UNIVERSITY OF ALBERTA

Date: Thursday, March 10, 2022 4:42:35 PM Print Close

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1.1 Study Identification

*All questions marked by a red asterisk * are required fields. However, because the mandatory fields have been kept to a minimum, answering only the required fields may not be sufficient for the REB to review your application.*

Please answer all relevant questions that will reasonably help to describe your study or proposed research.

1.0 * **Short Study Title** *(restricted to 250 characters)*:
PERFORMANCE ASSESMENT OF A MYOELECTRIC DEEP SENSING HAND PROSTHESIS

2.0 * **Complete Study Title** *(can be exactly the same as short title)*:
PERFORMANCE ASSESSMENT OF A MYOELECTRIC DEEP SENSING HAND PROSTHESIS

3.0 * **Select the appropriate Research Ethics Board (***Detailed descriptions are available at here***):**
Health Research Ethics Board - Health Panel

4.0 * **Is the proposed research:**
Unfunded

5.0 * **Name of local Principal Investigator:**
Hossein Rouhani

6.0 * **Type of research/study:**
External Researcher (external to U of A, AHS and Covenant Health)

7.0 **Investigator's Supervisor***(required for applications from undergraduate students, graduate students, post-doctoral fellows and medical residents to REBs 1 & 2. HREB does not accept applications from student PIs)*:

8.0 **Study Coordinators or Research Assistants:** People listed here can edit this application and will receive all email notifications for the study:

Name	Employer
Leonardo Esteban Torres Cerdan	EN Mechanical Engineering

9.0 **Co-Investigators:** People listed here can edit this application and will receive email notifications *(Co-investigators who do not wish to receive email, should be added to the study team below instead of here).*
If your searched name does not come up when you type it in the box, the user does not have the Principal Investigator role in the online system. Click the following link for instructions on how to Request an Additional Role.

Name	Employer
Vahid Abdollah	MH Medicine

10.0 **Primary Admin Contact** *(a member of study team)*:

11.0 **Study Team:** *(co-investigators, supervising team, and other study team members) - People listed here cannot view or edit this application and do not receive email notifications.*

Last Name	First Name	Organization	Role/Area of Responsibility	Phone	Email

There are no items to display

ID: Pro00117863 **Pro00117863** 1.2 Additional Approval
Status: Pre Submission

1.2 Additional Approval

1.0 * **Departmental Review:** ***Please note only ONE Department Review is required. Please ensure that this section reflects only the PRIMARY Department of the study PI.***

EN Mechanical Engineering

2.0 **Internal Review** *(If the Principal Investigator is in the Department of Medicine complete the Department of Medicine Request for Internal Approval form and upload it to the "Documentation" section of this application under item 11.0 "Other Documents". Note that all fields in the form are required. The form is available at here)*:

ID: Pro00117863 **Pro00117863** 1.4 Conflict of Interest
Status: Pre Submission

1.4 Conflict of Interest

1.0 * **Are any of the investigators or their immediate family receiving any personal remuneration (including investigator payments and recruitment incentives but excluding trainee remuneration or graduate student stipends) from the funding of this study that is not accounted for in the study budget?**

○ Yes ● **No**

2.0 * **Do any of investigators or their immediate family have any proprietary interests in the product under study or the outcome of the research including patents, trademarks, copyrights, and licensing agreements?**

○ Yes ● **No**

3.0 * **Is there any compensation for this study that is affected by the study outcome?**

○ Yes ● **No**

4.0 * **Do any of the investigators or their immediate family have equity interest in the sponsoring company? (This does not include Mutual Funds)**

○ Yes ● **No**

5.0 * **Do any of the investigators or their immediate family receive payments of other sorts, from this sponsor (i.e. grants, compensation in the form of equipment or supplies, retainers for**

ongoing consultation and honoraria)?

◯ Yes ● **No**

6.0 * **Are any of the investigators or their immediate family, members of the sponsor's Board of Directors, Scientific Advisory Panel or comparable body?**

◯ Yes ● **No**

7.0 * **Do you have any other relationship, financial or non-financial, that, if not disclosed, could be construed as a conflict of interest?**

◯ Yes ● **No**

Please explain if the answer to any of the above questions is Yes:

Important

If you answered YES to any of the questions above, you may be asked for more information.

