex Test thresholds can be successfully measured in both Nucleus and Med-El CI users. These thresholds appear to correlate well with behavioral MCLs in Med-El users but are moderately correlated with C levels of Nucleus CI users. ESRT thresholds can be used to generate programming maps in Med-El users when behavioral programming is not possible. In Nucleus CI users, for programming noncooperative patients, C levels can be set at 15-20 current units below the ESRT thresholds.

Clinicains are usually concerned about overstimulating and/or stimulating above the C levels of patients when using objective levels to map the speech processor. Progressive maps with increasing dynamic range or volume settings can be programmed for acclimatization to the new ESRT-based maps, especially in young children.

Electrical Stapedius Reflex Test is a reliable and useful tool for programming uncooperative, difficult-to-test young patients.

Ethics Committee Approval: The study was approved by the Marmara University Clinical Studies Ethical Commitee (21032012-8) and it was conducted according to the ethical standards of the University Ethical Commitee and the 1964 Helsinki Declaration.

Informed Consent: Written informed consent were obtained from the subjects participated to the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - A.Ç., Ç.A.; Design - A.Ç., Ç.A.; Supervision - A.Ç.; Resource - A.Ç., Ç.A.; Materials - A.Ç., Ç.A.; Data Collection and/or Processing - Ç.A.; Analysis and/or Interpretation - A.Ç., Ç.A.; Literature Search - Ç.A; Writing - A.Ç., Ç.A.; Critical Reviews - A.Ç.

Conflict of Interest: The authors have no conflict of interest to declare.

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