CONSENT TO PARTICIPATE IN RESEARCH

Project Title: Effect of cutaneous activation on fatigue related changes in rate of torque development of the plantar flexor muscles.

You are invited to participate in a research study conducted by Laura Marrelli and Dr. Leah Bent from the Department of Human Health and Nutritional Sciences at the University of Guelph. This study is sponsored by the Natural Sciences and Engineering Research Council of Canada.

If you have any questions or concerns about the research, please feel free to contact Leah Bent, 519-824-4120 ext. 52116.

PURPOSE OF THE STUDY

Skeletal muscle fatigue can induce changes in motor coordination, movement stability, and proprioception (sense of body position), which can further affect an individual's physical performance in a fatigued state. It has been well established that skeletal muscle activity can be altered due to sensory feedback, such as sensory information from the skin. However, the effect of skin feedback on muscle fatiguability is not well understood. The goal of this study is to assess if activating the skin on various regions of the foot decreases lower limb muscle fatiguability and reduces the negative effects fatigue has on contraction speed.

If you volunteer to participate in this study, we will ask you to complete following procedures:

- General health questionnaire
- Application of electrodes on the right lower limb/ankle
- Electrical stimulation of nerves on the right lower leg
- Electrical stimulation of the skin on the right foot
- Fatiguing and non-fatiguing contractions of the right calf muscle group

See below for more information regarding the procedures in this study.

Laboratory Visit – ANNU 276

Upon completion of the General Health Questionnaire, if you are eligible to participate in the study, 3 laboratory visits separated by 1 week, with each visit lasting approximately 2 hours. During each laboratory visit you will be asked to wear shorts. Throughout the duration of the experiment you will be asked to expose the skin of your right leg/foot. This will ensure the researchers access to the skin for various experimental tests on the right lower limb (see below).

General Health Questionnaire

In this form you will be asked basic questions pertaining to your treatment history, physical activity status, skin sensitivity and history of any other musculoskeletal or neurological disorders. This form is comprised of seven yes/no, short answer questions and should take approximately 5 minutes to complete. This form will be completed over the phone or email prior to your first laboratory visit. If you are not eligible to participate in the study, the medical questionnaire information will be safely discarded and will not be used for any other purposes.

Inclusion/Exclusion Criteria

Inclusion:

- Individuals must be aged 18-40 years

Exclusion:

- Previous injury to their right lower limb/ankle
- Skin sensitivity or allergy to adhesives
- Musculoskeletal or neurological disorder

Experimental Setup

Each subject will take part in three laboratory visits of approximately 2 hours in duration. The subjects will be placed in a seated position with the hip flexed 80˚, right knee flexed 110˚, and the right ankle at 90˚. The subject will have their torso strapped into the seat and their right foot will be strapped against the dynamometer foot plate as shown below (Figure 1).

Figure 1. *Experimental set up showing the position of each subject throughout the protocol.*

Throughout all laboratory procedures we will be measuring the activity of lower limb muscles of the right leg using electromyography. Electrodes will track the electrical activity of muscles of the right leg (Figure 2). Prior to adhering any electrodes, each location will be lightly shaved using a new disposable razor and cleaned with alcohol for each participant to minimize impedance from the skin. Two electrodes will also be applied across the heel of the foot and the metatarsals of the foot to allow for stimulation of the skin on the foot sole (Figure 3).

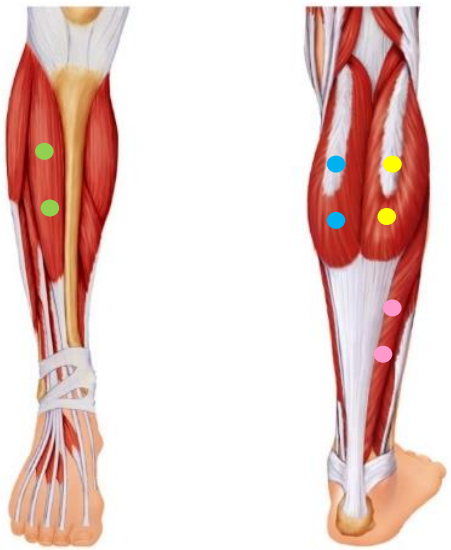

Figure 2. *Experimental setup showing the approximate locations of the electrodes that will be taped to your foot/ankle, indicated by dots on the lower limb.*

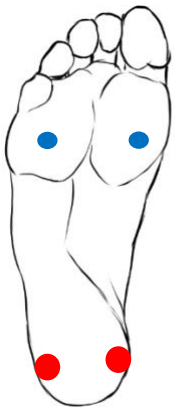

Figure 3. *Approximate placement of electrodes on the heel (red) and across the forefoot (blue).*

Determining Mmax

Mmax represents how much a muscle twitches involuntarily when stimulated electrically. This will be determined by applying brief electrical stimulation (200 microseconds) to the back of the knee,

the stimulations will increase in intensity until the maximal twitch is evoked.The electrical stimulation will evoke a contraction of the calf muscles. This process will be repeated with stimulation below the knee, resulting in contraction of the muscles on the front of the lower leg. Stimulation may cause some discomfort over the regions where it is applied, however, any discomfort will subside once the stimulus is removed.

Maximal Voluntary Contractions

A maximal voluntary contraction of the right plantar flexors will be conducted three times to determine the maximal amount of force that one can voluntarily produce. Stimulation will be applied across the back of the knee for a duration of 200 microseconds at the same intensity at which Mmax occurred prior to, during, and directly following the contraction. Maximal voluntary contractions will also be conducted throughout the fatigue and non-fatigue protocols.

