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# **Cochlear implant upper stimulation levels: eSRT vs. loudness scaling**

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# **Abstract**

**Objective:** To assess the difference in speech recognition and sound quality between programming upper stimulation levels using behavioral measures (loudness scaling) and electrically evoked stapedial reflex thresholds (eSRT).

**Study Design:** Double-blinded acute comparison study

**Setting:** Cochlear implant (CI) program at a tertiary medical center

**Patients:** Eighteen adult (mean age = 60) CI users and 20 ears

**Main Outcome Measures:** Speech recognition scores and sound quality ratings

**Results:** Mean word and sentence in noise recognition scores were 8- and 9-percentage points higher, respectively, for the eSRT-based map. The sound quality rating was 1.4-points higher for the eSRT-based map. 16 out of 20 participants preferred the eSRT-based map.

**Conclusions:** Study results show significantly higher speech recognition and more favorable sound quality using an eSRT-based map compared to a loudness-scaling map using a doubleblinded testing approach. Additionally, results may be understated as 18 of 20 ears had eSRTs

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CONFLICT(S) OF INTEREST TO DECLARE:

None directly related to this study

JTH: advisory board for Advanced Bionics and MED-EL, consultant for Cochlear

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measured prior to study enrollment. Results underscore the importance of incorporating eSRTs into standard clinical practice to promote best outcomes for CI recipients.

#### **Keywords**

cochlear implant; programming; eSRTs; upper stimulation levels

# **INTRODUCTION**

Despite the overwhelming success of cochlear implants (CI), variability in speech recognition outcomes remains high, and much of the variability is outside of the clinician's control (e.g., etiology, duration of deafness, age). One malleable variable within the clinician's control is the programming of the external processor $1-3$ . Specifically, previous studies have demonstrated the importance of upper stimulation levels in patient performance<sup>4–8</sup>. Optimized upper stimulation levels have been associated with better speech and language outcomes for children as well as improved spectral and temporal discrimination<sup>9–11</sup>.

Upper stimulation levels are most frequently set with three primary methods: loudness scaling (71%), electrically-evoked stapedial reflex threshold (eSRT, 14%), or electrically evoked compound action potentials ( $eCAPs$ ,  $15\%$ )<sup>10,12,13</sup>. Behavioral loudness scaling requires a CI user to rate the loudness of a short burst of stimulation typically delivered on individual or groups of electrodes. Once the manufacturer specific desired response (i.e., "comfortable," "most comfortable") is obtained, the upper stimulation level is set at the corresponding charge. This method of programming requires patients to provide reliable feedback about loudness and comfort, which can be difficult for children, patients with cognitive disabilities, and adults with long-term deafness<sup>5,14–16</sup>. Further, loudness rating in general is highly variable in individuals with hearing  $loss^{5,14-16}$ . Given the importance of accurately setting upper stimulation levels, reliance upon behavioral loudness scaling methods may result in suboptimal outcomes for some patients<sup>13,17</sup>.

A less common but potentially more accurate approach to programming upper stimulation levels involves the use of eSRTs. The stapedial reflex can be elicited via electric stimulation through the CI. When the stimulus is high enough to elicit contraction of the stapedial muscle, the resultant increased stiffness of the tympanic membrane can be measured via an immittance meter. This response is time-locked to the stimulus presentation, and the magnitude of the reflex is positively associated with the stimulation level. Stimulation levels that elicit the response have been shown to provide an objective correlate to a stimulation level perceived as "loud but comfortable" on average<sup>4,18–25</sup>. The disadvantages of this programming method include the need for additional equipment (immittance meter), required patient compliance, and potential absence of reflex. The advantage of this programming method is that it does not require patient response or engagement and is thus not subject to the previously described limitations associated with behavioral loudness scaling.

