# Effect of Probe-Tone Frequency on Ipsilateral and Contralateral Electrical Stapedius Reflex Measurement in Children With Cochlear Implants

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**Objectives:** The upper loudness limit of electrical stimulation in cochlear implant patients is sometimes set using electrically elicited stapedius reflex thresholds (eSRTs), especially in children for whom reporting skills may be limited. In unilateral cochlear implant patients, eSRT levels are measured typically in the contralateral unimplanted ear because the ability to measure eSRTs in the implanted ear is likely to be limited due to the cochlear implant surgery and consequential changes in middle ear dynamics. This practice is particularly limiting in the case of fitting bilaterally implanted pediatric cases because there is no unimplanted ear option to choose for eSRT measurement. The goal of this study was to identify an improved measurement protocol to increase the success of eSRT measurement in ipsilateral or contralateral or both implanted ears of pediatric cochlear implant recipients. This work hypothesizes that use of a higher probe frequency (e.g., 1000 Hz compared with the 226 Hz standard), which is closer to the mechanical middle ear resonant frequency, may be more effective in measuring middle ear muscle contraction in either ear.

**Design:** In the present study, eSRTs were measured using multiple probe frequencies (226, 678, and 1000 Hz) in the ipsilateral and contralateral ears of 19 children with unilateral Advanced Bionics (AB) cochlear implants (mean age = 8.6 years, SD = 2.29). An integrated middle ear analyzer designed by AB was used to elicit and detect stapedius reflexes and assign eSRT levels. In the integrated middle ear analyzer system, an Interacoustics Titan middle ear analyzer was used to perform middle ear measurements in synchrony with research software running on an AB Neptune speech processor, which controlled the delivery of electrical pulse trains at varying levels to the test subject. Changes in middle ear acoustic admittance following an electrical pulse train stimulus indicated the occurrence of an electrically elicited stapedius reflex.

**Results:** Of the 19 ears tested, ipsilateral eSRTs were successfully measured in 3 (16%), 4 (21%), and 7 (37%) ears using probe tones of 226, 678, and 1000 Hz, respectively. Contralateral eSRT levels were measured in 11 (58%), 13 (68%), and 13 (68%) ears using the three different probe frequencies, respectively. A significant difference was found in the incidence of successful eSRT measurement as a function of probe frequency in the ipsilateral ears with the greatest pair-wise difference between the 226 and 1000 Hz probe. A significant increase in contralateral eSRT measurement success as a function of probe frequency was not found. These findings are consistent with the idea that changes in middle ear mechanics, secondary to cochlear implant surgery, may interfere with the detection of stapedius muscle contraction in the ipsilateral middle ear. The best logistic, mixed-effects model of the occurrence of successful eSRT measures included ear of measurement and probe frequency as significant fixed effects. No significant differences in average eSRT levels were observed across ipsilateral and contralateral measurements or as a function of probe frequency.

**Conclusion:** Typically, measurement of stapedius reflexes is less successful in the implanted ears of cochlear implant recipients compared with measurements in the contralateral, unimplanted ear. The ability to measure eSRT levels ipsilaterally can be improved by using a higher probe frequency.

**Key words:** Cochlear implant, Electrical stapedius reflex threshold.

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## INTRODUCTION

In cochlear implants (CIs), an array of intra-cochlear electrodes is used to deliver electrical stimulation and restore auditory sensitivity in children and adults with varying degrees of hearing impairment. Many patient-specific factors are known to influence cochlear implant outcomes (e.g., electrode position, neural survival, etc.), and many of these factors are beyond the control of the patient or the clinician (Holden et al., 2013). Nevertheless, the process of device fitting or mapping does afford the clinician an opportunity to optimize electrical stimulation to best address the patient's situation. Among the very important fitting parameters that influence outcome is the amount of electrical stimulation delivered to the cochlear implant user. Loudness reports by the patient are commonly used to assess the appropriateness of the amount of stimulation delivered. While electrical stimulation at soft-to-moderate overall loudness is known to adversely affect implant outcome due to diminished audibility of low-level portions of the speech signal, overly high levels of electrical stimulation can produce loud or distorted percepts or both, which can result in poorer speech perception, as well. Therefore, ideally, it is important to determine an optimum level of electrical stimulation to achieve best implant outcome (e.g., Hodges et al., 1997; Geers et al., 2003).

In adult CI recipients, the upper limit of electrical stimulation is readily determined by the patients' loudness judgments for different levels of electrical stimulation. However, this method offers limited value while estimating upper limits of electrical stimulation in CI users with inconsistent loudness judgment and recipients who cannot provide subjective feedback (e.g., children, multiply impaired individuals, etc.). In these patients, electrically evoked, stapedius-reflex thresholds (eSRT) can be used to set the upper limit of electrical stimulation. During eSRT measurement, electrical stimulation is delivered through the cochlear implant, and the resulting change in acoustic admittance produced by the contraction of the stapedius muscle is measured in the ear canal. In normal-hearing subjects, acoustical, stapedius-reflex threshold (aSRT) is measured in the range of 70 to 90 dB SPL for a pure-tone stimulus and is perceived to be "loud-but-comfortable" in the loudness domain. This loud-but-comfortable level is approximately the

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perceptual level used to map M-levels in Advanced Bionics cochlear implant patients. It then follows that the stimulus level that first elicits a stapedius reflex can be used to set M-levels for AB cochlear implant patients.

