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**A group sequential test strategy for objective auditory brainstem response detection methods**

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**Background**: Objective auditory brainstem response (ABR) detection methods have an advantage over visual inspection, as they do not depend on the expertise of the examiner. A potential disadvantage is that the number of ABRs required for a positive detection can vary between subjects, which makes choosing a suitable sample size prior to the test difficult. A solution is to apply the objective detection method repeatedly over time, i.e. a group sequential test strategy can be adopted. This allows the test protocol to be stopped early when a significant response is detected, and potentially prolonged otherwise. A drawback to the group sequential test, however, is an inflated false positive rate (FPR) due to multiple tests being performed over time. One of the challenges for the group sequential test is therefore to maintain a set FPR by adjusting the critical decision boundaries for rejecting the null hypothesis throughout the test. Group sequential tests furthermore introduce a trade-off between a potential reduction in test time versus a reduction in statistical power, which needs to be explored for ABR detection before a suitable group sequential test protocol can be designed.

**Objectives**: The goal for this study is to evaluate the performance of a group sequential test in terms of specificity, sensitivity, and detection time when detecting ABRs in simulations and in subject recorded data, and to compare its performance of the single shot test (where the statistical method is applied just once to a fixed sample size). In addition, a new method (based on the convolution of null distributions) for calculating the critical decision boundaries for rejecting the null hypothesis is presented. Because this method has, to the author’s knowledge, not yet been used in a group sequential test setting, an extensive assessment of its specificity is provided. The trade-off between a decrease in sensitivity versus a potential decrease in detection time for the group sequential test is also explored.

**Design**: Specificity was assessed using a large number of simulated white noise, simulated coloured noise, and real EEG background noise recordings (obtained from 20 normal hearing adults under different noise conditions). Sensitivity and detection time were then assessed using simulations and subject recorded ABR threshold data. The data for the simulations consisted of simulated coloured noise for representing the EEG background noise, and coherently averaged and scaled ABR waveforms for representing a response. The subject recorded ABR data was furthermore obtained from 12 normal hearing adults using click stimuli of various intensity levels, presented at a rate of 33.33 Hz. The statistical method selected for the analysis was the Hotelling's T2 test, which was applied in the time domain.

**Results**: No significant (p<0.05) deviations from the expected 0.05 FPR were observed for the specificity assessment when using a high-pass cut-off frequency of 100 Hz and a stimulus rate of 33.33 Hz, which suggests that the underlying statistical assumptions were met, or that violations to the assumptions were negligible. However, additional simulations show that the independence assumption (between epochs) is violated when using alternative settings for the high-pass cut-off frequency and stimulus rate. With respect to sensitivity and detection time, the results demonstrate a potentially large reduction in detection time for the group sequential test, with no loss in detection rate relative to the single shot test.