Evaluation of the Electrically-Evoked Stapedial Reflex Threshold in Pediatric Cochlear Implant Users with High-Frequency Probe Tones

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Abstract

Introduction Measurement of the electrically-evoked stapedial reflex threshold (ESRT) is an objective tool used to set the comfort levels in pediatric cochlear implant (PCI) users. The levels of ESRT have a strong correlation with comfort levels. However, the clinical utility of ESRT is limited because the ESRT response is not observed in all cochlear implant users.

Objective To assess the effects of probe-tone frequency on ESRT and its relationship with the behavioral comfort levels in PCI users.

Methods A total of 14 PCI users aged between 5 and 8 years participated in the study. The ESRT levels were measured using high-frequency probe tones (678 Hz and 1,000 Hz), and the default 226 Hz probe tone. The ESRT was measured with single-electrode stimulation across the three electrode locations (basal [E01]; middle [E11]; and apical [E22]). The ESRT levels measured with different probe tone frequencies were compared with the behavioral comfort levels.

Results The mean ESRT levels using 1,000 Hz and 678 Hz were lower than those measured using 226 Hz, but there was no main effect of probe-tone frequency ($p > 0.05$). A significantly high incidence of successful ESRT measurements occurred with higher-frequency probe tone ($p < 0.039$). Additionally, ESRT using higher probe tones significantly correlated with comfort levels.

Conclusion The ESRT with higher probe tones was correlated with behavioral comfort levels and increased the success rate of the measurements. Higher-frequency probe tones may be useful whenever ESRT with 226 Hz is not measurable.

Keywords
► cochlear implant
► electrical stapedius reflex threshold
► comfort levels
► probe tone

Introduction

Programming/mapping cochlear implants plays a significant role in determining the outcomes of the patients who will use them. Mapping involves setting the lower stimulation levels/threshold levels (the minimal amount of electrical stimulation required for the auditory system to perceive sound) and upper stimulation levels/comfort levels (the upper limit of electrical stimulation deemed to be the most comfortable, or loud but comfortable) across the electrode array. There is a range of objective measures from which to choose when mapping the implants of pediatric

cochlear implant (PCI) users, since reliable behavioral responses are challenging to obtain. One of them is the measurement of the electrically-evoked stapedius reflex threshold (ESRT), which is defined as the lowest level of electrical stimulation that elicits a contraction of the stapedius muscle. Numerous studies[1–6] have shown a strong correlation between postoperative ESRT and the comfort levels of patients. However, the clinical usefulness of ESRT is limited because responses to it are not observed in all the cochlear implant (CI) users. A survey[7] involving 47 cochlear implant centers worldwide revealed that only 14% of used ESRT measurements while setting the comfort levels. The successful measurement of the ESRT with the default probe-tone frequency of 226 Hz varied from 63% to 80%.[1–3,5,8] These measurements can be affected by any insignificant alteration in the functioning of the middle ear.[9] Several conditions could increase the middle ear's stiffness, such as CI surgery in the implanted ear and previous history of middle ear disorders in the non-implanted ear.[10] Recent studies have reported that the use of higher-frequency probe tones yielded better ESRT responses. Wolfe et al.[11] reported that the use of higher-frequency probe tones (of 678 Hz or 1,000 Hz) resulted in lower ESRT levels than those obtained with 226 Hz in adult CI users. In a similar study in PCI users, Carranco Hernandez et al.[12] reported that a higher probe tone could increase the successful measurement of the ESRT, especially in ipsilateral ears.

The middle ear maturational aspects affect the ESRT measurements in PCI users because a developmental trend in middle ear transmission is observed between 5 to 9 years of age.[13] In ESRT measurements, it is essential to understand the use of different probe-tone frequencies and their relationship with comfort levels in younger children. There is a dearth of studies on the effectiveness of higher-frequency probe tones in ESRT measurements in the literature, especially in younger children. In addition to that, there is a need to identify the most appropriate probe-tone frequency for ESRT measurements in PCI users.

Hence, the objectives of the present study were to assess the effect of probe-tone frequencies on ESRT measurements and their relationship with behavioral comfort levels in PCI users.

