Study Protocol and Statistical Analysis Plan

Protocol Title
Adaptive and Individualized AAC

Sponsor
Altec Inc., Natick, MA 01760

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Principal Investigator
Paola Contessa

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Note: The text below was extracted from the IRB protocols for this study, which were first approved on 12/16/2019 for testing at Madonna Rehabilitation Hospital (Nebraska) and on 08/20/2019 with an amendment approved on 04/26/2021 for testing at Altec, Inc.

Study Protocol

Background

More than 1.3% of Americans, including over 150,000 children, suffer from severe physical impairments (SPI) that impede their ability to communicate. Over 500,000 of these individuals are adults and children with SPI who require augmentative and alternative communication (AAC) technology to be able to express themselves. These include a wide range of technologies and methods ranging from sign language and gestures to hi-tech speech-generating devices. However, many individuals with SPI lack the manual dexterity required to operate these assistive technologies and, as a result, require an alternative means of computer access such as head-or eye-tracking. Even then, these alternative access methods are often too tedious for individuals with SPI, as they require frequent recalibrations and readjustments to accommodate changes in disease progression, body position, and/or environment. It is therefore not uncommon that prospective users invest weeks or months of training time into using these devices, only to achieve inconsistent or inaccurate performance that impedes effective and intuitive communication. There is an urgent need to develop turnkey AAC devices that are able to automatically accommodate the unique physical access needs of individuals with SPI.

Goal of the Overall Study

Our team of experts in wearable sensor systems, algorithms, and human machine interfaces at Altec, Inc., in collaboration with a team of speech researchers and clinicians from Boston University (Stepp Lab) and Madonna Rehabilitation Hospital's Institute for Rehabilitation Science & Engineer (Communication Center Lab), aims to develop a more reliable, portable, and intuitive AAC device for individuals with SPI. This device will leverage direct recordings of head movement and facial muscle contractions from a combined surface electromyographic (sEMG) and inertial measurement unit (IMU) sensor to provide a means for controlling cursor movements and selection on an individualized keyboard interface that allows to adapt the device to the unique residual motor function of each user for improved communication capabilities. Through this innovation, we aim to provide individualized AAC solutions to all individuals – including those with the most complex needs – to preserve the fundamental human right of communication.

This work is a continuation of pilot studies by our team over the past 4 years, which have focused on the development of sensor-based access methods and adaptive interfaces that shift the burden of learning from the patients to the device. Since sEMG and IMU signals directly measure muscle control and body kinematics, such as occurs to produce head movement, they provide a reliable, portable, and intuitive means to adapt the device to the unique residual motor function of each user.

Study Sites

Data collection will take place in the research laboratories of Altec, Inc. (Natick, MA) under the supervision of the project PI, Dr. Paola Contessa, and the study coordinator, Dr. Serge Roy; the Communication Center of Excellence laboratory at Madonna Rehabilitation Hospital Institute for Rehabilitation Science and Engineering (Lincoln, NE) under the supervision of Susan Fager, Ph.D., CCC-SLP, Director of the Communication Center of Excellence - one of four Centers of Excellence within the Institute for Rehabilitation Science and Engineering at Madonna; or the Boston University Stepp Lab at Boston University (Boston, MA) under the supervision of Cara Stepp, Ph.D., another key collaborator on the project and speech expert, founder and Director of the STEPP LAB for Sensorimotor Rehabilitation Engineering at Boston University. When

necessary, we will exercise the option of conducting the data collection procedure in an offsite location that is convenient to the prospective subject.

Specific Aims

A series of experiments will be performed where control subjects and participants with SPI will be asked to perform head movements and eyeblinks to control the movement of a cursor and the selection of targets on a computer or tablet screen while IMU and sEMG signals are recorded from a sensor placed on the participants' forehead. These experiments will demonstrate that a novel sEMG/IMU-based access method is uniquely capable of characterizing subject-specific variations in movement capabilities in a heterogeneous sample of individuals with SPI to inform the adaptation of an AAC keyboard interface that accommodates residual motor function unique to each user. Specifically, sEMG and IMU signals during head movement and eyeblinks will be translated into repeatable cursor control and target selection that replicate subject-specific movement capabilities. This information will be used to adapt the configuration, orientation, and layout of an AAC orthographic keyboard interface to accommodate the head movement characteristics unique to each subject. The newly developed sEMG/IMU-based models and personalized keyboard interface will be tested to demonstrate that this new access method improves AAC performance when compared to communicating on a generic cursor-to-text AAC interface that uses the same configuration but is not optimized for the individual.