Several studies have measured eSRT levels and have shown a strong correlation with the upper limit of electrical stimulation used in cochlear implants. Typically, for unilaterally implanted adult and pediatric cochlear implant patients, eSRT levels are measured in the contralateral unimplanted ear using a standard, low-frequency probe tone such as 226 Hz (Jerger et al., 1986; Jerger et al., 1988; Spivak and Chute, 1994; Spivak et al., 1994; Shallop and Ash, 1995, Hodges et al., 1997; Battmer et al., 1990; Stephan et al., 1990a, 1990b, 1991, 1998; Stephan and Welzl-Muller, 1992, 1994, 2000; Bresnihan et al., 2001; Allum et al., 2002; Gordan et al., 2004; Lorens et al., 2004; Brickely et al., 2005; Han et al., 2005; Polak et al., 2005; Walkowiak et al., 2011; Asal et al., 2016). This procedure results in a successful stapedius reflex measurement in the majority of the test ears without any middle ear pathology. While several studies have reported an incidence of 100% contralateral eSRT in their selected study participants (e.g., Lorens et al., 2004; Walkowiak et al., 2011; Wolfe et al., 2017), many studies have reported an incidence of anywhere between 67 to 87% of contralateral eSRT measurements in cochlear implants (Battmer et al., 1990, (76%); Spivak and Chute, 1994, (68%); Hodges et al., 1997, (71%); Bresnihan et al., 2001 (76%); Gordon et al., 2004, (67%); Brickley et al., 2005 (87%); Kosaner et al., 2009, (83%); Wolfe and Kasulis. 2008, (79%); Asal et al., 2016, (77%)).

A successful eSRT measurement in the implanted (ipsilateral) ear is considered to be more difficult (e.g., Gordon et al., 2012) possibly due to changes in the mechanical properties of the middle ear following cochlear implant surgery. This difficulty limits the success of eSRT measurements in bilaterally-implanted CI patients because there is not an unimplanted ear of choice for eSRT measurement. Such a limitation is important in children, especially the very young, who are often implanted bilaterally but who may not provide reliable loudness judgments for different levels of electrical stimulation.

There are few reports of the relative success in measuring eSRT levels in implanted vs. unimplanted ears in the literature. Kosaner et al. (2009) measured eSRT levels in 211 out of 254 children implanted unilaterally with a cochlear implant. They first measured middle ear pressure in both the implanted and unimplanted ears and then chose the ear showing the more normal middle ear pressure (between -150 to 50 daPa) for eSRT recording, presumably using a standard probe tone frequency of 226 Hz. Unfortunately, they did not report separately the incidence of successful eSRT measurement in the ipsilateral and contralateral ears of their study participants. They also reported that the incidence of 83% was from "children fitted over time and not from once-off fitting. This means that in some instances children normally fit using eSRT technique may at one point have had a middle ear problem preventing eSRT testing which was later resolved".

Recently, Wolfe et al. (2017) measured eSRT levels in 23 adults (13 unilateral, 10 bilateral) with cochlear implants using 226 Hz, 678 Hz, and 1000 Hz probe tones. For the unilateral patients, they measured eSRT levels in the contralateral ear, and for the bilateral patients eSRT levels were measured in the implanted ear with the most favorable peak compensated static acoustic admittance (0.3–1.5 mmhos). Using a 226 Hz probe tone, they measured eSRT levels in 19 ears (12 unilateral, 7 bilateral), whereas eSRT levels were measured in all ears using the higher probe frequencies (678 and 1000 Hz). Wolfe et al. suggested that the cochlear implant surgery likely increased middle ear stiffness and consequently limited the transmission of lower probe tones through the middle ear which in turn limited the ability to measure middle ear muscle contraction in the ipsilateral ear canal. Use of a higher probe frequency closer to the middle ear mechanical resonance was suggested to improve the ability to measure stapedius reflexes in the implanted ear.

The experience reported by Wolfe et al. is analogous to the difficulty encountered while measuring acoustically-elicited stapedius reflex thresholds in neonates using a low-frequency probe tone. In normal-hearing adults, acoustical stapedius reflexes can be measured using either a 226 or a 1000 Hz probe tone; however, in neonates with presumably normal middle and inner ear function use of a 226 Hz probe tone is less likely to result in a successful aSRT measurement compared with use of a higher probe tone such as 1000 Hz (Weatherby and Bennett, 1980; Jacob-Corteletti et al., 2015). Weatherby and Bennett (1980) showed that the point of reversal from a stiffness-dominated to a mass-dominated middle ear system is around 665 and 1200 Hz in normal-hearing adults and neonates, respectively. Due to the higher middle ear resonant frequency of the neonatal ear, it is difficult to measure aSRT in neonates using a low-frequency probe.

While the use of a higher-frequency probe is suggested to improve the incidence of eSRT measurements in implanted adults (Wolfe et al., 2017), it is unknown whether the use of a high-frequency probe tone is likely to improve the incidence of eSRT measurements in children with cochlear implants. The goal of the present study was to assess the relative success in measuring electrical stapedius reflexes as a function of probe frequency (226, 678, 1000 Hz) in ipsilateral and contralateral ears of unilaterally-implanted children.

## METHODS

### Patients

In the present study, eSRT levels were measured as a function of probe frequency (226, 678, and 1000 Hz) in the ipsilateral and contralateral ears of 19 children (mean age = 8.6 years, SD = 2.29) implanted unilaterally with Advanced Bionics HR90K cochlear implants. Table 1 shows individual and summary demographic data, electrode type, and insertion method (cochleostomy or round window) for the studied patients. The study protocol was approved by Instituto Nacional De Enfermedades Respiratorias ethics and research committee.