1.5 Research Locations and Other Approvals

1.0 * **List the locations of the proposed research, including recruitment activities. Provide name of institution, facility or organization, town, or province as applicable**

1) Neuromuscular Control and Biomechanics Laboratory, 4-9 MechanicalEngineering Building
2) 4th Floor of the MechanicalEngineering Building

2.0 * **Indicate if the study will use or access facilities, programmes, resources, staff, students, specimens, patients or their records, at any of the sites affiliated with the following** *(select all that apply):*

Not applicable

List all health care research sites/locations:

3.0

Multi-Institution Review

* **3.1 Has this study already received approval from another REB?**

◯ **Yes** ● **No**

4.0 **If this application is closely linked to research previously approved by one of the University of Alberta REBs or has already received ethics approval from an external ethics review board***(s)*, **provide the study number, REB name or other identifying information. Attach any external REB application and approval letter in the Documentation Section – Other Documents.**

2.1 Study Objectives and Design

1.0 * **Provide a lay summary of your proposed research which would be understandable to general public**

This study aims to design a low-cost and multi-functional prosthetic hand. The first goal is to use two brands of EMG sensors to record many grasps for classification. This study will help develop a classification algorithm for a hand prosthesis. EMG classification helps the user perform different movements thus improving their life quality. Also, it will be the first step to do a future study with transradial amputees.

Besides, participants will attend an experiment for sensory substitution function development. The current commercial prosthetic hands don't offer any sensation. Adding this mechanism will enable to transfer of the sensed force at the fingertips to the skin. This study tries to develop a function to transfer force as vibrations on the skin.

2.0 * **Provide a full description of your research proposal outlining the following:**

- **Purpose**
- **Hypothesis**
- **Justification**
- **Objectives**
- **Research Method/Procedures**
- **Plan for Data Analysis**

PERFORMANCE ASSESSMENT OF A MYOELECTRIC DEEP SENSING HAND PROSTHESIS

1. INTRODUCTION

The World Health Organization (WHO) estimated in 2017, that around the world 0.5% of the total number of people need prostheses, orthoses and rehabilitation treatment, which is equivalent to approximately 35 to 40 million people. On the other hand, in that same study they pointed out that between 85% and 95% of people who require the use of some orthopedic support device such as prosthesis or orthosis, do not have access to these due to their high costs [1]. Meanwhile, according to a market study conducted by the consulting and market research company Grand View Research, there are more than 100 million people in the world with limb loss and about one million amputations are performed annually [2].

In Peru, according to the national census of the National Institute of Statistics and Informatics (INEI) in 2017, 15.1% of Peruvians with disabilities have a difficulty to move or walk and use arms or legs [3]. On the other hand, according to the first specialized national survey on disability by INEI in 2012, only 0.001% of people with locomotion and/or dexterity disability use arm prosthesis [4]. This may be due to various factors, such as the high cost of the prosthesis, the little or no functionality of the device, or the lack of esthetics.

The importance of the hand lies in the fact that this limb is extremely versatile, one can perform complex movements and grips that allow day-to-day activities [5]. For this reason, when a person loses his or her upper limb, the physician recommends acquiring a prosthesis that allows him or her to recover the necessary functionality to perform his or her tasks more easily [6].

The Peruvian market for prostheses for transradial amputees is strongly divided. On the one hand, the most accessible prostheses are offered by the National Institute of Rehabilitation (INR), these are aesthetic or mechanical, and have approximate costs that can be between S/. 3,885 [7] and S/. 5,634 [8], and are manufactured by the INR itself. On the other hand, in recent decades, prostheses that use myoelectric signals to improve their function have been developed and marketed [6]. However, the biggest problem with these prostheses is their high cost in the current market, since they have an approximate price that starts at $ 6,600 USD for prostheses such as the Hero Arm from Open Bionics and can reach up to $ 60,000 USD such as the Michelangelo Hand from Ottobock [9].

Deep sensing function is an important feature to add in neuroprosthetic prosthetic hands because it provides the tactile feedback that is lost during hand amputation. This sensing system is achieved with a touch sensor to measure the force or pressure, and a stimulator to provide the feedback on the skin of the residual limb. The stimulator could be a vibration motor or an electrical stimulation. It’s important to mention that the feedback in both cases is non-invasive, and in some research invasive

approaches have been studied. However, most commercial prosthetic hands do not have deep sensing function due to high cost, so the amputees cannot have sensory feedback while doing the grasps.