It is important to note that eSRTs are not the only available objective programming measure, yet they have been shown to result in the most accurate estimate of upper stimulation

levels15,24. eCAPs are another common objective measure used to guide the programming of both lower and upper stimulation levels<sup>12</sup>.  $e$ CAPs are appealing because they do not require additional equipment, and they do not require the patient to be engaged or compliant. Despite these advantages, several previous studies have shown that eCAPs are poor predictors of upper stimulation levels and should only be used to confirm device and nerve function and/or as a last resort for the programming of upper stimulation levels<sup>15,23,26–30</sup>. The electrically evoked auditory brainstem response (EABR), has been shown to be present in a majority of patients, however it is time-consuming and results are more likely to correlate to behavioral thresholds than to upper loudness tolerance  $\lim$ its<sup>23,31</sup>. Lastly, cortical auditory evoked potentials (CAEPs) can also be used to guide CI programming. Indeed, there is a growing number of studies demonstrating a highly significant correlation between CAEP N1-P2 thresholds and behavioral CI thresholds or lower stimulation levels $32-34$ . Because the N1-P2 response does not fully mature until adolescence35, a CAEP-based approach to programming lower stimulation levels may be limited to older children and adults. However, there is emerging evidence that P1 thresholds could also be useful for CI programming in infants and young children $32$ .

Existing literature suggests that maps using eSRTs to set upper stimulation levels have shown equal<sup>4,18</sup> or better<sup>6,36</sup> speech recognition results compared to behavioral-based (loudness scaling) maps. Further, eSRT-based maps have been shown to result in equal loudness across the electrode array, and patients tend to prefer eSRT-based maps over behavioral maps<sup>15</sup>. In a comparison by Wolfe and Kasulis<sup>6</sup> of speech perception, users with eSRT maps performed better on speech in noise and single word repetition than users with conventional behavioral maps. Spivak and Chute  $(1994)^{19}$  and Hodges et al.  $(1997)^4$  also demonstrated better sound quality with eSRT-based programming compared to loudness scaling. Together, these findings support eSRT measurements as not only a valuable objective measure to be used in the absence of reliable behavioral information, but also to create optimized programs for improved speech perception and sound quality for all CI recipients with measurable responses.

Several published studies have demonstrated the reliability and accuracy of eSRT measurements for determining upper stimulation levels. However, existing studies comparing speech perception outcomes of eSRT-based maps and behaviorally based maps lack blinding and standardization of map creation. While commonly used in clinical trials, blinding is not as prevalent in CI research. In a hearing aid comparison study examining the effect of expectation on outcomes, participants performed better on speech perception tasks and reported more satisfaction with sound quality for a "new" hearing aid versus a "conventional" hearing aid, despite these two devices being identical  $37$ . Overall, hearing aid literature would suggest the placebo effect can influence performance outcomes  $37-39$ . Without double-blinding, it is difficult to determine if differences in self-perceived benefit were due to the placebo effect or if participants experienced improved listening. Another variable accounted for by the addition of double-blinding is the bias of the experimenter, specifically the phenomenon of confirmation bias. Referring to the tendency to give more weight or attend more accurately to information that validates a hypothesis, it can alter judgement and increase diagnostic errors $40,41$ . Related to the current study's objective, by blinding the researcher to the experimental condition (eSRT versus behavioral), we

remove the tendency to match preconceived beliefs to outcome data. In other words, the experimenter's rating of speech perception by the CI user will not be influenced by knowledge of which map the study participant is using.

The purpose of this study was to compare CI maps differing only in the programming of upper stimulation levels. Specifically, we aimed to compare maps using eSRT and behavioral (loudness scaling) methods to set upper stimulation levels in terms of speech recognition and sound quality outcomes. Based on previous studies, we hypothesized that eSRT-based maps would result in superior speech-recognition scores and sound quality ratings than behavior-based maps.