### Equipment

A medical-grade otoscope was used to examine the tympanic membrane and the ear canal. A custom, integrated middle ear analyzer (iMEA) designed by Advanced Bionics was used to measure eSRT levels. In the iMEA system, an Interacoustics Titan middle ear analyzer was used to perform middle ear measurements while operating synchronously with research software running on an Advanced Bionics Neptune sound processor to control the delivery of electrical stimulation. Synchrony between the two instruments was achieved by routing the pure-tone output from the contralateral port of the middle ear analyzer into

**TABLE 1. Individual and Summary Demographic Along With Electrode Type and Insertion Method for the 19 Children With Unilateral Cochlear Implants Included in the Study**

| Patient | Age (y) | Age of Implantation (y) | Electrode Type | Method of Electrode Insertion |
|---|---|---|---|---|
| CI1 | 9 | 3 | HiFocus 1J | Cochleostomy |
| CI2 | 12 | 6 | HiFocus 1J | Cochleostomy |
| CI3 | 6 | 3 | HiFocus 1J | Round window |
| CI4 | 7 | 3 | HiFocus Mid-Scala | Round window |
| CI5 | 10 | 2 | HiFocus 1J | Cochleostomy |
| CI6 | 4 | 4 | HiFocus Mid-Scala | Round window |
| CI7 | 11 | 2 | HiFocus 1J | Round window |
| CI8 | 13 | 12 | HiFocus 1J | Cochleostomy |
| CI9 | 7 | 2 | HiFocus 1J | Round window |
| CI10 | 6 | 3 | HiFocus 1J | Round window |
| CI11 | 9 | 3 | HiFocus 1J | Round window |
| CI12 | 9 | 3 | HiFocus 1J | Cochleostomy |
| CI13 | 10 | 3 | HiFocus 1J | Round window |
| CI14 | 10 | 2 | HiFocus 1J | Round window |
| CI15 | 8 | 2 | HiFocus 1J | Cochleostomy |
| CI16 | 7 | 4 | HiFocus 1J | Cochleostomy |
| CI17 | 7 | 3 | HiFocus 1J | Round window |
| CI18 | 11 | 2 | HiFocus 1J | Cochleostomy |
| CI19 | 8 | 3 | HiFocus 1J | Round window |
| Mean (SD) | 8.6 (2.3) | 3.4 (2.3) | N = 17 (1J) + 2 (MS) | N = 8 (Co} + 11 (RW) |

the auxiliary input port of the Neptune research processor to produce controlled levels of electrical stimulation to elicit stapedius reflexes. The level of the electrical stimulation delivered to the patient was based on the magnitude of the pure-tone output of the Titan middle ear analyzer. By using the iMEA system, the clinician was able to efficiently use the Titan middle ear analyzer to control electrical stimulation levels, observe stapedius reflex occurrences, and assign an eSRT measure as the rising electrical stimulation level, which first elicited a stapedius reflex.

### Calibration of the iMEA Link Between the Tympanometer and the CI

In the iMEA system, delivery of the electrical stimulation by the Neptune processor is controlled by the level of the acoustic reflex activator signal from the tympanometer. To calibrate the iMEA system, an acoustic reflex activator pure tone is presented from the contralateral (activator) port of the Titan middle ear analyzer. Custom software implemented on the Neptune processor analyses the magnitude of the incoming signal and adjusts the level of the electrical stimulation output accordingly. This integrated system was calibrated such that a 2000 Hz activator signal at 80 dB SPL from the Titan middle ear analyzer was mapped to an output electrical signal of 250 clinical units (CU) of charge per phase, which was delivered by the Neptune processor via the implanted stimulator.

### Operational Control of the Levels of Electrical Stimuli Delivered by the CI

After the calibration was completed, the clinician could change the pure-tone presentation level of the tympanometer in 1 dB steps to produce 10 CU step changes in electrical stimulation by the CI. If required, the clinician could modify this mapping to achieve specific stimulus levels as needed to elicit stapedius reflexes across individual patients. Typically, in making an eSRT measurement, the electrical stimulation began at 50 CU and was incremented upward to a charge level that elicited a stapedius reflex. An eSRT level was defined as the stimulus level, expressed in CUs, that produced a measurable reflex twice in a row. A measurable reflex was defined as a reproducible deflection of at least 0.02 mL while measuring stapedius reflexes using the Titan instrument. Whenever possible, the stimulus level was increased by 10 CU above the assigned eSRT level to verify an increase in stapedius reflex amplitude. In general, the incrementing electrical stimulation was terminated on the measurement of a stapedius reflex, with the report of the electrical stimulus being too loud, or by clinical observation that the patient was uncomfortable. For each measurement, the clinician would monitor the shape of the acoustic reflex and also watch for any obvious physical movement by the patient, as is routine in clinical practice. Any reflex measurement that was obviously contaminated with physical movements was discarded.

### Characteristics of the CI Stimulation

Electrical stimulation in this study involved an investigator-defined "all-electrode mode," which consisted of a train of balanced-biphasic pulses delivered sequentially across up to 15 electrodes in a staggered order (E1, E5, E9, E13, E2, E6, E10, E14, E3, E7, E11, E15, E4, E8, E12) with one pulse delivered on each active electrode before repeating the sequence. No electrical stimulation was delivered on the basal-most electrode, E16, because in some patients this electrode may produce unacceptable sound quality or a sensation of pain. Also, electrical stimulation was not delivered on electrodes that were disabled in patients' clinical maps. Each biphasic pulse had a phase duration of 40 μsec/phase. The pulses were presented at a rate of 825 pulses per second (regardless of the number of active electrodes) and continued for a total pulse train duration of approximately 500 ms based on the duration of the activator signal from the tympanometer. Nonstimulation intervals between trains of stimulation were controlled by the clinician to avoid biasing the eSRT measures due to cumulative stimulation effects.