Protocol

The experiments require the subjects to utilize head motion to move a cursor on a computer or tablet screen interface. These interfaces will be of two general kinds: an interface that affords us the opportunity to assess generic cursor sensor control for targets located at different orientations and distances; and an orthographic interface where letters are arranged in either a standard (QWERTY) keyboard configuration or an optimized configuration specific to their individual control capabilities. During all experiments, participants will be seated in front of a monitor or tablet and asked to move a cursor appearing on the screen based on data extracted from a wireless Trigno Avanti (Delsys, Inc.) sensor worn on their forehead. When the cursor reaches the target, the subject must select the target by contracting their facial muscle (i.e.: via sEMG signals from either eye blinking or raising their eyebrows).

In some tasks, letters will be highlighted in the appropriate sequence to spell words presented to the subject. The selection and capture of the targets by the subject will be achieved by blinking or raising their eyebrow while the cursor is hovering at or near the target. In other tasks, participants will be asked to spell a series of words presented to them on the computer interface by moving the cursor with the aid of the head mounted IMU and select the target with the aid of the measured sEMG activity. The number of sentences will be arranged in consultation with our clinical collaborators so that the procedures can be completed within a reasonable timeframe.

Additional data acquisition during these experiments may include standard video recordings to assist in post-processing interpretation of results; and user-rated report of fatigue, effort, perceived benefit, ease of use or satisfaction through a brief Likert-type questionnaire.

Each session should require 1-3 hours over 1-2 sessions (depending on subject stamina) with rest periods provided at least every 10 minutes to avoid fatigue or lack of attentiveness.

Involvement of Human Subjects

Children and adults (male/female; ≥8 y.o.), including healthy controls and individuals with SPI, will be recruited.

Sex considerations: Even though some SPI have a sex preference – as for example the prevalence of people who sustain spinal cord injuries is greater in males than females – we plan to recruit equal numbers of males and females to assess possible differences between men and women with regards to the expected outcomes of this work.

Age considerations: SPI affect both children and adult populations who may develop verbal communication impairments and require the need for AAC devices. We will therefore include children ≥8 yo. who are able to spell, follow 2-3 step directions, have functional vision sufficient to read point text, and have a motor impairment that requires the use of AAC technology.

Racial/Ethnic origin considerations: We plan to recruit a subject population that includes equal participation of minorities and is representative of the racial and ethnic diversity of the greater Boston and Lincoln areas.

Other considerations: Subjects must speak English so that we can accurately develop an AAC keyboard interface and speech model based on English-language and must be literate in English so that they can read speech task prompts from a computer monitor.

Recording apparatus: All sensors used in this study will be non-invasive and electrically isolated for subject safety. A Trigno Avanti https://www.delsys.com/trigno/research/ wireless data acquisition system (Delsys Inc., Natick, MA) designed for detecting both sEMG and IMU signals from the same sensor will be located on the subject's forehead for these experiments. The sensor wirelessly communicates with either a Trigno Base station or a Tablet. Signals from the sensors will be sampled at 2000 samples/sec using EMGWorks software (Delsys Inc., Natick, MA), and interfaced over USB to a PC workstation for post processing. The sensor will be secured to the skin using a disposable medical-grade double-sided interface.

Sensor locations: The skin area of each sensor location will be prepared using alcohol wipes to cleanse the skin surface and repeated tape peels to remove possible superficial contaminants (oil; dead skin) so as to improve signal quality. Facial hair may be shaved with the subjects' permission using a disposable safety razor in the immediate area of the sensor recording sites. We anticipate placement of no more than 1 sensor at any one time, with the IMU body placed on the participant's forehead and the sEMG mini-head placed adjacent to the eye to record muscle activations from either blinking or raising the eyebrow.

