Statistical Analysis Plan

"MyoVoice to Restore Natural, Hands-free Communication to Individuals With Vocal Impairments"

NCT04762043

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The goal of our statistical design is to achieve secondary endpoints that are analyzed post hoc. This is not the type of clinical trial in which endpoints result from subjects being randomized and for which the trial is powered. Instead, our statistical plan was designed to assess the perceived naturalness ratings of our Phase II sEMG-based silent-speech synthesizer by comparison of ratings with 3 alternative synthesized speech modalities that including: electrolaryngeal speech (EL), synthesized speech with a flat prosodic contour (SP), and synthesized speech with a prosodic contour generated by our Phase I algorithms (GP). Each sample was rated on a visual analog scale from 0 to 100, which 0 anchored at “least natural” and 100 anchored at “most natural.” A mixed effects model will be used to demonstrate that the effects of both listener (i.e. random effect) and speech type (fixed effect) meet a level of significance ($p<0.05$) have a significant effect on the speech naturalness ratings. Post-hoc testing using a Tukey analysis will be used to make pair-wise comparisons across the SP, GP, and FP methods.