Methods

The present prospective cross-sectional study was conducted in a tertiary care hospital from January 2019 to March 2020, and the participants were recruited from the Cochlear Implant Clinic at the Department of Ear, Nose and Throat (ENT). The study received approval from the institutional Ethics Committee for Human Studies (JIP/IEC/2018/46). The sample was composed of 14 PCI users (Nucleus CI24RE with full-band straight electrode, Cochlear, New South Wales, Australia). Only 1 out of the 14 participants was a bilateral CI user, and the remaining 13 were unilateral CI users. The mean age of the sample was 6.14 years (range: 5 to 8 years; standard deviation [SD] = 1.02; 10 males and 4 females). All the participants were diagnosed with bilateral severe to profound hearing

Table 1 Demographics of the study sample

Partici-pant	Age (years)	Age at implantation	Experience with the cochlear implant (years)	Unilateral/Bilateral	Implant
P01	7	4	3	Bilateral	CI24RE(ST)
P02	7	4	3	Unilateral	CI24RE(ST)
P03	7	5	2	Unilateral	CI24RE(ST)
P04	5	3	2	Unilateral	CI24RE(ST)
P05	5	2	3	Unilateral	CI24RE(ST)
P06	6	3	3	Unilateral	CI24RE(ST)
P07	8	4	4	Unilateral	CI24RE(ST)
P08	5	3	2	Unilateral	CI24RE(ST)
P09	7	4	2	Unilateral	CI24RE(ST)
P10	6	2	4	Unilateral	CI24RE(ST)
P11	7	2	5	Unilateral	CI24RE(ST)
P12	5	3	2	Unilateral	CI24RE(ST)
P13	6	4	2	Unilateral	CI24RE(ST)
P14	5	2	3	Unilateral	CI24RE(ST)
Mean (SD)	6.14 (1.02)	3.21 (0.97)	2.85 (0.94)	NA	NA

Abbreviations: NA, not applicable; SD, standard, deviation; ST, straight array.

loss. ►**Table 1** shows the demographics of the participants and their experience with the CI device.

All of the test procedures were performed in a sound-treated room with appropriate acoustic isolation and noise within the maximum permissible levels. The present study involved the following tests.

ESRT Measurements

Before the ESRT measurements, all of the participants underwent an otoscopic examination and tympanometry to rule out possible middle-ear dysfunction. The Tympstar Pro (Grason-Stadler Industries [GSI], Eden Prairie, MN, Unites States) immittance audiometer was used to perform the tympanometry and measure the ESRT, whose levels were estimated in unilaterally-implanted participants by placing the probe in the contralateral non-implanted ear. In the case of the bilateral CI user, the ESRT levels were estimated by placing the probe in the ear contralateral to the ear stimulated. All of the participants had type-A tympanograms in the probe ear, that is, the static compliance fell between 0.3 mL and 1.75 mL, and the peak pressure ranged from -100 to +60 daPa. ►**Table 2** shows the tympanometric results of the participants.

The procedure for ESRT measurements was as follows: In the immittance meter, reflex decay mode with a recording duration of 60 seconds was selected. The stimulus levels were set at a minimum (35 dBHL) and enabled the contralateral reflex measurement. The probe-tone frequency was set at 226 Hz, 678 Hz, or 1,000 Hz, and the ESRT levels were estimated for all 3 probe tones.

Table 2 Tympanometric results of the test ear

Participant	Ear	Ya (mmho)	Pressure (daPa)	ECV (mmho)
P01	Right	0.32	−33	1.1
P01	Left	0.42	−21	0.9
P02	Right	0.63	−7	0.8
P03	Right	0.71	−37	1.2
P04	Right	0.49	−35	1.3
P05	Left	0.52	−4	1.1
P06	Right	0.84	−77	0.8
P07	Right	1.11	−16	1.5
P08	Left	0.36	−39	0.8
P09	Right	0.32	−35	0.8
P10	Left	0.9	−15	1.1
P11	Right	0.88	−21	1.1
P12	Right	0.41	−44	0.9
P13	Right	0.61	−16	0.8
P14	Right	0.44	−14	0.8
Mean (SD)	NA	0.59 (0.24)	−27.6 (18.41)	1.00 (0.22)

Abbreviations: NA, not applicable; SD, standard deviation; Ya: Admittance/static compliance; ECV: ear canal volume.