Inclusion/Exclusion Criteria

INDIVIDUALS WITH SPI

Inclusion criteria:

- Adults or Children; age> 8 y.o.
- Male or Female.
- All participants will be: (a) able to spell, (b) able to follow 2-3 step directions, (c) have functional vision sufficient to read 40 point text, and (d) have a motor impairment that requires the use of an alternative access strategy to communicate and/or use technology.
- Current or prospective AAC user with complex communication needs representing a broad spectrum of developmental and acquired SPI disabilities resulting from high spinal cord injury,

chronic Guillain-Barré syndrome, brain stem stroke, cerebral palsy, locked-in syndrome, among others

- Sufficient head control and voluntary facial muscle activation (on the basis of clinical evaluation by Dr. Susan Fager and her team) to use the proposed wearable EMG/IMU sensor for the purposes of this study.
- Evidence of at least partial voluntary head movement in at least 2 degrees of freedom (Individual differences in providing controlled movements of the head in various degrees of freedom due to their disease or trauma is not only acceptable but desirable).
- Sufficient stamina and developmental maturity (on the basis of clinical evaluation by Dr. Susan Fager) to attend to the approximately 1-hour protocol outlined in Aims 1 and 3 without excess fatigue or distraction.
- Availability for at least 3-4 testing sessions over the study period.
- No medical or safety restrictions of active head and neck movement (as determined by Dr. Susan Fager in consultation with her clinical team).
- Clinical evidence of preserved cognition by a score of 0 or 1 on NIHSS Consciousness and Communication item.
- Ability to voluntarily blink eyes or raise eyebrows on command.

Exclusion criteria:

- Non-English speaker.
- Inability to follow simple instructions in English.
- Medical history of musculoskeletal conditions (arthritis, spondylosis, etc.) that severely limit head movement or causes pain on head movement.
- Restricted active or passive rotation of head and neck resulting from unstable vertebral, spinal cord, or nerve roots that places the subject at risk.
- Medical history of cardiac or respiratory complications, or similar disorders that would severely reduce stamina and/or place the subject at risk for conducting the different motor activities.
- Skin disorders that result in open lesions or hyper-sensitive/fragile skin on the forehead, preventing the use of medical-grade adhesive tapes to secure the sensors to the skin.
- Unable to provide informed consent in English.

CONTROLS

Inclusion Criteria:

- Adults and Children; >8 y.o.
- Male or Female.
- All participants will be: (a) able to spell, (b) able to follow 2-3 step directions, (c) have functional vision sufficient to read 40 point text.
- No history of communication disorders.
- No history of neurological disorders affecting speech or head movement.

Exclusion Criteria:

- Non-English speaker.
- Inability to follow simple instructions in English.
- Restricted ROM of the head or neck.
- Pain with head movement.

- Medical history of cardiac or respiratory complications, or disorders that would place the subject at risk for conducting the different motor activities.
- Skin disorders that result in open lesions or hyper-sensitive/fragile skin on the forehead, preventing the use of medical-grade adhesive tapes to secure the sensors to the skin.
- Unable to provide informed consent in English.

Recruitment Process

Participants with SPI meeting the Inclusion/Exclusion criteria will be recruited primarily through referrals from Dr. Susan Fager and Dr. Cara Stepp who provide a primary point of contact for AAC evaluation and intervention for children and adults with SPI. Control subjects meeting the Inclusion/Exclusion criteria will be recruited primarily through posting and flyers in the Boston University region in Boston, MA (Downtown and Mid-town Campuses in Boston) and in the immediate area around Altec, Inc. at local cafes, shopping malls, and fitness centers.

Informed Consent

All subjects will be properly informed of the purpose of the study by the research team. The prospective subjects will have the opportunity to read an IRB-approved informed consent form outlining the experimental procedures, risks, and rights as a human subject and see the actual equipment demonstrated to them. Written consent will be obtained from adults, written parental consent and assent will be obtained from pediatric participants. A signed and dated copy of the consent form will be provided to each subject/parent. All researchers involved in the experimental procedures and analysis of human subject data as outlined in this proposal have training certification on file and are familiar with the appropriate Federal guidelines regarding the use of human subjects for research.

Potential Risk and Protection against Risk

The identifiable risks, which fall into the category of less than minimal physical risks, are described below.

1. The primary medical risk includes possible irritation to the skin caused by securing and removing the sensors from the skin. The risk is comparable to having a Band-Aid on the skin and peeling it off. To mitigate this risk, the skin will be inspected before and following removal of the sensors and wiped using an alcohol swab. An over-the-counter skin moisturizing cream will be available should the subject feel any irritation or dryness at the sensor locations.