In that sense, the need persists to provide a more affordable alternative for upper limb amputees, without compromising the efficacy and utility of the prosthesis. Therefore, the focus of the project is to develop a low-cost deep sensing myoelectric transradial prosthesis with different grasp types. To achieve this goal, it is necessary to have a closed loop model with bio-feedback (provided by the EMG signals), environmental feedback (provided by the forces on the fingertips), and prosthetic actuation system (action is achieved by the motors and vibrators). This study aims to obtain EMG data from two sensors: a low-cost, MYOstack from ELEMYO, and an expensive, Trigno from DELSYS. The EMG sensors will be in the forearm of able-bodied people. It is hypothesized that with a proper classification algorithm, a good performance will be achieved in both EMG sensors despite their signal quality differences. Also, this study will gather motion capture data, and data obtained from a force sensor, flexible sensor and vibrators. With these a proper transfer function will be estimated to transform the sensed force in the fingertips into a vibration in the arm.

2. Objectives

The main objective of this study is to provide different numerical and analytical models that can:

1. Map EMG signals to different grasp configurations, a classification problem.
2. Map EMG signals to finger joint angles, a regression problem
3. Map forces on the fingertips to the vibrations on forearm skin, a sensory substitution problem.
4. Closed loop model between bio-feedback, environmental feedback, and prosthetic hand action.

2.1 Specific Aims

1. We will determine if the recorded EMG signals from ELEMYO's sensor provide a good signal quality like the sensor from DELSYS.
2. We will identify which time-domain features extracted from the EMG data have more significance in the classification algorithm performance.
3. We will identify which classification algorithm, machine learning and deep learning models, have the best performance predicting the grasp types using the extracted EMG data.
4. We will determine whether changes in the number of grasp types are associated with the algorithm performance.
5. We will identify which regression algorithm, machine learning and deep learning models, have the best representation to map the EMG signal with the finger joint angels during different grasps.
6. We will develop a function that maps fingertip forces to vibrations on the skin; this behaviour should effectively substitute the lost sensory feedback from the amputee hand.
7. We will develop a closed-loop function which can effectively fuse the EMG signal and forces on fingertips and provides both motor movement and vibration on the skin.

3. Hypothesis

1. The quality of EMG data obtained using four channel MYOstack sensor will give good performance metrics in the classification algorithm, with similar values to the ones obtained from Trigno sensor.
2. The motion trackers in the finger joints and EMG sensors in the forearm provide sufficient information to generate an ML regression model which accurately maps the joint angles during grasps.
3. The vibrators on the forearm skin provides sufficient information to transfer the force applied at fingertips.

4. Methodology

4.1 Experimental design

This study will compare the performance of classification models using MYOstack and Trigno four channel EMG sensor.

4.2 Subjects

After obtaining approval from the University of Alberta Research Ethics Board (REB), 40 healthy volunteers will be invited to consent and participate in this study. The sample size would be enough to have a normal distribution of the sample means, following the central limit theorem. Subjects will be recruited at 1) Sport Medicine Centre of the University of Alberta, 2) the Mechanical Department of the University of Alberta, 3) the University of Alberta Participate in Research website, 5) word of mouth and 4) ads placed in and around the university campus.

4.2.1 Selection criteria for healthy subjects

We will include males and females, aged between 20 and 65, able to walk independently and able to read and understand English instructions. The inclusion criteria will be no arm pain or stiffness in either arm/hand or use of medications for arm pain in the last year. Also, participants with the following will be excluded:

1. History of any inflammatory/infectious arthritis, fracture or surgical intervention in the studied arm
2. Pregnancy
3. Obesity (BMI ≥ 40)
4. No allergic reactions to skin electrodes

4.3 Procedures

The EMG and motion capture data acquisitions will be carried out at the Neuromuscular Control & Biomechanics Laboratory at the Mechanical Department in the University of Alberta.

1. **EMG acquisition and loading procedures**

The EMG parameters for the Trigno sensor will be as follows: number of channels: 4-16 (both EMG brands); sampling rate: 500 HZ (MYOstack) and 2 kHz (Trigno); muscles targeted: extensor digitorium, flexor carpi radialis, palmaris longus, and flexor digitorium superficialis; twenty grasping types detailed in *Fig. 1*.

Graphical user interface, application, PowerPoint Description automatically generated

Fig. 1 A comprehensive mapping of the repertoire of hand grasps available to human subjects [10].

1. **EMG acquisition protocol**

Volunteers will be asked to sit in the laboratory's chair and roll up the sleeve of their forearm. Then, the Trigno EMG sensors will be placed in their corresponding muscles, located with palpation. The participants will be informed that those sensors need an adhesive to stick in the skin. They will be asked to do three tests, one for each of the twenty grasp types. Each test has a two-minute duration which consist of performing the corresponding grasp for five seconds and resting for five more seconds, until reaching the specified time. Then, there will be a three-minute resting period before starting the next test. After finishing the tests, the participants will be asked to withdraw the EMG sensors and there will be a six-minute break before starting with the tests using the MYOstack EMG sensors. Those sensors will be fitted in the same muscle locations of the participants as the Trigno sensors using an elastic band; then the same tests will be done. After finishing the last test, the EMG sensors will be withdrawn from the participants.