The participant's speech processor (CP800 series or Freedom speech processor, Cochlear) and the Custom Sound EP (Cochlear) software, version 4.2, were used to measure the ESRT. The impedance was measured for all the electrodes before the measurement of the ESRT, and it was found to be within normal limits across all the electrodes for all the study participants. For ESRT measurements, biphasic pulse trains were presented with a duration, pulse width and stimulus rate of 500 msec, 25 μs and 900 pulses per second, respectively. The ESRT was measured for 3 electrodes (E01, E11, and E22) across the array, and the levels were first estimated in the apical electrode (E22), followed by a middle electrode (E11), and the basal electrode (E01). The threshold (T) level of the existing MAP used by the child at the time of testing served as the starting level for the ESRT measurements. The stimulation then increased in 5 current level (CL) steps until a time-locked visible decrease in admittance was noted. The stimulation levels increased 3 to 4 times in 2 CL steps and confirmed the growth and repeatability of the time-locked ESRT by presenting the biphasic pulse trains at each level 2 to 3 times. The presence of ESRT response was confirmed by a replicable decrease in admittance and by the growth in reflex amplitude.

Then, the bracketing method was incorporated by increasing and decreasing pulse amplitude in 2 CL steps, depending on the presence or absence of reflex. Thus, the ESRT measurement was performed using both ascending and descending runs alternatively. The ESRT threshold is defined as the lowest CL, which produces a definite, repeatable deflection ≥ 0.03 mmho that could be detected at least twice during the measurements. During the ESRT measurements, a 5-point rating scale (very soft, soft, medium, loud but okay, very loud) was used to classify the participants' loudness. The ESRT measurement terminated at the level where the ESRT response was observed or when the stimulus levels were classified as "very loud" in the loudness rating. In the present study, the stimulations levels used were well within the voltage compliance in all tested electrodes and for all the participants.

Measurement of Behavioral Comfort Level
The measurement of behavioral comfort levels was performed independently, using an ascending approach, after the completion of the ESRT testing. Stimulation started at the T level of the participant's existing MAP at the time of testing. The same scale was used to classify the loudness. During the measurement, a loudness chart with pictorial representations of loudness levels was used. The stimulation levels increased in 5 CL until the child indicated "medium" on the scale; then, they increased in 2 CL steps until the child indicated "loud but okay." Along with the loudness scale, the child's physiological state was monitored during or a short period after the stimulus presentation by observing their auditory behavior, like changes in facial expression or level of activity. The behavioral comfort level (estimated individually in 3 electrodes: E01, E11, and E22) is considered the maximum current level, which is classified as "loud but okay."

The statistical analysis was performed using the Statistical Package for the Social Sciences (IBM SPSS Statistics for Windows, IBM Corp., Armonk, NY, United States), version 19.0. The one-sample Kolmogorov-Smirnov test revealed that all the data (►**Appendix A**) followed a normal distribution ($p > 0.05$). The ESRT levels measured using 3 different probe-tone frequencies (226 Hz, 678 Hz, and 1,000 Hz) across 3 electrode locations (apical, middle, and basal) were analyzed using two-factor repeated measures analysis of variance (ANOVA). The independent variables for the analysis were probe-tone frequencies and electrode locations. To measure the incidence of successful ESRT measurement as a function of probe-tone frequencies, the Cochran Q test, was performed. A correlational analysis (Pearson correlation) was performed to measure the relationship between ESRT measurements across different probe-tone frequencies and comfort levels for each electrode location. Values of $p < 0.05$ were considered statistically significant.

Results

The average ESRT measurements with the probe-tone frequencies of 1,000 Hz and 678 Hz were lower than those measured using 226 Hz. ►**Fig. 1** shows the average ESRT values across different probe-tone frequencies and electrode locations.