2. Some temporary tiredness and muscle fatigue may result in the participants with SPI from performing the head movement activities. This risk is similar to a light exercise session and is a natural consequence of using one's muscles in daily life, or using a head mounted control for AAC, and will be minimized by offering frequent rest periods.

3. Risks of injury or discomfort to the cervical spine caused by active movement of the head and neck for persons with SPI from head or neck injuries such as traumatic high-level spinal cord injury will warrant special consideration. SPIs in the acute phase of recovery following a spinal cord injury will be excluded as well as those who are immobilized using an orthotic or traction to minimize head movement will also be excluded. All prospective subjects with spinal cord injury regardless of stage of recovery will be careful screened by Dr. Susan Fager and her medical

team so that all prospective subjects are medically cleared to perform active head and neck movements of the kind described in this study.

4. The risk of electric shock is highly unlikely and greatly minimized because the sensors used in this study are wireless and designed to completely isolate the subject from sources of electrical current. These circuits ensure subject safety in compliance with United States and European EN60601 safety standards for medical instrumentation. They are in compliance with CE and FDA Medical Device Standards for allowable leakage currents.

5. Although unlikely, a breach in the secure network at our facilities could cause video or research data to become publicly available. All data will be kept on secure servers and will be shared with collaborators only through secured connections. All data will be coded for safety.

Vulnerable Subjects

Children and subjects with SPI can be considered as vulnerable populations and we will abide by the federal regulations in effect for inclusion of such research participants as overseen by IRB review and approval.

Confidentiality

The file linking subjects' name to codes will be in paper form and will be stored in a locked file cabinet along with signed consent forms. All sensor data will be password protected on lab servers. Access will only be available to those working on the project. For cases where data are shared between clinical collaborators and Altec, Inc. only de-identified, raw data will be shared. This removes risk that a patient's privacy may be compromised. In case the subject gives explicit permission to take photo and video recordings during the experiment these will be stored in the password protected project folder on the lab servers. All digital data will be identified only by subject codes. To help us protect privacy, this project also has a certificate of Confidentiality from the Federal Government.

Potential Benefits to the Subjects

There are no anticipated benefits for subjects in this study aside from the potential benefits to the population of individuals with SPI in need of AAC devices for communication if our results lead to a more adaptable and optimized AAC system.

Alternatives to Participation

This study does not involve medical diagnostics or treatments for which alternatives should be offered.

Data & Statistical Analysis Plan

A series of signal acquisition and processing software will be developed to collect and analyze sEMG and IMU signals from wearable sensors to develop algorithms for person-centric AAC cursor control, which will then serve to train machine learning algorithms to achieve an individualized AAC keyboard interface. We will validate these developments to show that an individualized keyboard interface can provide improved communication performance compared to a generic (QWERTY) keyboard interface.

The analyses of sEMG and IMU data will be guided by our knowledge of sensor and signal processing solutions for human machine interfaces for preliminary prototype studies and early development of concepts rather than to prove efficacy. We purposely want to collect data from a diverse group to be able to capture a range of movement limitations so that we have a variety of potential "adaptations" the interface can make. ***A single-subject design approach will therefore be adopted to evaluate these different, personalized adaptations. For this reason, data analysis will be conducted across participants to compare individualized AAC device performance to generic (QWERTY) AAC device performance.***

Data analysis will follow the U.S. Department of Education standards for single-subject statistical designs as each participant engages in a series of transcription (scripted) tasks to examine user-specific communication performance between our individualized AAC device and a generic (QWERTY) AAC device. Participant communication performance will collected within a single session for each device; the QWERTY keyboard will be analyzed in the second session (Day 2) to serve as a reference for communication performance (i.e., due to widespread familiarity in using the QWERTY keyboard for mobile device communication) once participants are familiar with the sEMG/IMU access method.

The change in level (mean) and variability (standard deviation) of communication performance will be evaluated via metrics of information transfer rate (bits/min), movement time (sec), target selection accuracy (%), movement variability (unitless), and perceived usability for each participant across the two conditions. Average level and variability metrics will be reported for each metric to understand the effects of using an individualized keyboard interface compared to a generic one.

The output of these tasks will be a novel body-worn sensor-based access method, an access assessment test protocol and individualized keyboard interfaces that provide more accurate and accessible AAC over generic interfaces for individuals with SPI.