### **METHODS**

#### **Participants**

Study was approved by the institutional review board (IRB approval: 180939). Before experimentation, all participants provided informed, written consent. Participants were recruited from the center's CI patient pool. English-speaking adults with at least six months of CI use and normal or near-normal middle ear function were eligible for inclusion. Participants were 19 postlingually deafened adult CI recipients who utilized electric-only stimulation in the implanted ear. One enrolled participant had no measurable eSRTs and thus was unable to complete the study, and two participants were bilaterally implanted. This resulted in a final sample size of 18 adults and 20 total ears. The 18 adults had a mean age of 60 years (range 19 – 89 years old). Nine ears used Cochlear (NSW, Australia) devices, and 11 ears used Advanced Bionics (Valencia, CA) devices. 95% of ears demonstrated normal tympanograms; one ear had normal middle ear pressure with hypercompliance (compliance = 1.59 ml). Nine of 20 ears were using maps programmed strictly using eSRT, 7 using loudness scaling, and 4 using unknown or combination of programming methods in their everyday listening condition. Eighteen of 20 previously had eSRT measurements completed. All Cochlear users utilized an ACE programming strategy, and all Advanced Bionics users utilized a HiRes Optima-S strategy except for two (one used HiRes-S and one used HiRes-S Fidelity 120). Additional demographic factors for the participants were not collected for the purpose of this study due to the acute testing methodology; however, the sample is comparable to or slightly higher performing than a typical clinical sample of postlingually deafened adults using electric-only stimulation listening with the implanted ear alone. This is evidenced by an overall average word recognition score of  $64.8\%^{8,42-45}$  and aided detection thresholds obtained in the normal to mild hearing loss range.

#### **Study Design**

This study was designed to assess the difference between programming upper stimulation levels using behavioral measures (loudness scaling) and eSRT. The study design included one visit where two maps were created using the two different methods of measuring upper stimulation levels. Aside from upper stimulation levels, all remaining mapping parameters and processor settings were confirmed as matched between the behavioral and eSRT-based maps. The participant was then tested acutely using each map. Measures of

speech recognition and sound quality were collected, and the participant and researcher were blinded to which map was being used during testing to avoid bias.

#### **Cochlear Implant Programming**

Prior to programming upper stimulation levels, aided detection was measured with the participant's everyday map in a calibrated sound field using frequency modulated pure tones in the 250- to 6000-Hz range. Fifty-five percent (55%) of ears showed adequate aided detection (15–25 dB HL) prior to programming changes. Lower stimulation levels were adjusted for frequencies outside of the 15–25 dB HL range and detection was confirmed following programming changes. For Advanced Bionics' users, lower stimulation levels were 'unlocked' from upper stimulation levels prior to upper stimulation level adjustment for consistency across the two maps.

For the behavioral-based map, the upper stimulation level for each electrode was measured using conventional loudness scaling and set according to manufacturer specifications (Cochlear Americas: "loud but comfortable" and Advanced Bionics: "most comfortable"). Specifically, measurement of upper stimulation levels started at the level of the lower stimulation level and was increased until the participant reported the appropriate loudness using the corresponding loudness scaling chart. Electrodes with no loudness percept were deactivated. Lower stimulation levels remained unchanged as described above.

We started eSRT measurements with a 678 Hz probe tone in the contralateral ear based on previous report by Wolfe and colleagues<sup>13</sup>, which showed this configuration to have the highest probability for eSRT measurement. Ninety percent (90%) of eSRT measurements were obtained using the 678-Hz probe, with the remaining patients requiring use of the 226 Hz probe tone to obtain a measurable response. Seventy-five percent (75%) of eSRT responses were measured in the contralateral ear. Considering all consented participants, eSRT responses were present in 95% of ears. The eSRT was measured using conventional acoustic immittance in all 20 ears, with the eliciting stimulus delivered to at least five electrodes across the array. Acoustic admittance was continuously recorded on the Grason-Stadler (Eden Prairie, MN) Tympstar while biphasic pulse trains were presented with three bursts at each stimulation level. The presentation level of the electrical stimulus was increased until a visible, time-locked, repeatable change in admittance was observed. The stimulus was then delivered at the same level to confirm the presence of the time-locked response. The lowest stimulation level (in clinical units) in which a change in admittance of ≥0.02 mmho was observed was recorded as the eSRT. Upper stimulation levels were set to eSRT responses then globally decreased per patient preference.

Behavioral and eSRT-based maps were saved randomly to two programming slots on the same processor for the speech recognition evaluation portion of the study visit. Specifically, a second researcher completed the testing, or a second researcher completed the saving of the programs such that the tester and participant did not know which program was in which processor slot. Random assignment resulted in 50% of the eSRT maps being saved to slot one indicating that each map was tested first equally.