1. **Motion capture data acquisition and loading procedures**

The hand kinematics will be measured using a glove with small IR trackers placed in each joint of the fingers, like the illustration in *Fig. 2*.

1. **Motion capture data acquisition protocol**

Volunteers will be asked to sit in the laboratory's chair and wear a glove with the IR trackers. At the same time, the motion capture cameras will be used and the Vicon software will start to record and analyze the hand

kinematics. The same tests as in the EMG data acquisition protocol will be taken simultaneously with the EMG sensor and the motion capture glove. After finishing the last test, the glove will be withdrawn from the participants.

1. **Glove equipped with force sensors data acquisition procedure**

The force sensor data will be obtained using a glove with the force sensitive resistors (FSR) placed in its fingertips, like the illustration in *Fig. 3*.

1. **Flexible sensors data acquisition procedure**

The flexible sensors will be placed along each finger position of the glove. They will follow the same procedure of the force sensors.

1. **Glove equipped with force sensors data acquisition protocol**

Volunteers will be asked to sit in the laboratory's chair and wear a glove with the force sensors on its fingertips. Then, two main tests will be done, the first one will be performed at the same time of the EMG test, to get the force data while doing different grasps. The second test will be done simultaneously with the vibrators to assess the proposed sensory feedback. The steps of that test are explained in the vibrators usage protocol. After finishing the last test, the glove will be withdrawn from the participants.

1. **Vibrators installation procedure**

The sensory feedback will be achieved with several vibration motors attached to an arm band, like the illustration in *Fig. 4*. Different levels of intensity will be introduced for amplitude (0.1-0.5mm neutral to peak) and frequency (60-120Hz).

1. **Vibrators usage protocol**

Volunteers will be asked to sit in the laboratory's chair and wear an armband with several vibration motors attached to it, also they will be asked to wear the glove with force sensors. Then, they will be asked to do one test that has two main parts. The first part will be about finding the best configuration of the vibration motors per finger, its amplitude and frequency range while doing grasps, with the hand that isn't using the glove and armband, at different intensities perceived by the force sensor. The second part will require 10-minute training using the glove and armband with the best configuration. After that, the volunteers will be asked to remain still while using just the armband and an eye mask to have the eyes covered. Then, the investigator will grasp some objects with different intensities measured by the force sensor, and the participants will be asked what intensity they perceive and in which of their fingers. After finishing the last test, the armband and eye mask will be withdrawn from the participants.

1. **Signal processing and segmentation**

EMG signal pre-processing will be carried out offline using scripts developed by our team. First, the program will be used to filter the raw EMG signal. Then, for every test, segments of each grasp repetition will be extracted. Some segments of the resting hand will also be extracted as an additional class of the three grasps. After that for every class, features will be calculated in every segment, some of the proposed features are [11]: 1) mean absolute value; 2) zero crossing; 3) slope sign changes; 4) waveform length; 4) log detector; 5) root mean square of EMG amplitude; 6) willison amplitude; and 7) maximum absolute value.

After obtaining the features, machine learning and deep learning algorithms will be used to get the classification model. Some of the proposed algorithms are: 1) logistic regression; 2) support vector machine (SVM); 3) linear discriminant analysis (LDA); 4) K-means clustering; 5) multilayer perceptron (MLP); 5) convolutional neural networks (CNN); and 6) long short-term memory (LSTM) networks.

References

For references, please check the study protocol.

3.0 **Describe procedures, treatment, or activities that are above or in addition to standard practices in this study area** *(eg. extra medical or health-related procedures, curriculum enhancements, extra follow-up, etc)*:
All tests used are standard clinical assessments. However, the use of EMG sensors can be considered non-standard.
Each 4.7cm x 3cm x 1.3cm sensor is composed of small electrodes, data processing electronic units, and a battery. The sensors are completely non-invasive and do not apply an electrical or mechanical charge to the body.

4.0 **If the proposed research is above minimal risk and is not funded via a competitive peer review grant or industry-sponsored clinical trial, the REB will require evidence of scientific review. Provide information about the review process and its results if appropriate.**
NA

5.0 **For clinical trials, describe any sub-studies associated with this Protocol.**
NA

2.2 Research Methods and Procedures

Some research methods prompt specific ethical issues. The methods listed below have additional questions associated with them in this application. If your research does not involve any of the methods listed below, ensure that your proposed research is adequately described in Section 2.1: Study Objectives and Design or attach documents in the Documentation Section if necessary.

