Title of study

Wearable Monitoring Systems for Swallowing Function and Disorders

NCT #

NCT04243577

Latest Approval Date

10/18/2023

Study Protocol & Statistical Analysis Plan

STUDY PROTOCOL

Objective

Wearable tele-rehabilitation technology allows for the efficient provision of rehabilitation services from a distance, facilitating tele-management of many disorders. The proposed research aimed to develop and validate a mechanically compliant, easy-to-use, and inexpensive wearable tele-monitoring system, for future use in the rehabilitation of swallowing disorders (dysphagia). The hypothesis was that the newly developed surface electromyographic (sEMG) wearable sensors would have equal or better performance than traditional wired sEMG sensors used today in clinical practice. Factors related to signal quality and patient reported outcomes (e.g., satisfaction/comfort level, adverse effects etc.) were examined.

Design and Devices

This study is a within subject randomized cross-over design study. Two iterations of a wearable surface EMG sensors patch we developed were tested against commercially available wired devices. The first iteration of the wearable sensor patch was an ultrathin patch with a honeycomb-inspired design that included sEMG and strain sensors in order to capture muscle activity and thyroid movement signals from the submental area during swallows and swallow maneuvers/exercises. The second iteration was a more durable slightly thicker flexible, non-stretchable, and double-sided thin patch. The exact same methods were used to test both iterations against commercially available conventional sensors. For both iterations' testing, the order of the experimental conditions differed across groups. Group A participants completed the experimental protocol with the conventional electrodes first, and Group B participants completed the protocol with the experimental patch first. There was a 10-min rest period between the two experimental conditions.

The first iteration testing was completed in 40 healthy older adults. Results revealed technical improvements were needed and therefore a second improved version of the sensor was then developed. The second iteration testing was done in an additional sample of 30 healthy older adults. A total of 70 healthy older participants were included in the study.

Methods

Participants

Healthy older adults 50-85 years old (the typical age range of our target clinical population for future studies) were recruited in this study. Inclusion criteria were: 1) no history of dysphagia, 2) no history of neurological disease, head/neck cancer, radiation or surgery, 3) a score in the normal/mild range on the Montreal Cognitive Assessment (MoCA), and 4) a score of <3 on the Eating Assessment Tool (EAT-10; a self-report screening for dysphagia). Exclusion criteria were: 1) history of dysphagia; 2) history of neurological disease, head/neck cancer, radiation or surgery, 3) a score in moderate-severe range on MoCA, and 4) a score of >2 on the EAT-10.

Instrumentation Validation – Data Collection

For each iteration of the device, a group of participants was tested using the experimental device/sensors and the commercially available ones in counterbalanced order. Results were analyzed to allow design improvements before the next iteration was developed and tested.
To validate each of the two iterations of the newly developed sEMG patch, we used wired electrodes (e.g., AED Brands, A snap-style pad) connected to a commercially available wireless amplifier (BioRadio, GLNeuroTech Inc.), as the comparison system. During this experiment, the electrodes were placed on the submental muscles (under the chin). The sEMG signals were sampled while subjects remained as still as possible and sat upright with the head in neutral

position. Participants were asked to complete several types of swallows multiple times. Each set of tasks was tested with one type of device first (conventional or experimental) and was repeated 10 min after the first set with the other type of device. For both types of devices, swallows were confirmed via a nasal airflow cannula to detect the swallow apnea (nasal airflow cessation), and an observer's button that was be pressed at swallow completion.

Outcome Measures and Data Analysis

Primary Outcome Variables – Signal Quality parameters

Signal quality outcomes tested across both iterations' tests included normalized task-related EMG amplitude (primary outcome), and signal to noise (S/N) ratio. Because task sEMG amplitudes vary among subjects (e.g., as a function of electrode impedance), we expressed amplitude in microvolts and normalized these values within subjects. For normalization, participants produce 3 trials of maximum lingual press, and we expressed the task-related EMG amplitudes as percentages of the amplitude of this criterion gesture. For analysis, research assistants blinded to sensor type conducted analyses using a custom MATLAB script.

Secondary Outcome Variables – Preclinical parameters

We examined adverse effects and safety by thoroughly inspecting participants' submandibular skin before and after each experiment. Specifically, we documented the incidence of skin irritations in the subjects. A visual inspection form including a binary scale (YES/NO) was devised by the investigators (no formal name) and was used by a rater who thoroughly inspected the participants' submandibular skin before and after each experiment. For any irritation or change in appearance YES was selected and the type of irritation was descriptively recorded (e.g., red skin). This form was completed by a rater who was not part of the data collection process and who was blinded to sensors type to avoid any bias. The number of YESs were used to calculate the incidence of these adverse effects in the sample. This inspection was completed immediately after removal of each sensor type and 5 minutes later as well.

Ease-of-use/comfort was examined using a survey (using a positive centered 5-point Likert scale) with questions about ease-of-use/comfort after each experiment with each device. This survey included statements related to the participants' ease-of-use/comfort during the experimental protocol (e.g., I was comfortable while the experimenter placed the sensors on my skin). The answers were rated on a 10-point scale (i.e., 1 = extremely uncomfortable, 10 = extremely comfortable). Higher values indicated better or higher satisfaction/ comfort scores. Total scores were compared across conditions/devices tested.

STATISTICAL ANALYSIS PLAN

The study was designed to have at least 80% power to detect a difference in the primary variables of interest, that is, SNR, and normalized mean amplitude of swallow trials. The sample size was determined via a power analysis based on pilot results. Alpha level was set to .025 to correct for multiple comparisons. Quantile–quantile plots and the Shapiro–Wilk test was also used to assess normality. For S/N ratio comparisons non-inferiority tests were used for both iterations' testing. For the normalized amplitude data, equivalency testing was used for both iterations' testing. Margins for these tests were calculated using our preliminary data acquired with the conventional electrodes, which were considered as the current gold standard. Descriptive statistics (frequency counts) were used to report adverse effects (skin related effects). Paired t tests were used to test for differences in satisfaction/comfort level.