The statistical analysis using two-factor repeated measures ANOVA revealed no main effect of probe-tone frequencies (F [2, 20] = 1.24; $p > 0.05$; $\eta p^2 = 0.11$]) on the ESRT levels; however, there was a significant main effect of the
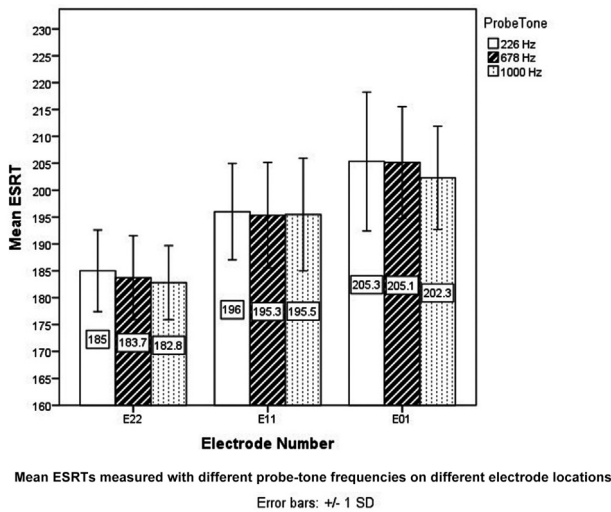
Mean ESRTs measured with different probe-tone frequencies on different electrode locations

Error bars: +/- 1 SD

Fig. 1 Mean ESRTs measured with different probe-tone frequencies on different electrode locations. The error bars indicate $+/-$ 1 standard deviation (SD) from the mean.

electrode locations ($F [2, 20] = 18.7$; $p < 0.0001$; $\eta p^2 = 0.65$]). The mean ESRT levels on the apical electrode were significantly lower, by 11.8 CL, compared with the middle electrode, and lower by 22.2 CL than the levels measured on basal electrode. When comparing the levels measured on the middle and basal electrodes the mean levels on the middle electrode were significantly lower, by 10.3 CL. There was no interaction effect observed between probe-tone frequency and electrode location ($F [4, 40] = 0.84$; $p > 0.05$; $\eta p^2 = 0.07$]). Regarding the electrode locations, the mean behavioral comfort levels were lowest for the apical electrode (E22), followed by the middle electrode (E11), and the highest levels were observed in the basal electrode (E01). ►**Fig. 2** shows the average comfort levels across different electrode locations.

The results of the measurements showed that, for the 226-Hz probe-tone frequency, the ESRT was measurable in 12/15
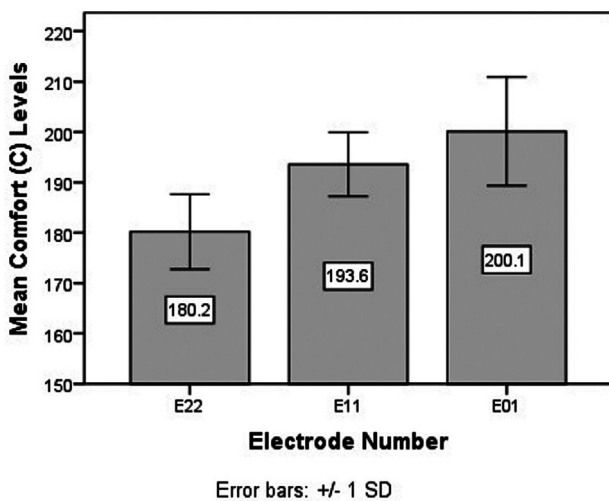

Error bars: +/- 1 SD

Fig. 2 Mean behavioral comfort (C) levels for different electrode locations. The error bars indicate $+/-$ 1 standard deviation (SD) from the mean.

ears (80%), 14/15 ears (93.33%), and 14/15 ears (93.33%) on the basal, middle, and apical electrodes respectively; for 678 Hz, 12/15 ears (80%), 15/15 ears (100%), and 14/15 (93.33%) had successful ESRT measurements on the basal, middle, and apical electrode respectively; and, for 1,000 Hz, 14/15 ears (93.33%) on the basal electrode, and 15/15 ears (100%) on both the middle and apical electrode.

Overall, out of 45 electrodes tested, measurable responses were found in 40/45 (88.8%), 43/45 (95.5%), and 44/45 (97.7%) electrodes using the probe-tone frequencies of 226 Hz, 678 Hz, and 1,000 Hz respectively. A total of 3 participants (P04, P06, and P10) showed no measurable ESRT at 226 Hz, but had measurable ESRTs with 678 Hz or 1,000 Hz. The Cochran Q test was used to determine the incidence of successful ESRT measurements (present or absent) as a function of probe-tone frequencies, and it revealed a significant difference in the incidence of successful ESRT measurements as a function of 3 probe-tone frequencies ($Q [2] = 6.5$; $p = 0.039$). The highest pair-wise difference was between 226 Hz and 1,000 Hz ($p = 0.046$).

