

## **Place-Based Mapping in EAS Listeners**

**NCT04722042**

**Modified Date: 2/17/2025**

## Statistical Power and Design

For the first experiment under Aim 1, we plan to investigate monaural speech for EAS users listening with a place-based versus a default map. We plan to recruit 40 subjects from the UNC Adult CI Program (~140 surgeries/year) at initial activation (~2-4 weeks postop). Inclusion criteria are 18-65 years of age, MED-EL array recipient, and a postoperative unaided detection threshold of  $\leq 65$  dB HL at 125 Hz. Recruitment is limited to recipients of one manufacturer to control for number and separation of electrodes, as well as coding strategy. Subjects will be fit with the Sonnet2EAS device. Subjects must identify English as their native language since test materials are in English. Subjects will be excluded if they report or present with a cognitive delay or impairment, as indicated with the Mini Mental State Examination (Folstein, Folstein, & McHugh; 1975). Subjects will be randomized into one of 2 groups: 1) default map, or 2) place-based map. In addition to these 40 CI users, age-matched NH listeners will be recruited for reference.

Monaural speech perception will be compared between groups over the study period (activation, and 1, 3, 6, & 12 mos). Subjects will be evaluated with the alternative map at the initial activation and 12-mo intervals for within-subjects comparisons. The tester will be blinded to map condition to limit bias. Test measures include: CNC word recognition in quiet, AzBio sentence recognition in noise (10 dB SNR), and vowel recognition. Word and sentence recognition will be assessed in the sound field, at one meter from the speaker. Recorded materials will be presented at 60 dB SPL, and masking will be delivered to the contralateral ear via an insert phone when warranted. Vowel recognition is essential for speech perception and is sensitive to changes in low-to-mid frequency representation in EAS simulations. Vowel recognition will be assessed using the English Vowel Recognition Test from TigerSpeech Technology®, a tool that assesses recognition of 12 vowel sounds, presented in a /h/-vowel-/d/ context. The EAS device will be connected to the computer via a direct-connect cable. The subject will listen to the target and select the perceived vowel from a closed-set list, with responses scored in percent correct; confusion matrices are also provided. An age-matched, NH control group will complete the CNC and AzBio tests while listening to EAS simulations of the default and place-based maps based on parameters characterizing stimulation for individual CI subjects; NH listeners are tested only once.

Dependent measures are vowel recognition, word recognition in quiet, and sentence recognition in noise. Linear Mixed Models (LMM) will be used to assess the main effects of group (default vs place-based) and interval (activation, 1, 3, 6, & 12 mos), and the interaction between group and interval on each measure, with a significance criterion of  $\alpha=0.05$ . Aided acoustic audibility as measured with the Speech Intelligibility Index (SII) will be included as a within-subjects variable to control for differences in residual hearing. Subject demographic data to be reported include: gender, age, unaided thresholds, AID of the most apical electrode, and mismatch. Mismatch will be quantified as the absolute semitone deviation at 1500 Hz (~267° using the SG function), which has been shown to be an important region for frequency alignment in vocoder simulations. Reduced models will assess the main effects of map (default vs place-based) and interval (activation & 12 mos), and the two-way interaction for the within-subjects comparison. Results from the NH control group will be compared to EAS users at activation, to corroborate effects of mapping approach in the findings from the CI subjects.

For Aim 2, we plan to investigate the binaural hearing abilities of EAS users listening with a place-based map versus a default map. We plan to recruit 24 subjects from the experiments under Aim 1 with thresholds  $\leq 65$  dB HL at 125 Hz in the contralateral ear. For NH subjects listening to a bilateral CI simulation, SRM is ~8 dB (95% CI: ~7 dB) with no interaural mismatch and ~4 dB (95% CI: ~11 dB) with an interaural mismatch of 1 mm (Xu et al., 2020). Similar results are obtained with bilateral CI recipients (Hu et al., 2018). Based on these data, our experiment is powered to observe effect sizes of  $d \geq 0.90$  ( $\alpha < 0.05$ ,  $1-\beta = 0.8$ ).

Binaural hearing will be assessed in the soundbooth, using an 11-speaker arc spanning -90° to 90°. Subject listen with EAS+HA or EAS+NH at the 1, 3, 6, & 12-month intervals. Binaural hearing measures include: 1) spatially masked sentence recognition, 2) localization, and 3) subjective benefit. Spatially masked sentence recognition will be completed, with performance calculated as  $SRM_{EAS}$  and  $SRM_{Contra}$ . The dB SNR for each subject will be determined at the 1-month interval in the co-located condition, by decreasing the dB SNR from 10 dB to 0 dB in 5 dB steps until the subject scores  $< 50\%$  correct. Subjects will be evaluated at the same SNR for the subsequent intervals. Localization will be assessed by calculating the root-mean-squared (RMS) error of sound source identification using 200-ms noise bursts at varied intensity levels (52, 62, or 72 dB SPL). Subjective benefit will be assessed using the Speech, Spatial, and Qualities of Hearing Scale (SSQ;

Gatehouse & Noble, 2004), with results evaluated on the 3 subscales and 10 pragmatic subscales (defined by Gatehouse & Akeroyd, 2006).

The primary analysis is the effect of group (default vs place-based) on  $SRM_{EAS}$ ,  $SRM_{Contra}$ , and localization. An LMM will assess the main effects (group and interval) and the associated interaction, with a significance criterion of  $\alpha < 0.05$ . Secondary analyses will include the effect of group on subjective benefit, assessed for the Spatial Hearing subscale, and relevant pragmatic subscales, including: 1) Speech in Speech Contexts, 2) Segregation of Sounds and Objects, and 3) Listening Effort.