### Procedure

Before eSRT measurements, an otoscopic examination of the ear canal was performed, and a tympanogram was measured to rule out any external and middle ear pathology. Each patient was seated in their parent's or the clinician's lap while the middle ear measurements were performed. Then an amplitude-growth sequence of stimulation was begun. As the electrical stimulation was increased to elicit a stapedius reflex, the patient was asked to indicate the loudness sensation of the stimulus on a 10-point loudness scale (0: Off; 1: Just noticeable; 2: Very soft; 3: Soft; 4: Comfortable but too soft; 5: Comfortable but soft; 6: Most comfortable; 7: Loud but comfortable; 8: Loud; 9: Upper loudness limit; 10: Too loud). The eSRT measurement procedure was terminated if the electrical stimulation was judged to be level 9 or greater and no stapedius reflexes were measured. The procedure was repeated for all three probe frequencies on

both the ipsilateral and contralateral sides relative to the side of implantation.

## RESULTS

In Figure 1, the top and the bottom panels show the occurrence of ipsilateral and contralateral reflexes measured in 19 unilaterally-implanted children. The green-, blue-, and magenta-colored bars indicate the stimulus levels, which elicited a measurable electrical stapedius reflex (i.e., an eSRT level) using probe frequencies of 226, 678, and 1000 Hz, respectively. The cross-hatched bars show the maximum tolerable stimulus levels, which did not elicit a stapedius reflex using the three different probe frequencies. The letters above each bar graph (A, As, B, or C) indicate the type of tympanogram measured for each patient (Liden, 1969; Jerger, 1970). Any tympanogram with a peak pressure between -150 and +50 daPa and a peak amplitude between 0.3 and 1.75 mL was defined as an "A" type tympanogram. A tympanogram with peak amplitude of less than 0.3 mL was labeled as "As" type tympanogram, and a tympanogram with peak pressure of less than -150 daPa was classified as a "C" type tympanogram. A tympanogram with no peak was classified as a "B" type tympanogram.

For most patients, except patients C2 and C19, either type "A" or "As" tympanograms were measured in the ipsilateral and contralateral ears with no obvious external or middle ear pathology based on otoscopic examination (Fig. 1). This suggests that the lack of stapedius reflexes in these ears can be attributed to factors other than middle ear pathology. For patients C2 and C19, "B" and "C" type tympanograms were measured, respectively, in the ipsilateral ear, which is consistent with abnormal middle ear function that may have contributed to the inability to measure reflexes in these two ears. In ears with conductive pathology it is not possible to monitor changes in acoustic admittance in the ear canal, hence the lack of reflex measurement in these ears was expected (e.g., Jerger, 1970; Zwislocki and Feldman, 1970). Excluding the two patients with "B" or "C" type tympanograms, no significant relationships were found using one-way analysis of variance (ANOVA) between the ipsilateral tympanometric measures (compliance, peak, gradient, volume and 1st principal component of all four measures) and the method of electrode insertion (RW vs. cochleostomy) nor between the tympanometric measures and measurement ear (ipsilateral vs. contralateral).

Across the 19 patients, ipsilateral eSRTs were obtained in 3, 4, and 7 ears using probe tones of 226, 678, and 1000 Hz, respectively, for corresponding success rates of 16%, 21%, and 37%. By using a higher probe frequency, ipsilateral reflexes were measured in 7 cochlear implant ears as compared with the 3 ears measured with a 226 Hz probe frequency (Fig. 1). Contralateral eSRTs were successfully measured in 11, 13, and 13 ears for the three probe frequencies with 58%, 68%, and 68% success, respectively. For the remaining patients, electrically elicited stapedius reflexes could not be measured at their upper limit of tolerance for electrical stimulation in the ipsilateral or contralateral ear. A Chi-square test revealed statistically significant