The correlation analysis (►**Table 3**) revealed a high positive correlation between ESRT measurements using different probe-tone frequencies for all electrode locations tested. A significant relationship between ESRT values was observed using different probe-tone frequencies and comfort levels across different electrode locations. The correlation coefficient for the electrode locations ranged from 0.66 to 0.86, 0.54 to 0.96, and 0.61to 0.84 for the frequencies of 226 Hz, 678 Hz, and 1,000 Hz respectively. The linear-regression analysis revealed that the measurements with the frequencies of 226 Hz, 678 Hz and 1,000 Hz on different electrode locations can be used to reliably predict the behavioral comfort levels ($p < 0.01$). ►**Fig. 3** shows the scatter plot for the measurements with different frequencies versus the behavioral comfort levels.

Discussion

Effect of Probe-Tone Frequency on ESRT Measurements

The main objective of the present study was to assess the effect of three different probe-tone frequencies on ESRT measurements and their relationshipwith the behavioral comfort levels in PCI users.

In the present study, there was no significant difference in ESRT measurements for different probe-tone frequencies across all tested electrodes. This may be due to the relatively small sample size compared with that of other studies.[11,12] Wolfe et al.[11] measured the ESRT with 226 Hz, 678 Hz, and 1,000 Hz in 23 adults using Advanced Bionics (Stäfa, Switzerland) implants. The authors[11] reported that the use of higher probe-tone frequencies (of 678 Hz or 1,000 Hz) resulted in ESRT levels that were 11 to 12.5 clinical units lower when compared with the default frequency of 226 Hz. All of the 23 participants in this study[11] had measurable ESRTs with higher probe tone frequencies, whereas, at 226 Hz, 17 out of 23 (73.9%) participants had measurable ESRTs. Similarly, Carranco Hernandez et al.[12] evaluated the

Table 3 Correlation analysis (Pearson correlation) between ESRT and comfort levels on different electrode locations

Objective measure	Comfort levels					
	E22		E11		E01	
	r	p	r	p	r	p
ESRT (226 Hz)	0.869*	< 0.001	0.666*	< 0.01	0.790*	< 0.01
ESRT (678 Hz)	0.960*	< 0.001	0.544*	< 0.05	0.746*	< 0.01
ESRT (1000 Hz)	0.842*	< 0.001	0.613*	< 0.05	0.781*	< 0.01