#### **Evaluation**

Recorded speech stimuli were presented at 60 dB SPL from a single loudspeaker inside a sound booth which was calibrated using a sound-level meter prior to every test session. Testing was completed in the CI-alone condition; the opposite ear was plugged for bimodal listeners. Bimodal/bilateral testing was not completed. Speech recognition measures included Consonant-Nucleus-Consonant (CNC) monosyllabic word recognition<sup>46</sup> and AzBio sentence<sup>47</sup> in  $+5$  dB signal-to-noise ratio (SNR) noise recognition. The participant was also asked to judge the sound quality of a recorded passage from 1 (very bad) to 10 (very good) using each program. Following testing, the participant was asked two questions: "Which map did you prefer?" and "Which map sounded louder?"

#### **Statistics**

Statistical analyses were performed with GraphPad Prism version 9.4.1 for Windows (GraphPad Software, San Diego, CA). All variables were found to be normally distributed except for CNC word recognition using the eSRT map. Continuous variables were summarized using means when normally distributed and medians when not. Speech recognition results and sound quality ratings were assessed by paired t-tests except for CNC word recognition for which a Wilcoxon matched-pairs signed rank test was used due to non-normal distribution. A  $p$ -value less than 0.05 was considered statistically significant.

#### **RESULTS**

#### **Speech Recognition**

Individual and mean speech recognition scores are shown in Figure 1. Median CNC word recognition scores for the 18 participants (20 ears) were 70% for the eSRT-based map and 64% for the behavioral-based map. Percentage scores were converted to rationalized arcsine units (RAU) for statistical analysis in an effort to address ceiling effect. A Wilcoxon matched-pairs signed rank test indicated that CNC scores for the eSRT-based map were significantly higher than the behavioral-based map ( $z = -3.30$ ,  $p = .0005$ ). The average improvement in CNC word recognition scores associated with the eSRT-based map compared to the behavioral-based map was 8.0 percentage points (range  $= -4 - 32$ ) percentage points). Mean AzBio in +5 dB SNR noise scores were 35% for the eSRT-based map and 26% for the behavioral-based map. Percentage scores were converted to RAU for statistical analysis in an effort to reduce the floor effect. A paired t-test indicated that AzBio in noise scores were significantly higher than the behavioral-based map,  $t(19)$  = 3.645,  $p = .002$ . The average improvement in sentence recognition scores associated with the eSRT-based map compared to the behavioral-based map was 9.1 percentage points (range = −4 – 24 percentage points).

#### **Sound Quality Rating**

Individual and mean sound quality ratings are shown in Figure 2. Mean sound quality rating was 7.6 for the eSRT-based map and 6.2 for the behavioral-based map. A paired t-test indicated that sound quality ratings for the eSRT-based map were significantly more

favorable than the behavioral-based map,  $t(19) = 3.18$ ,  $p = .005$ . Additionally, 16 out of 20 patients preferred the eSRT-based map.

#### **Upper Stimulation Levels**

Differences in upper stimulation levels were analyzed using an ANOVA to compare upper stimulation levels between the participant's everyday map, eSRT-based map, and behaviorbased map. A one-way ANOVA revealed that there was a statistically significant difference in upper stimulation levels between at least two maps  $(F(2, 42) = [19.55, p < 0.001)$ . The post-hoc paired t-test using a Bonferroni correction indicated that the everyday map was significantly different than the eSRT-based map ( $p < 0.001$ ) but not significantly different than the behavioral-based map ( $p = 0.4778$ ). Additionally, the eSRT-based map was significantly different than the behavioral-based map ( $p < 0.001$ ).

General trends in upper stimulation levels were that eSRT-based maps had higher stimulation levels than behavioral-based maps especially for the high-frequency channels. The greatest difference was observed on electrodes 13–16 and 1–2, which represent the most basal electrodes for Advanced Bionics and Cochlear respectively. Statistical analysis for upper stimulation levels on specific electrodes was not conducted based on low sample size after separating by implant manufacturer and electrode number; 14 of 20 participants had at least one electrode deactivated in their map.