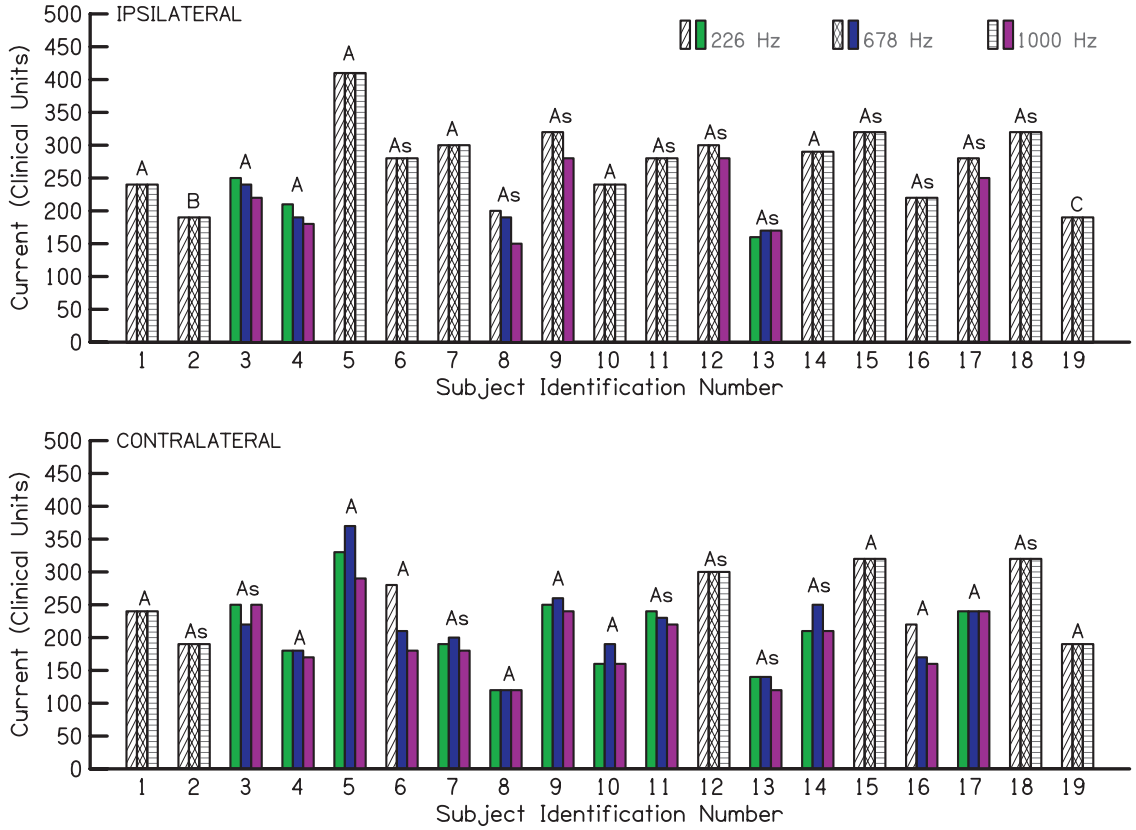


Figure 1. Electrical stapedius reflex measurements in the ipsilateral (top panel) and contralateral (bottom panel) ears using tympanometry probe frequencies of 226, 678, and 1000 Hz. The cross-hatched, black and white bars show the maximum current level (CU) used for electrical stimulation, which did not produce a measurable eSRT. The colored bars show the current levels that resulted in a successful eSRT measurement. The tympanogram type measured for each ear is shown above the bars.

differences ($X^2$ (2, n = 114) = 18.76, $p < 0.05$) between the incidence of electrical stapedius reflexes in the ipsilateral and contralateral ears across all probe frequencies. For each probe frequency individually, Cochran's Q Test for paired, nominal data (Mangiafico, 2016) revealed significant differences in the incidence of successful eSRT measurement across ipsilateral and contralateral ears paired by subject: 226 Hz, (Q (1) = 8, p = 0.005); 678 Hz (Q (1) = 9, p = 0.003) and 1000 Hz (Q (1) = 4.5, p = 0.034). Looking across all probe frequencies for each measurement ear separately, Cochran's Q Test revealed a significant difference in the incidence of successful eSRT measurement as a function of probe frequency in the ipsilateral ears (Q (2) = 6.5, $p = 0.039$) but not in the contralateral ears (Q (2) = 4, $p = 0.135$). The greatest ipsilateral pair-wise difference between probe tones was between the 226 and 1000 Hz ($p = 0.045$)

In the three ears, where ipsilateral reflexes were measured with the three different probe frequencies (C3, C4, and C13), average eSRT levels and standard deviations (SD) of 207 (±45), 200 (±36), and 190 (±26) CUs were measured using probes at 226, 678, and 1000 Hz, respectively. The eSRT stimulation levels were compared across probe frequencies using one-way ANOVA. The results showed no significant differences (F (2, 6) = 0.157, $p = 0.85$) between the ipsilateral eSRTs measured with the different probe frequencies. In the 11 contralateral ears with measurable stapedius responses for all probe frequencies (C3-5, C7-11, C13-14, and C17), average eSRT stimulation levels and SD of 210 (±60), 218 (±66), and 200 (±54) CUs were measured. One-way ANOVA showed no significant differences (F (2, 34) = 0.361, $p = 0.7$) between the three contralateral eSRT levels.

To determine which independent and observed experimental factors significantly influenced the occurrence of successful eSRT measurements, R statistical software (Version 3.4.4, 2018) was used (glmer module in the lme4 package, Version 1.1–17; Bates et al., 2015) to perform a logistic, mixed-effects, repeated-measures analysis. Fixed effects entered included subject age, ear of measurement (ipsi vs. contralateral), probe tone frequency, and the five tympanometric measures described earlier. The two subjects with "B" or "C" type tympanograms were excluded to maximize the influence of the tympanometric measures included in the model. Random effects entered included random intercepts by-subject number and by-electrode type. A series of candidate models was developed by introducing effects in all combinations one at a time. Candidate models were compared using the Akaike Information Criterion of information lost and p-values ($p < 0.05$) obtained by likelihood ratio tests comparing the current best model against the next best candidate (Winter, 2013). Adoption of a candidate model was based on whether the new model reduced the amount of information lost and was statistically different from the previous model based on a likelihood ratio test between the two models. Inspection of residual plots did not reveal obvious deviations from homoscedasticity and normality. Factor interactions were also modeled and found not to be significant. The simplest, significantly different, logistic, mixed-effects model of the occurrence of eSRT measurement success included the fixed effects of ear of measurement (ipsi vs. contralateral) ($X^2(1) = 42.6$, $p < 0.001$) and probe frequency ($X^2(2) = 6.9$, $p = 0.032$) and included random effects by-subject.

## DISCUSSION

In the present study, eSRT levels ipsilateral and contralateral to the ear of insertion were measured using probe frequencies of 226, 678, and 1000 Hz in children with unilateral cochlear implants. Of the 19 patients who participated in this study, eSRT levels were successfully measured in 7 (37%) cochlear implanted, ipsilateral ears and in 13 (68%) unimplanted, contralateral ears for at least one probe frequency. The simplest logistic, mixed-effects model of the occurrence of successful eSRT measures included ear of measurement and probe frequency as significant fixed effects. Each of these effects is discussed separately.