1.0 * **This study will involve the following***(select all that apply)*
None of the above

NOTE 1: Select this ONLY if your application SOLELY involves a review of paper charts/electronic health records/administrative health data to answer the research question. If you are enrolling people into a study and need to collect data from their health records in addition to other interventions, then you SHOULD NOT select this box.

NOTE 2: Select this option if this research ONLY involves analysis of blood/tissue/specimens originally collected for another purpose but now being used to answer your research question. If you are enrolling people into the study to prospectively collect specimens to analyze you SHOULD NOT select this box.

3.1 Risk Assessment

1.0 * **Provide your assessment of the risks that may be associated with this research:**
Minimal Risk - research in which the probability and magnitude of possible harms implied by participation is no greater than those encountered by participants in those aspects of their everyday life that relate to the research (TCPS2)

2.0 * **Select all that might apply:**

Description of Possible Physical Risks and Discomforts	
Possibly	Participants might feel physical fatigue, e.g. sleep deprivation
No	Participants might feel physical stress, e.g. cardiovascular stress tests
Possibly	Participants might sustain injury, infection, and intervention side-effects or complications
No	The physical risks will be greater than those encountered by the participants in everyday life

Possible Psychological, Emotional, Social and Other Risks and Discomforts	
No	Participants might feel psychologically or emotionally stressed, demeaned, embarrassed, worried, anxious, scared or distressed, e.g. description of painful or traumatic events
No	Participants might feel psychological or mental fatigue, e.g intense concentration required
No	Participants might experience cultural or social risk, e.g. loss of privacy or status or damage to reputation
No	Participants might be exposed to economic or legal risk, for instance non-anonymized workplace surveys
No	The risks will be greater than those encountered by the participants in everyday life

3.0 * **Provide details of all the risks and discomforts associated with the research for which you indicated YES or POSSIBLY above.**

The tests are not dangerous at all and are not physically intensive. Some participants may feel (not severely) tired from the testing session. It is highly unlikely that the tests will cause injury. If any discomfort is experienced, it will be minimal and transient.

Although we will use anti-allergic medical tape for attaching the markers and sensors, in some rare situations, some participants may still develop some skin irritation.

There could also be pain while removing the tape.

Although it is rare they may have some discomfort after the tests.

There is a minimum risk of contraction of COVID-19 by participants or research staff.

4.0 * **Describe how you will manage and minimize risks and discomforts, as well as mitigate harm:**

Participants will be explained by the procedures. If participants are in pain or feel uncomfortable in performing any of the tests they can withdraw from the study.

The potential allergy risk will be minimized by asking the participants for any know allergies and utilizing hypoallergenic tape.

To mitigate the risk of COVID-19 the following procedure will be exercised by both research staff and participants:

1. All research staff and participants must fill out the COVID-19 Self-Assessment for Albertans https://myhealth.alberta.ca/journey/covid-19/Pages/COVID-Self-Assessment.aspx

2. All research staff and participants must wear a face mask during the experiments.

3. All research staff and participants must use their personal vehicles or walk to the campus.

4. All equipment needed for the experimentation and surfaces will be disinfected using alcohol solutions (at least 70% alcohol).

5. All participants will be welcomed outside of the Mechanical Engineering building.

6. The signed consent form will be collected while maintaining a minimum 2-meter distance.

7. All study questionnaires (age, sex, body height, body mass, etc.) will be collected while maintaining a minimum 2-meter distance.

5.0 **Is there a possibility that your research procedures will lead to unexpected findings, adverse reactions, or similar results that may require follow-up** *(i.e. individuals disclose that they are upset or distressed during an interview/questionnaire, unanticipated findings on MRI, etc.)***?**

◯ Yes ● **No**

6.0 **If you are using any tests in this study diagnostically, indicate the member(s) of the study team who will administer the measures/instruments:**

Test Name	Test Administrator	Organization	Administrator's Qualification

There are no items to display

7.0 **If any research related procedures/tests could be interpreted diagnostically, will these be reported back to the participants and if so, how and by whom?**
NA

3.2 Benefits Analysis

1.0 * **Describe any potential benefits of the proposed research to the participants. If there are no benefits, state this explicitly:**
Participants may not get any benefit to participate in this research study. However, this study will benefit human society by helping individuals with transradial amputation to regain a part of their abilities to do some of their daily activities. In addition, it provides them a chance to afford a low-cost myoelectric prosthesis with multiple hand grasps and different functionalities.