#### **DISCUSSION**

The current study compared acute speech recognition abilities and sound quality ratings using a double-blinded approach for maps generated using two different methods, eSRT and behavioral loudness scaling. We analyzed CNC word recognition, AzBio sentence recognition in  $+5$  dB SNR noise, and sound quality rating (subjective rating  $1-10$ ) acutely following creation of maps using eSRT and loudness scaling methods. Speech recognition and sound quality ratings were significantly higher for the eSRT-based map, and 16 of 20 participants preferred the eSRT-based map.

In 2014, Vaerenberg and Colleagues<sup>12</sup> reported that only 14% of audiologists routinely use eSRT measurements to guide CI programming. This is concerning because alternative measures have been shown to be prone to error. Loudness scaling is highly variable across individuals especially those with long durations of profound hearing loss and is also highly influenced by the clinician<sup>5,14–16</sup>. Further, a more commonly used objective measure, eCAPs are poor predictors of upper stimulation levels<sup>23,26,27,29,30,48–50</sup>. As a result, eCAPs are not recommended as the primary measure to guide upper stimulation level programming.

Although less pervasive, data continue to support eSRTs as the most accurate approach to setting upper stimulation levels. Data from the current study is in agreement with prior studies that demonstrated equal<sup>4,18</sup> or better<sup>6,36</sup> speech recognition compared to behavioralbased maps. Further, the current data also support prior work demonstrating patient preference for eSRT-based maps<sup>15</sup>. The double-blinded approach used in the current study further solidifies prior findings by removing the potential for participant and investigator bias.

Just as it is best practice to use research-based fitting targets to fit hearing aids, evidence suggests that audiologists should use eSRTs to guide upper stimulation level programming for all patients with normal middle ear status in at least one ear. The American Academy of Audiology (AAA) currently recommends six programming visits in the first year following implant surgery. Without the use of eSRTs, these appointments are used to measure upper stimulation levels using behavioral loudness scaling, which slowly evolves with listening experience. With the use of eSRTs, the audiologist is able to identify an objectively determined "target" for upper stimulation levels, which has been shown to be stable over time51. Although patients may still require time to adapt to the 'loudness' of the implant, progressive maps can be used by the patient at home to achieve the upper stimulation levels that promote optimal speech understanding in fewer appointments.

The limitations to the current study are the relatively small sample size, acute rather than chronic testing, and influence of the patient's starting map. All of these factors may have contributed to the statistically significant but small (9 percentage point) difference between the average speech recognition scores of the two maps calling into question the clinical significance of speech recognition scores at the group level. Because our clinic primarily uses eSRTs to program upper stimulation levels, it is possible that the results of this study are understated. Patients who are used to higher stimulation levels guided by eSRTs may be inclined to select higher levels during loudness scaling than patients who have never had eSRTs measured before. Although all patients in the study were not directly mapped based on eSRT, 18 of 20 had previously measured eSRTs. Thus it is possible that patients who have never had eSRTs measured previously would show greater improvement with an eSRT-based map. Further, patients performed better acutely with the eSRT-based map despite it using significantly different upper stimulation levels than their everyday map. This suggests that the significant improvement in performance and preference for the eSRT map by 16/20 participants was not associated with familiarity or utilization of levels closer to the subject's everyday map. With chronic use of the eSRT map, speech recognition scores may improve even further. Future work should consider chronic use of eSRT vs. behavior-based maps.

#### **CONCLUSION**

Study results show significantly higher speech recognition and more favorable sound quality using an eSRT-based map compared to a loudness-scaling map using a double-blinded testing approach. 16 of 20 patients preferred the eSRT-based map. Results underscore the importance of incorporating eSRTs into standard clinical practice for determining upper stimulation levels to promote best outcomes for CI recipients.

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#### **Figure 1.**

Individual and mean CNC word recognition and AzBio sentence recognition (+5 dB signalto-noise ratio) scores are shown. Black squares indicate the mean, and the bars indicate the standard deviation. (CNC = Consonant-Nucleus-Consonant word recognition)



#### **Figure 2.**

Individual and mean subjective sound quality ratings are shown. The mean is indicated with a black square, and the bars represent the standard deviation.