### Ipsilateral and Contralateral eSRT Measurements

The results obtained in this study are divided across five patient groups based on the incidence of measured reflexes ipsilateral and contralateral to the side of implantation and as a function of the probe frequency. Table 2 summarizes the groupings of stapedius reflexes obtained across the 19 unilateral cochlear implant patients in the present study. The data shown in Figure 1 were reorganized by these patterns and plotted in Figure 2. These groupings are consistent with data clusters suggested by the coefficients of the logistic, mixed-effects model of eSRT measurement occurrence and are similar to the acoustic reflex categories used in clinical evaluation of crossed and uncrossed acoustic reflexes (Jerger and Jerger, 1977). For purposes of this discussion, we largely assume the peripheral and central components of the ipsilateral and contralateral reflex neural pathways are functionally intact in the studied population; however, such defects cannot be ruled out especially in the absence of a recordable reflex. Specific diagnosis of such defects is beyond the scope of this study. In group 1, ipsilateral and contralateral eSRTs were successfully measured using each studied probe frequency in three patients (CI3, CI4, and CI13).

**TABLE 2. Based on the Success in Measuring Ipsilateral and Contralateral Reflexes (Relative to the Side of Implantation) Across the 19 Cochlear Implant Patients, the Data Were Divided Into Five Different Groups**

| Groups | Ipsilateral Reflex | Contralateral Reflex | Patients |
|---|---|---|---|
| Group 1 | Present with all probe frequencies | Present with all probe frequencies | CI3, CI4, CI13 |
| Group 2 | Absent with 226 Hz probe but present with use of a higher-frequency probe tone | Present with all probe frequencies | CI5, CI7, CI8, CI9, CI10, CI11, CI14, CI17 |
| Group 3 | Absent with all probe frequencies | Present with use of a higher-frequency probe tone | CI6, CI16 |
| Group 4 | Absent with all probe frequencies | Absent with all probe frequencies | CI1, CI2, CI15, CI18, CI19 |
| Group 5 | Present with use of a higher-frequency probe tone | Absent with all probe frequencies | CI12 |

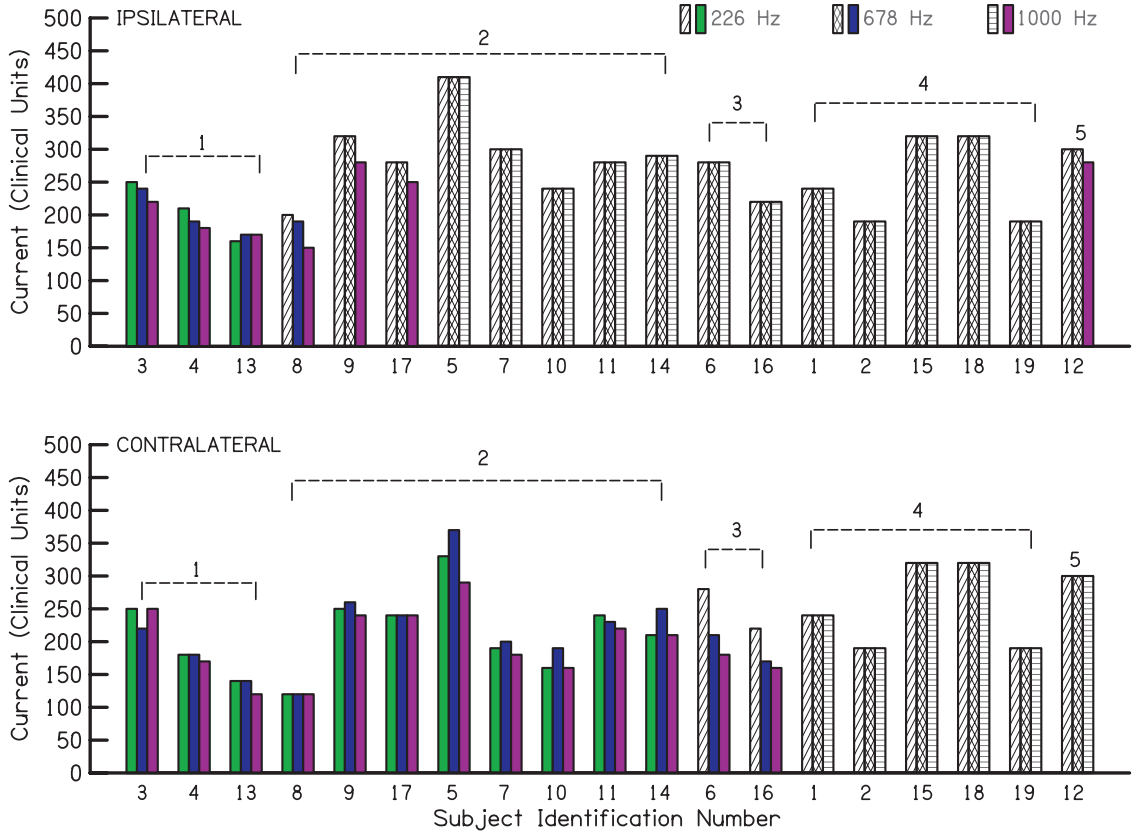


Figure 2. Electrical stapedius reflexes measured for the five different groups using three different probe frequencies of 226, 678, and 1000 Hz. The cross-hatched, black and white bars show the maximum stimulus level (CU) used for electrical stimulation, which did not produce a measurable eSRT. The colored bars show the stimulus levels that resulted in a successful eSRT measurement. The number above the bars shows the group classification number as described in the discussion section.