2.0 * **Describe the scientific and/or scholarly benefits of the proposed research:**
Our research will contribute to the current knowledge about deep-sensing myoelectric prosthetic hands. This research will provide preliminary information about the mapping of the sensed force to proper feedback to the patient's arm. This information will inform the next phase of our pilot work, which involves developing a low-cost deep-sensing myoelectric prosthetic hand for transradial amputees.

3.0 **If this research involves risk to participants explain how the benefits outweigh the risks.**
The research has the potential to address gaps in knowledge surrounding prosthetics technology, the benefits significantly outweigh the risks as the risks are no greater than one would experience in daily activities. This study will help us provide preliminary information about the mapping of the sensed force to proper feedback to the patient's arm. This information will inform the next phase of our pilot work, which involves developing a low-cost deep-sensing myoelectric prosthetic hand for transradial amputees.

4.1 Participant Information

1.0 * **Will you be recruiting human participants** *(i.e. enrolling people into the study, sending people online surveys to complete)***?**

● **Yes** ○ No

1.1 Will participants be recruited or their data be collected from Alberta Health Services or Covenant Health or data custodian as defined in the Alberta Health Information Act?

○ Yes ● **No**

1.2 Would you like to include information about this study on the Be The Cure searchable database?

○ Yes ● **No**

4.2 Additional Participant Information

1.0 **Describe the participants that will be included in this study. Outline ALL participants** *(i.e. if you are enrolling healthy controls as well):*

As this is a validation study, physical diversity (differences in age, sex, body mass index, and activity level) would be beneficial since the inclusion of a diversity of participants would show that the sensors are able to work accurately under different conditions. The main criteria for inclusion are males and females, aged between 18 and 65, the ability to read and understand English instructions, and with no arm pain or stiffness in either arm/hand or use of medications for arm pain in the last year.

2.0 * **Describe and justify the inclusion criteria for participants** *(e.g. age range, health status, gender, etc.):*

We will recruit people
1) without any prior history of neurological, vestibular, musculoskeletal injuries or disorder or any other balance-related disorder that affect arm/hand's ability,
2) aged between 18 and 65 years,
3) leg length discrepancy <15 mm, and
4) the ability to read and understand English

3.0 **Describe and justify the exclusion criteria for participants:**

Participants with the following will be excluded:

1. History of any inflammatory/infectious arthritis, fracture, or surgical intervention in the studied arm
2. Pregnancy
3. Obesity (BMI ≥ 40)
4. No allergic reactions to skin electrodes

4.0 **Participants**

4.1 How many participants do you hope to recruit *(including controls, if applicable?)*
30
4.2 Of these, how many are controls, if applicable?
0
4.3 If this is a multi-site study, how many participants do you

anticipate will be enrolled in the entire study?
0

5.0 Justification for sample size:
As this is a pilot study no sample size calculation has been undertaken. The results of the proposed pilot study will inform future sample size calculations if needed.

4.4 Recruitment of Participants (non-Health)

1.0 Recruitment

1.1 How will you identify potential participants? Outline all of the means you will use to identify who may be eligible to be in the study*(i.e. response to advertising such as flyers, posters, ads in newspapers, websites, email, list serves, community organization referrals, etc.)*
Subjects will be recruited at 1) Sports Medicine Centre of the University of Alberta, 2) the Mechanical Department of the University of Alberta, 3) the University of Alberta Participate in Research website, 5) word of mouth, and 4) ads placed in and around the university campus.

1.2 Once you have identified a list of potentially eligible participants, indicate how the potential participants' names will be passed on to the researchers AND how will the potential participants be approached about the research.
Potential participants will contact the PI by email or phone to express their interest in participating in the study. The coordinator will make a phone call to potential participants to perform a screening interview for determining their eligibility and answer their possible questions. S/he will then send them an email with the study information sheet and consent form to study in advance. If a potential participant expresses their interest in taking part in the study, s/he will be booked for a visiting research study session (1 hour in total) at the Neuromuscular Control & Biomechanics Laboratory at the Mechanical Department in the University of Alberta

2.0 Pre-Existing Relationships

2.1 Will potential participants be recruited through pre-existing relationships with researchers*(e.g. Will an instructor recruit students from his classes, or a physician recruit patients from her practice? Other examples may be employees, acquaintances, own children or family members, etc.)*?
● **Yes** ○ No

2.2 If YES, identify the relationship between the researchers and participants that could compromise the freedom to decline*(e.g. clinician/patient, professor/student)*
Some lab members may be invited to take part in this study.