Abbreviations: ESRT, electrically-evoked stapedius reflex threshold.
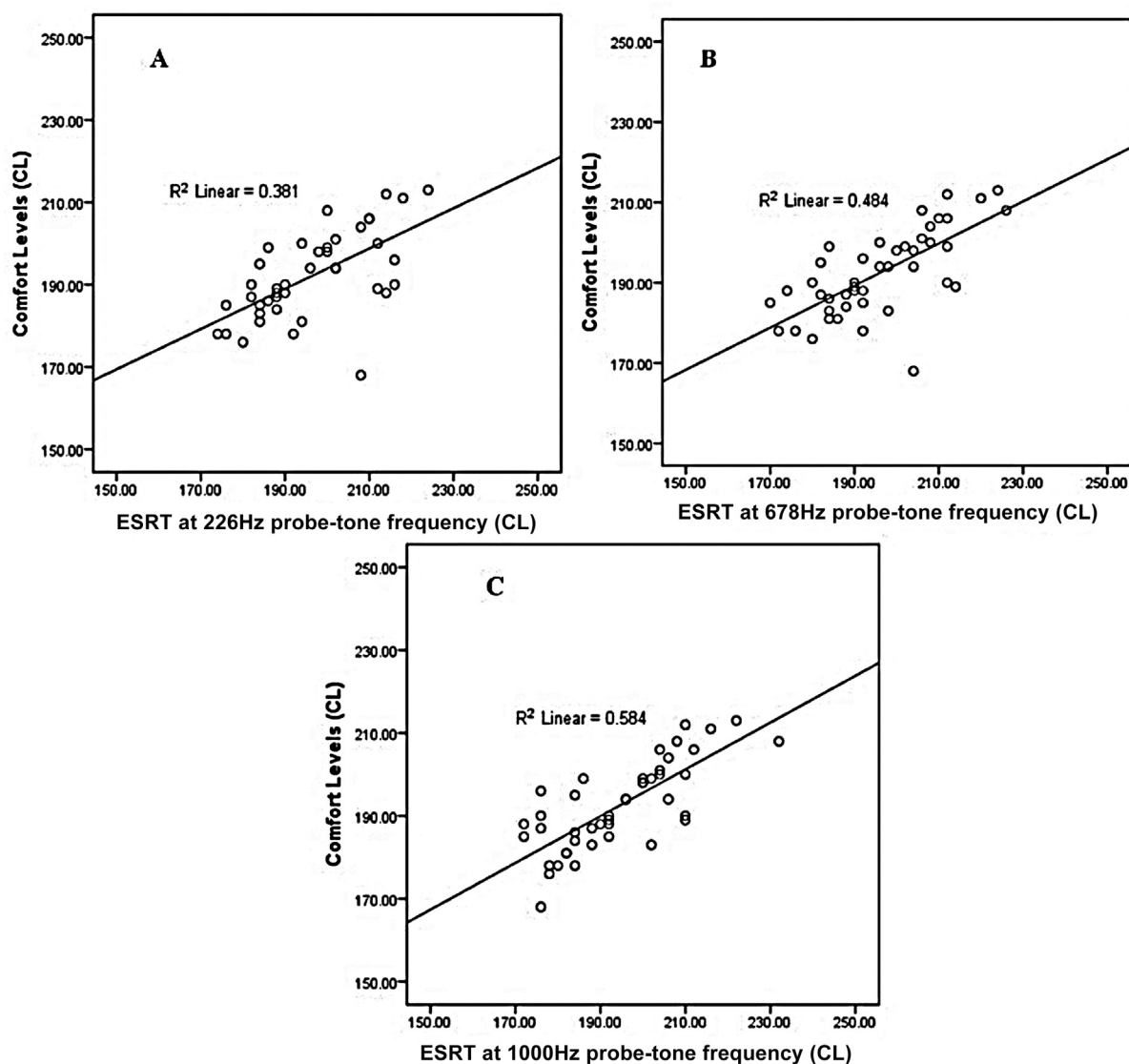Note: * Significant ($p < 0.05$) in the Pearson correlation.

Fig. 3 Scatter plots of behavioral comfort levels versus ESRT levels. (**A**) ESRT (226 Hz) versus comfort levels; (**B**) ESRT (678 Hz) versus comfort levels; and (**C**) ESRT (1,000 Hz) versus comfort levels.

effect of probe-tone frequency on ESRT measurements in ipsilateral and contralateral ears of 19 pediatric users of the Advanced Bionics HiRes 90 K CI. The ipsilateral ESRT was measured in 3 (16%), 4 (21%), and 7 (37%) ears, and the contralateral ESRT, in 11 (58%), 13 (68%), and 13 (68%) ears for 226 Hz, 678 Hz, and 1,000 Hz respectively. There was no significant difference in mean ESRT levels as a function of probe-tone frequency and ipsilateral or contralateral measurements.

In the present study, there was a higher success rate of ESRT measurements and lower thresholds with higher-frequency probe tones. During ESRT measurements, reflex-

induced changes were predominantly observed across 500 Hz to 2000 Hz frequency region[14], and hence high success rate of ESRT measures was observed with high-frequency probe tones.[14] Similarly, another study reported that the reflex induced changes in admittances were more significant for the 1000Hz than 250 Hz, and the lower reflex thresholds with 1000Hz than measured with 226 Hz probe tone.[15]

