Informed Consent Form

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

NCT04762043

Approved 06-26-23

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: EMG Voice Restoration

PROTOCOL NO.: R44DC017097
WCG IRB Protocol #20182089

SPONSOR: Altec Inc.

INVESTIGATOR: Gianluca De Luca, MSc
23 Strathmore Rd
Natick, MA 01760

SITE(S): Altec Inc.
23 Strathmore Rd
Natick, MA 01760

STUDY-RELATED PHONE NUMBER(S): **Principal Investigator:** Gianluca De Luca, MSc
508-545-8202 (Office Hours)

Study Coordinators:
Serge H. Roy, Sc.D., P.T.
508-545-8235 (Office Hours)

SUB-INVESTIGATOR: Jennifer M. Vojtech, Ph.D.
508-545-8208 (Office Hours)

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

What should I know about this research?

- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you do not understand, ask questions.
- Ask all the questions you want before you decide.

PLEASE READ THIS CONSENT FORM CAREFULLY!

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

In this consent form "you" generally refers to the research subject.

Why is this research being done?

The purpose of this research is to develop a device that can be used for non-verbal communication based on the electrical signals that emanate from the speech muscles of the face and neck. The study device is intended to non-invasively record and process the electrical signals from these muscles during non-auditory speech (silently mouthing a word or phrase). Such a device may be useful for persons with speech disorders that result from a laryngectomy.
The test procedures that you are being asked to participate in are designed to help the researchers attain a capability for a device that is not currently available. This capability would enable the device to recognize when you are emphasizing words in a sentence—as, for instance, when you want to convey a question or make a statement of fact—and then translate this directly to a synthesized (artificial) voice.

What happens to me if I agree to take part in this research?

You are being asked to participate because you either have either have healthy speech muscle function or have undergone a laryngectomy. Your participation may last for as few as one session, or as many as 5 sessions, depending on how many sessions you are willing and available

to complete. Each session will take no more than 3 hours, including breaks. During some study tasks, you may be provided with feedback about your task performance during the task itself.

Today, you will be asked to perform the following experimental tasks (check-marked):

- ❑ *Speech Production:* You may be asked to produce speech. If so, you will produce vowels by themselves, read text that we provide you, and answer questions we may ask to capture your spontaneous speech. You may be asked to wear insert earphones or headphones while you produce speech. For those who are experienced in communicating via an electrolaryngeal speech aid or by means of a tracheoesophageal voice prosthesis (TEP), you may be asked to recite some of the text using this method of speech production.

- ❑ *Voluntary Body Movement*: You may be asked to move your body (e.g., head, hands) or to contract your muscles without otherwise moving your body. For instance, we may ask you to turn your head or tense up the muscles in your neck while you speak. Electrical signals from muscles and/or your body motion may be measured non-invasively with up to 8 small sensors from the surface of the skin; if body mounted sensors are being used, they will be attached using medical tape to your skin to sense real-time body motion.
- ❑ *Responding to Self-Rating Scales:* You may be asked to respond to questionnaires that ask you to complete a self-rating scale (e.g., rating how easy or difficult it was to perform a task on a scale from 1 "most easy" to 10 "most difficult"). The investigator will help you to rate yourself on the presented scale.

During the study tasks, we may collect acoustic (voice) data from you. You will wear a headset microphone or a contact microphone on your neck or face (A contact microphone sits on the surface of the skin and can detect surface vibrations and tiny movements). Any contact sensors may be removed and re-attached to immediately adjacent sites to test the effect of sensor position on signal quality. Video recordings and photographs may be taken of you to help analyze the data.

All research will take place in Altec, Inc. at 23 Strathmore Rd., Natick, MA 01760 or offsite at a location most convenient for you.

We will collect the following types of data today (check-marked):

- ❑ *Acoustic:* You will wear a headset microphone or a contact microphone on your neck or face. (A contact microphone sits on the surface of the skin and can detect surface vibrations and tiny movements.)
- ❑ *Skin-surface Electrical Activity:* Electrical signals from the surface of the skin can be measured non-invasively using small sensors. These signals will be measured from your arms, neck, or face with 1–8 commercially available surface sensors.
- ❑ *Body Movement:* Movement of your body during hand or speech tasks will be measured using 1–16 sensors. If body mounted sensors are being used, they will be attached using medical tape to your skin or using dental adhesive to the inside of your mouth to sense real-time body motion.