Determining Skin Sensitivity Threshold

Electrical stimulation will be applied across the skin of the right heel throughout the stimulation part of the experiment. Stimulation will be applied throughout the duration of the 5 plantarflexion explosive contractions and turned off during the other portions of the protocol. This will be delivered via electrodes placed on the heel and the metatarsals.

Fatigue Protocol

During the fatigue protocol on each day, you will maintain a submaximal plantarflexion contraction until you fall below 30% MVC. After this, you will perform five explosive contractions. On two of the days, stimulation will be applied across the heel or metatarsals for the duration of the five explosive contractions. The fatigue protocol will be repeated three more times on each day.

Non-Fatigue Protocol

During the non fatigue protocol on each day, you will be asked to perform five explosive contractions. On two of the days, stimulation will be applied across the heel or metatarsals for the duration of the five explosive contractions. The non-fatigue protocol will be repeated three more times on each day.

The researchers wish to be inclusive in their recruitment process. This project requires:

- Interaction one on one with a female technician/researcher
- Being comfortable exposing skin of the right leg/foot
- Being comfortable with having medical sensors affixed to the skin
- Avoiding alcohol, caffeine, and strenuous exercise 12 hours prior to each session
- Possible shaving of small sections of the right leg/foot
- Maximal and submaximal contractions of the right plantar flexor muscles
- Electrical stimulation across the tibial nerve, superficial fibular nerve, and the skin of the foot sole

If for any reason you feel uncomfortable taking part, please let us know and we can discuss potential accommodations to address your concerns.

If you would like a feedback letter detailing the results of the study this will be emailed to you at the completion of the study, and you may provide your email on the final page of this form.

POTENTIAL RISKS AND DISCOMFORTS

This study will require participants to come into the laboratory 1 day every week for three weeks.

After each laboratory visit, the plantar flexor muscles will be fatigued which may cause discomfort. If needed, time will be given after the experimental protocol for recovery.

Some participants have a risk of developing irritation, itchiness/redness and minor inflammation to the area of skin in contact with any adhesives or shaving. Although most adhesives used within this study are hypoallergenic without any traces of rubber or latex, please let us know if you have sensitive skin, including sensitivities to rubber/latex. There is also a small risk of minor cuts and irritation from shaving the skin. Shaving can be done by either the researcher or the participant, depending on comfort.

There is a small risk of muscle strain associated with the muscle contractions. If you suffer a foot/ankle injury, or any foot/ankle discomfort, from participating in this study use the contact information above to contact Dr. Leah Bent immediately, and as appropriate seek the advice of the proper medical professionals.

POTENTIAL BENEFITS TO PARTICIPANTS AND/OR TO SOCIETY

You will not receive any direct tangible benefits from this study.

The role of sensory feedback, specifically from the skin, on muscle activity is not well understood. The information found in this study could have implications for sensory feedback modalities and what could aid in mitigating fatigue.

PAYMENT FOR PARTICIPATION

There will be no financial compensation for your participation in this study.

CONFIDENTIALITY

Every effort will be made to ensure confidentiality of personal information that is obtained in connection with this study.

Coded data will be kept on a password-protected computer and all written material secured in a locked cabinet on site. Personal identifiers including the master list will be kept on an encrypted hard drive. All personal identifiers will be destroyed following completion of the entire study. De-identified data will be retained for 5 years, stored electronically in databases, with access granted to investigators in Dr. Bent's lab. You will be given a copy of the proposal of the study and will have the opportunity to obtain results from the overall outcome of the study

PARTICIPATION AND WITHDRAWAL

You can choose whether to be in this study or not. Your decision to participate or refrain from

participation will not have any effect on existing relationships with the researchers involved in the study. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. However, one month following data collection withdrawal of data will not be possible. You may exercise the option of removing your data from the study. Participants will be provided with the researcher's email addresses to connect if they want to remove their data or can inform researchers at the time of collection if they would like withdraw. You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise that warrant doing so.

RIGHTS OF RESEARCH PARTICIPANTS

You may withdraw your consent at any time and discontinue participation without penalty. You do not waive any legal rights by agreeing to take part in this study. This project has been reviewed by the Research Ethics Board for compliance with federal guidelines for research involving human participants. If you have questions regarding your rights and welfare as a research participant in this study (REB#), please contact:

Manager Research Ethics
University of Guelph

Telephone: (519) 824-4120, ext. 56606
E-mail: reb@uoguelph.ca

SIGNATURE OF RESEARCH PARTICIPANT

☐ I have read the information provided for the study “Modulation of fatigability and plantarflexor rate of force development using electrical stimulation of the foot sole” as described herein. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

☐ I have read the Informed Consent for In-Person Research Activities and any questions about the study and/or COVID-19 have been answered. I freely consent to participate in this research.

This project has been reviewed by the Research Ethics Board for compliance with federal guidelines for research involving human participants. If you have any questions regarding your rights and welfare as a research participant in this study (REB: 18-05-01), please contact: the Director of Research Ethics; University of Guelph; reb@uoguelph.ca; 519-824-4120 ext. 56606. You do not waive any legal rights by agreeing to take part in this study. Please contact us with any questions or concerns regarding the research. Laura Marrelli: lmarrell@uoguelph.ca. Dr. Bent: (519) 824-4210, ext 56442 or lbent@uoguelph.ca

If you decide to participate, **you are free to withdraw your consent and discontinue your participation at any time. You may also withdraw your data from the study at any time up to the point when the data are submitted for presentation/publication**. Should you withdraw your consent, your name and contact information will remain in our records should you need to be notified by Public Health for COVID contact tracing.

Your signature will be an indication that you have decided to partake in the experiment and have read the information provided above.

Name of Participant (please print)

_____

Signature of Participant Date

_____

Signature of Witness (Investigator) Date

If you wish to receive a copy of your data in the future or a copy of the publication, please provide your email below:

Email: _____