The use of higher-frequency probe tones increases the success rate of ESRT measurements. In the study by Carranco Hernandez et al.,[12] the success rates of ESRT measurements in children were of 58%, 68%, 68% for 226 Hz, 678 Hz, and 1,000 Hz respectively, when measured in contralateral non-implanted ears. In adult participants, Wolfe et al.[11] reported that 13 out of 13 showed measurable ESRTs with 678 Hz or 1,000 Hz, and 12 out of 13 (92.3%), with 226 Hz. The incidence of successful ESRT measurements in the present study was slightly higher than that of other studies.[3,12,16] The higher incidence of the measurable ESRTs in the present study could be because all the participants had normal tympanogram findings and individual electrode stimulation during ESRT measurements in the present study. The individual electrode stimulation enabled the presentation of higher CLs before reaching an uncomfortable level for the participants. The findings of the present study are in line with those of other studies[12] that used higher-frequency probe tones to measure the ESRT. There is a significantly higher success rate of ESRT measurements using higher-frequency probe tones than the 226 Hz probe tone. In other words, the success rate of the measurements was higher for 1,000Hz compared with 226 Hz, maybe because the frequency of 1,000 Hz is closer to the resonance frequency of the middle ear.[15,17] The resonance frequency of the middle ear in children aged between 6 amd 15 years ranges from 650 Hz to 1,400 Hz, with a mean resonance frequency of 1,000 Hz.[18] However, further studies are needed to provide evidence for these statements.

Relationship between ESRT and Comfort Levels
The correlation analysis revealed a significantly high correlation ($R^2 = 0.69$ to 0.94) between ESRT levels measured with different probe-tone frequencies and behavioral comfort levels across all tested electrodes. The correlation coefficient ranged from 0.61 to 0.96. The linear-regression analysis revealed that behavioral comfort levels can be reliably predicted with the ESRT measurements estimated using different probe-tone frequencies. The ESRTs estimated with higher-frequency probe tones also significantly correlated with the behavioral comfort levels. Lorens et al.[19] studied the relationship between ESRT and behavioral comfort levels in experienced PCI users, and reported a high correlation ($R^2 = 0.78$). Other studies[1,2] have reported that the estimation of comfort levels using the ESRT is reliable and useful in PCI users. Thus, we could state that ESRT measurements could be the most useful objective tool to establish the comfort levels in PCI users.

The present study has certain limitations. The ESRT responses were measured only on the contralateral side of the implanted ear. The probable reason for non-significant probe-tone effects on ESRT measurements is the relatively small sample size. Future studies should investigate middle-ear resonance in ESRT measurements in implanted and non-implanted ears in a larger population.

Conclusion

The findings of the present study indicate that higher-frequency probe tones, such as 678 Hz or 1,000 Hz, could increase the incidence of success in measuring the ESRT in PCI users. The ESRT with higher probe tones was correlated with behavioral comfort levels. Higher-frequency probe tones may be useful whenever ESRTs are not measurable with 226 Hz. The strong relationship of successful ESRT measurements with comfort levels means that these measurements could be used to estimate the comfort levels, especially in the pediatric population.

Conflict of Interests
The authors have no conflict of interests to declare.

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Appendix A Electrically-evoked stapedius reflex threshold (ESRT)

Participant	ESRT levels (current levels)									Comfort levels (current levels)		
	226 Hz			678 Hz			1,000 Hz					
	E22	E11	E1	E22	E11	E1	E22	E11	E1	E22	E11	E1
P01	184	188	188	184	188	190	188	188	190	183	187	188
P01	184	188	180	186	188	180	182	184	178	183	184	176
P02	174	202	224	176	206	202	180	204	200	172	200	213
P03	192	212	216	192	210	212	184	210	210	185	199	190
P04	NR	198	NR	NR	192	212	176	190	200	168	196	199
P05	186	190	196	184	192	196	184	192	196	182	188	194
P06	194	212	NR	184	208	208	182	210	206	181	200	208
P07	182	200	210	182	202	212	176	202	204	180	199	206
P08	202	202	NR	198	202	NR	196	200	NR	194	194	189
P09	182	198	218	180	200	220	176	200	216	180	198	211
P10	184	NR	200	192	198	204	192	198	200	185	183	198
P11	176	186	214	170	174	212	172	172	210	170	188	212
P12	184	186	208	182	184	208	184	186	206	180	199	204
P13	190	194	200	190	196	206	192	204	208	190	200	208
P14	176	188	210	172	190	210	178	192	208	170	189	206

Abbreviation: NR, no response.