2.3 How will you ensure that there is no undue pressure on the potential participants to agree to the study?
Although there may be a pre-existing relationship, it would not comprise the individual's freedom to decline. After providing potential participants with information about the study (either through social media, study poster, or word of mouth), the potential participants will be left to contact the research coordination if interested. As such, the potential participants'

freedom to decline is not compromised since it is entirely up to them to decide whether or not to contact the research coordinator.

3.0 **Will your study involve any of the following?** *(select all that apply)*
None of the above

4.5 Informed Consent Determination

1.0 **Describe who will provide informed consent for this study** *(i.e. the participant, parent of child participant, substitute decision maker, no one will give consent – requesting a waiver)*
Participants

1.1 Waiver of Consent Requested
If you are asking for a waiver of participant consent, please justify the waiver or alteration and explain how the study meets all of the criteria for the waiver. Refer to Article 3.7 of TCPS2 **and provide justification for requesting a Waiver of Consent for ALL criteria (a-e)**
NA

1.2 Waiver of Consent in Individual Medical Emergency
If you are asking for a waiver or alteration of participant consent in individual medical emergencies, please justify the waiver or alteration and explain how the study meets ALL of the criteria outlined in Article 3.8 of TCPS2 (a-f)**.**
NA

2.0 **How will consent be obtained/documented? Select all that apply**
Signed consent form

If you are not using a signed consent form, explain how the study information will be provided to the participant and how consent will be obtained/documented. Provide details for EACH of the options selected above:
The participant will sit down with the researcher and will go over the consent form in detail. The researcher will answer any question the participant has. The participant and researcher will sign and date the bottom of the consent form.

3.0 **Will every participant have the capacity to give fully informed consent on his/her own behalf?**
● **Yes** ○ No

4.0 **What assistance will be provided to participants or those consenting on their behalf, who may require additional assistance?** *(e.g. non-English speakers, visually impaired, etc.)*
NA, we only recruit people who are able to read and understand the English language.

5.0 * **If at any time a PARTICIPANT wishes to withdraw from the study or from certain parts of the study, describe when and how this can be done.**
Participants will be reminded that they can withdraw from the study at any point. To do so they will just need to inform a study representative. Once that has occurred testing will stop. Choosing to withdraw will have no impact on patient care or in any other way.

6.0 **Describe the circumstances and limitations of DATA withdrawal from the study, including the last point at which participant DATA can be withdrawn** *(i.e. 2 weeks after transcription of interview notes)*
Data will only be withdrawn from the study if a participant expresses a desire to withdraw their participation.

7.0 **Will this study involve any group(s) where non-participants are present? For example, classroom research might involve groups which include participants and non-participants.**
○ Yes ● **No**

5.1 Data Collection

1.0 * **Will the researcher or study team be able to identify any of the participants at <u>any stage</u> of the study?**
● **Yes** ○ No

2.0 **Primary/raw data collected will be** *(check all that apply)*:
Indirectly identifying information - the information can reasonably be expected to identify an individual through a combination of indirect identifers (eg date of birth, place of residence, photo or unique personal characteristics, etc)

3.0 **If this study involves secondary use of data, list all original sources:**
NA

4.0 **In research where total anonymity and confidentiality is sought but cannot be guaranteed** *(eg. where participants talk in a group)* **how will confidentiality be achieved?**
NA

5.2 Data Identifiers

1.0 * **Personal Identifiers:** will you be collecting - at any time during the study, including recruitment - any of the following *(check all that apply)*:
Surname and First Name
Telephone Number
Email Address
Age at time of data collection

2.0 **Will you be collecting - at any time of the study, including recruitment of participants - any of the following** *(check all that apply)*:
There are no items to display

3.0 * **If you are collecting any of the above, provide a comprehensive rationale to explain why it is necessary to collect this information:**
Volunteers' name, phone number, and email address will be collected for the purposes of arranging appointments for functional assessments. The multiple forms of contact information are being collected to ensure that contact can be achieved to arrange. Volunteers' age will be collected to determine of age confounds the relationship between outcomes collected with EMG sensors and gold standard instrumentation.

4.0 **If identifying information will be removed at some point, when and how will this be done?**
Participants' names, phone numbers, email address and age will be collected at the beginning of the study and will be encrypted and kept in a secure password protected computer. The research coordinator will then give each participant a unique identification number, which will be used for data collection (i.e. questionnaire). The key with the identifying information and assigned codes will be kept on an encrypted hard drive in Dr. Rouhani's laboratory, Faculty of Engineering.