Could being in this research hurt me?

The risks of injury to you during the test procedures are minimal. Whenever a recording device is placed on the skin (e.g., contact microphone), the sensor can irritate the skin by mild electric currents if the sensor were to malfunction, which could lead to a mild skin irritation. This risk is extremely small as we safeguard you from this possibility by using wireless battery-powered sensors (isolated from electrical sources such as wall sockets) and designing the sensors so that they comply with FDA and other stringent safety standards.

You may also experience a mild reddening or irritation of the skin due to the application and removal of the adhesive tape that holds the sensors to the skin. This includes a reaction from skin preparation, where we may wipe the skin with rubbing alcohol and/or shaving a 1×1 inch area for each sensor location using a disposable safety razor if there is facial hair or stubble. Sensor removal is similar to taking a Band-Aid off the skin. Medical-grade adhesives that are approved

by the FDA will be used and are designed to produce minimal irritation to the skin. The reddening of the skin, if it occurs, typically goes away in several minutes.

You may also feel some tiredness and boredom from the repeated task and duration of the study. To minimize this, you will be provided with rest periods as needed between these tasks to avoid fatigue. For sessions scheduled for 4–5 hours, we will provide a rest period of 30–40 minutes halfway into the study for nourishment and a beverage, as well as 5-minute rests every 30 minutes (or sooner if requested). We may also schedule the experiment over three to four sessions if you are easily tired. Bathroom breaks can be requested at any time.

Will being in this research benefit me?

There are no benefits to you personally from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include an increased quality of life and function for people with speech and voice disorders

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?

Your personal information will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor,
- People who work with the research sponsor,
- Government agencies, such as the U.S. Food and Drug Administration (FDA),
- WCG IRB, the Institutional Review Board (IRB) reviewed this research.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. All information regarding your participation in this study will be assigned a study ID. Only the investigator will have access to the master-code that links your personal information to the study ID number. The investigator will take appropriate care to protect the confidentiality of your private information. Yet there is a slight chance that others could learn information about you from this study; for this reason, we cannot promise complete secrecy.
Secondary analysis of data collected from you may be conducted by other study participants for the purposes of auditory-perceptual evaluations, such as rating or transcription of a speech sample. These samples may also be added to an online database for secondary analysis (e.g., on the MTurk crowdsourcing platform for analysis by MTurk workers). These data will only be used for the purpose of auditory-perceptual evaluation and will not contain any personal or identifiable information other than your voice itself.

Your information may be used in publications or presentations. However, the information will not include any personal information that will allow you to be identified. In addition, you will not be identified by photo or video in any publication of research results unless you sign a separate form giving your permission (release). Information from this study and study records may be reviewed and photocopied by the sponsor, the institution, and by regulators responsible for research oversight.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent reviews of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Can I be removed from this research without my approval?

Your participation in this study may be stopped at any time by the study investigator or the sponsor without your consent for any of the following reasons:

- it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you,
- or for any other reason.

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

Your participation in this study is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

Will I be paid for taking part in this research?

Payment of $25 per hour will be provided to pay you for your travel time and study participation time. You will be paid at the end of each session for the time you complete. Additional costs of transportation such as public transportation will be reimbursed upon arrival or pre-arranged by Altec, Inc. If you decide not to continue your participation in the study or do not qualify for the study, you will be paid at the rate of $25 per hour for the time completed.

The results from this study may lead to new commercial products or tests. If this happens you will not receive any compensation.

Your insurance will not be billed for any research-related activities.

Statement of Consent:

Your signature documents your consent to take part in this research.

I have read this consent form. All procedures have been explained to me and my questions have been answered.

I agree to participate as a research subject in this research study.

I authorize the release of my research records for research or regulatory purposes to the research sponsor, government agencies such as the FDA, and WCG IRB.

By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a subject in a research study.

Printed name of adult subject capable of consent	Date
Signature of adult subject capable of consent	
Signature of person obtaining consent	Date
Signature of person obtaining consent	