These data demonstrate that the electrically elicited stapedius reflex can be bilaterally active and can produce similar eSRT levels, regardless of which ear is being monitored and the probe frequency being used. Being aware there are only three subjects in this group, preliminary statistical analysis found no differences in ipsilateral- versus contralateral-measured eSRT levels across probe frequencies in contrast with the observation that contralateral-measured acoustic reflexes are 5–10 dB higher (Moller, 1962).

In group 2, contralateral electrical stapedius reflexes were successfully measured using the three different probe frequencies, but the ipsilateral stapedius reflexes were either absent (CI5, CI7, CI10, CI11, and CI14) or were successfully measured only with the use of a higher probe frequency (CI8, CI9, and CI17). Similar patterns have been reported in the literature with absent ipsilateral responses (Spivak and Chute, 1994; Wolfe et al., 2017) and success in recording ipsilateral responses with higher frequency probes (Wolfe et al., 2017). Both patterns may be attributed to changes in middle ear dynamics following cochlear implant surgery.

The cochlear implant surgery and the presence of a foreign body (implant lead) in the middle ear may have altered normal middle ear mechanics and thus interfered with the ability to measure electrical stapedius reflexes in the ipsilateral ear. Insertion of the electrode array in the cochlea and the fibrous tissue growth around the electrode array and round window following cochlear implantation is likely to increase the mechanical resistance encountered by the stapes footplate and consequently increase the stiffness reactance of the middle ear. Donnelly et al. (2009) measured the effect of cochlear implant electrode insertion on stapes movement in 7 patients during cochlear implant surgery. Their results show no changes in stapes displacement in 3 patients, a significant increase in stapes displacement in 2 patients, and a significant reduction in stapes movement in 2 other patients. In contrast, Huber et al. (2001) showed no significant differences in stapes movement due to cochlear implant electrode insertion in the cochlea of 7 patients during cochlear implant surgery. It is important to note that the stapes movement measurements of both Huber et al. (2001) and Donnelly et al. (2009) were both made acutely during surgical insertion of the electrode array and do not address possible long-term, chronic effects as might be expected in the present study population. In the present study, it was hypothesized that similar possible ipsilateral middle ear mechanical consequences of implantation might be observed via changes in the tympanometric measures; however, no relationships were observed between the ipsilateral tympamometric measures and the method of insertion or differences between the ipsilateral and contralateral tympanometric measures.

Considering further effects of implantation on middle ear function, an increase in the stiffness component of the middle ear is known to shift the middle resonant frequency higher, at which point the stiffness reactance of the middle ear is similar to the mass reactance (e.g., Ogut et al., 2008). The low-frequency

probe tone of 226 Hz is ideal for measuring changes in middle ear stiffness and is efficient in measuring stapedius reflexes in the case of a normal middle ear (Bennett and Weatherby, 1979). However, when the middle ear resonant frequency is pushed higher, the increase in stiffness of the ear drum shunts the higher impedance of the middle ear, and small impedance changes caused by the contraction of the stapedius muscle cannot be measured (Weatherby and Bennett, 1980). Therefore, use of a higher probe frequency such as 1000 Hz, which is closer to the middle ear resonant frequency, is likely to be more effective in measuring changes in middle ear impedances caused by the stapedius reflex (Bennett and Weatherby, 1979). Future studies should evaluate both acute and chronic changes in middle ear resonant frequency following cochlear implant surgery and correlate those changes (if any) with the ability to measure reflexes as a function of probe frequency in the implanted ear.

In group 3 (patients CI6 and CI16), contralateral eSRT levels were measured with higher probe frequencies of 678 and 1000 Hz but not with a 226 Hz probe frequency. Similar results were reported by Wolfe et al. (2017) in one of their unilateral adult cochlear implant study participants. No electrical stapedius reflexes could be measured in this patient in the contralateral ear with the 226 Hz probe tone. Wolfe et al. (2017) reported significantly higher eSRTs using a 226 Hz probe as compared with those measured with 678 and 1000 Hz probe tones. This difference may be attributed to higher probe frequencies being closer to the middle ear resonant frequency and consequently more sensitive in eliciting a change in the acoustic admittance in the ear canal. Therefore, the measurement pattern observed in group 3, namely the lack of eSRT measurement success in CI6 and CI16 with a 226 Hz probe, might be attributed to the stimulus level being insufficiently loud to produce a contralateral reflex. Several factors that may limit the use of an appropriately loud stimulus during eSRT measurement are described below (see description for Group 4).

In group 4, both ipsilateral and contralateral electrical stapedius reflexes were absent (patients CI1, CI2, CI12, CI15, CI18, and CI19). This failure to measure reflexes may be attributed to several factors. First, acoustically elicited stapedius reflexes are known to be absent in a some percentage (15–25% depending on the stimulus condition and ear of recording) of individuals in the general population (McGregor et al., 2018). Such individuals would also likely not have electrically elicited reflexes if they received a cochlear implant. It is possible that some individuals without a stapedius reflex due to conditions such as absent stapedius tendon may contribute to the overall failure rate of 26% (5/19) represented by group 4.