5.0 * **Specify what identifiable information will be RETAINED once data collection is complete, and explain why retention is necessary. Include the retention of master lists that link participant identifiers with de-identified data:**
Participants' age and gender will be kept for statistical analysis of the data, including analysis of the possible correlation between age and muscle response information.

6.0 **If applicable, describe your plans to link the data in this study with data associated with other studies (e.g within a data repository) or with data belonging to another organization:**
NA

ID: Pro00117863 **Pro00117863** 5.3 Data Confidentiality and Privacy
Status: Pre Submission

5.3 Data Confidentiality and Privacy

1.0 * **How will confidentiality of the data be maintained? Describe how the identity of participants will be protected both during and after research.**
Each participant will be given a unique encrypted code. The participant's identity and the code will be kept separate from the data collection documents both physically and electronically. Electronic data will be encrypted and password protected and physical data will be kept in a locked filing cabinet. Physical data will be kept in a locked filing cabinet. The anonymized questionnaire will be only used in the present study.

2.0 **How will the principal investigator ensure that all study personnel are aware of their responsibilities concerning participants' privacy and the confidentiality of their information?**

3.0 **External Data Access**

* **3.1 Will identifiable data be transferred or made available to persons or agencies outside the research team?**
○ **Yes** ● **No**

ID: Pro00117863 **Pro00117863**
Status: Pre Submission 5.4 Data Storage, Retention, and Disposal

5.4 Data Storage, Retention, and Disposal

1.0 * **Describe how research data will be stored, e.g. digital files, hard copies, audio recordings, other. Specify the physical location and how it will be secured to protect confidentiality and privacy.** *(For example, study documents must be kept in a locked filing cabinet and computer files are encrypted, etc. Write N/A if not applicable to your research)*
All collected data will be encrypted and kept strictly confidential on our

research server of the university with passwords locked by the principal investigator and the co-investigator; in a durable and appropriate form (Backup daily).
Data will be stored indefinitely in Dr. Rouhani's laboratories in the Mechanical Engineering building on the University of Alberta campus.

2.0 * **University policy requires that you keep your data for a minimum of 5 years following completion of the study but there is no limit on data retention. Specify any plans for future use of the data. If the data will become part of a data repository or if this study involves the creation of a research database or registry for future research use, please provide details.** *(Write N/A if not applicable to your research)*
The data will not be destroyed. At this time there are no plans for future use of the data.

3.0
If you plan to destroy your data, describe when and how this will be done? Indicate your plans for the destruction of the identifiers at the earliest opportunity consistent with the conduct of the research and/or clinical needs:
NA

ID: Pro00117863 **Pro00117863** Documentation
Status: Pre Submission

Documentation

Add documents in this section according to the headers. Use Item 11.0 "Other Documents" for any material not specifically mentioned below.

Sample templates are available by clicking HERE.

1.0 Recruitment Materials:

Document Name	Version	Date	Description
There are no items to display			

2.0 Letter of Initial Contact:

Document Name	Version	Date	Description
There are no items to display			

3.0 Informed Consent / Information Document(s):

3.1 What is the reading level of the Informed Consent Form(s):
9

3.2 Informed Consent Form(s)/Information Document(s):

Document Name	Version	Date	Description
There are no items to display			

4.0 Assent Forms:

Document Name	Version	Date	Description
There are no items to display			

5.0 Questionnaires, Cover Letters, Surveys, Tests, Interview Scripts, etc.:

Document Name	Version	Date	Description
There are no items to display			

6.0 Protocol/Research Proposal:

Document Name	Version	Date	Description
There are no items to display			

7.0 Investigator Brochures/Product Monographs:

Document Name	Version	Date	Description
There are no items to display			

8.0 Health Canada No Objection Letter *(NOL)*:

Document Name	Version	Date	Description
There are no items to display			

9.0 Confidentiality Agreement:

Document Name	Version	Date	Description
There are no items to display			

10.0 Conflict of Interest:

Document Name	Version	Date	Description
There are no items to display			

11.0 Other Documents:
For example, Study Budget, Course Outline, or other documents not mentioned above

Document Name	Version	Date	Description
There are no items to display			

Final Page

You have reached the end of the ethics application.
Click ‘Continue’ or ‘Exit’ below.

To submit for ethics review, click “SUBMIT for REVIEW” on the left side of the screen.

NOTE: Only the Principal Investigator can submit an application in Pre-submission (ie: the first time it is submitted).

Pro00117863

Reviewer Notes

No Reviewer notes to display.