Second, some pediatric participants may be fearful of louder sounds and unwilling to allow stimulus levels to be increased to levels sufficient to achieve stapedius reflexes. In addition, a few of our patients provided inconsistent loudness judgments when the same electrical stimulus was presented twice. These behaviors may have resulted from a fear of experiencing an uncomfortable loudness sensation. Both factors may have contributed to unsuccessful eSRT measurement in the ipsilateral and contralateral ears of our study participants when reflexes might have been measured at higher stimulus levels. To assess the possibility of such false negatives occurring, mean stimulation levels producing a reflex were compared with mean stimulus termination levels when no reflex was observed for ipsilateral and contralateral stimulation conditions (group 4). The chance of false negatives would be diminished if the measured eSRT levels based on reflex occurrence were less than stimulus termination levels for no-reflex cases. For ipsilateral measures mean eSRT levels (210 ± 42, n=14) were significantly less than mean no-reflex stimulus termination levels (275 ± 57, n = 33) at $p < 0.001$, 1-tail. For contralateral measures mean eSRT levels (206 ± 56, n = 37) were significantly less than mean no-reflex stimulus termination levels (259 ± 54, n = 20) at $p < 0.001$, 1-tail. It is also clearly the case in groups 2 and 3 when no ipsilateral eSRT is measured ipsilaterally but an eSRT is measured contralaterally that the electrical stimulus level was sufficient to elicit a reflex even though it could not be measured ipsilaterally. We conclude that it is unlikely that insufficient electrical stimulation was the primary cause of the group 4 failures to measure eSRTs.

In group 5 (patient CI12), ipsilateral eSRT was measured using a high probe frequency only, and contralateral reflexes could not be measured using the three probe frequencies. While several factors discussed earlier may have contributed in the pattern of reflexes measured in this patient, it is likely another example of a higher probe frequency being more effective in obtaining an eSRT measure.

In applying these findings to the targeted bilaterally implanted population, it is important to note that the current data are obtained in unilaterally implanted subjects, wherein the contralateral ear measures are unencumbered by the hypothesized middle ear consequences of implantation. This of course will not be the case in bilaterally implanted individuals. Ultimately, the best assessment of the preferred ear of measurement in bilateral cases must come from a similar study performed in a bilaterally implanted population. A benefit of the present study is that it demonstrates that useful eSRT measures can be obtained from implanted ears, especially with the use of higher-frequency probes. As such, the hope is to have set the stage for a similar follow-on study of bilaterally implanted individuals.

### Effect of Probe Frequency on Likelihood and Level of eSRT Measurement

It was hypothesized that use of higher probe frequencies might increase the measurement sensitivity and lead to greater success in ipsilateral reflex measurement. This expected pattern is observed in Figure 2 in patients CI8, CI9, and CI17 in group 2, as well as CI6 and CI16 in group 3 and CI12 in group 5. Cochran's Q Test revealed a significant difference in the incidence of successful eSRT measurement as a function of probe frequency in the ipsilateral ears but not in the contralateral ears with the greatest ipsilateral pair-wise difference between the 226 and 1000 Hz probe tones. Probe frequency was also determined to be a significant fixed effect in the logistic, mixed-effects model of the occurrence of successful eSRT measurement.

The present study found small, nonsignificant differences in average eSRT levels as a function of probe frequency. However, it is important to consider that clinical maps generated with different eSRT levels to estimate M-levels may lead to perceptible changes in loudness level in individual patients and potentially influence the implant outcome. Individual cases in this study where this variability may apply might be ipsilateral eSRT levels for CI3 and CI4 and contralateral eSRT levels for CI5 and CI14. While the use of a high-frequency probe is likely to increase the sensitivity in measuring eSRT and thus elicit a stapedius reflex at a lower stimulus level, a clinical map generated with these lower stimulus levels may be below the level needed to achieve comfortable loudness

sensation for individual cochlear implant patients. The present study suggests that an eSRT level measured with a higher probe frequency is 10 to 20 CUs lower than the reflex threshold measured with a lower frequency probe tone. This correction should be taken into account while using eSRT levels measured with a higher probe tone to set M-levels for a cochlear implant patient.

In the present study, electrical stimulation was delivered sequentially on electrodes 1 to 15, which is likely to elicit stapedius reflexes at stimulus levels lower than levels needed for reflex measurements with stimulation on individual electrodes. This method of stimulation was chosen to increase the efficiency of the protocol in eliciting either ipsi- or contra-lateral reflexes independent of possible eSRT levels across individual electrodes, consistent with the goals of the study. Further studies are needed to determine the effect of probe frequency on eSRT measurement on individual electrodes, which would likely be the preferred approach in a clinical protocol.

## CONCLUSIONS

In the present study, ipsilateral and contralateral eSRT levels were measured using probe frequencies of 226, 678, and 1000 Hz in children with cochlear implants. Contralateral stapedius reflexes were successfully measured in a larger number of test ears as compared with the incidence of ipsilateral reflexes in the implanted ears. This is consistent with the possibility that changes in middle ear mechanics, as a consequent of cochlear implant surgery, may interfere with the detection of a change in admittance should a stapedius muscle contraction occur. The results show that the ability to measure both ipsilateral and contralateral eSRT levels can be improved by using a higher probe frequency compared with the standard probe frequency of 226 Hz; however, the low incidence of electrical stapedius reflexes especially in the ipsilateral ear may limit the application of this technique to only a portion of children with bilateral cochlear implants. Future studies should investigate if there is a higher incidence of eliciting electrical stapedius reflexes in the contralateral ears as compared with the ipsilateral ears of bilaterally implanted recipients. Ipsilateral and contralateral eSRT measured with higher probe frequencies were in some cases 10 to 20 CUs lower than those measured with the routinely used lower probe frequencies. These level differences in individual cases should be taken into consideration while using eSRT levels measured with higher probe frequencies to program M-levels in pediatric cochlear implant patients.

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Author Carina Rodriguez is an Advanced Bionics employee (a cochlear implant manufacturer). Authors Charles C. Finley and Aniket A. Saoji were employed with Advanced Bionics when this study was completed.

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