A Standard Operating Procedure (SOP) is to be created to direct and guide researchers when performing study protocols, especially those that have the potential to cause harm (or increase risk) to a study participant such as those outlined as a controlled act in the Regulated Health Professions Act of Ontario (RHPA). SOPs are to follow the Deming Cycle, a cycle that identifies "Plan-Do-Check-Act." A SOP is created to:

- outline the procedures that must be executed to effectively follow the study protocol and outline the resources/equipment needed (i.e., PLAN),
- provide detailed instructions for research staff of the steps that must be implemented and the training that must be completed (i.e., DO),
- clearly document the study protocol (i.e., CHECK), and
- aid with continuous improvement (i.e., ACT)

All SOPs are to be maintained and controlled by the Principal Investigator/Faculty Supervisor. The Principal Investigator/Faculty Supervisor is responsible for the current and approved versions. Draft and archived/obsolete versions are not to be used.

Title of SOP: Protocol for the Use of Intramuscular Electromyography Insertion into the Rotator Cuff Muscles of Study Volunteers

Are there any controlled act(s) to be performed: [ X ] Yes [ ] No

If you checked yes, list the controlled act(s) below:

“Performing a procedure on tissue below the dermis”

A. PURPOSE AND BACKGROUND

This SOP describes the procedures for intramuscular electromyography in the rotator cuff muscles using a hypodermic needle containing two very thin wires. This procedure is considered a “controlled act” under Ontario’s Regulated Health Professions Act (1991). Note: these electrodes solely measure electrical activity from the specific muscles, they do not transmit any sort of stimulation to the muscle.

B. PROCEDURES/STUDY PROTOCOL

The study procedures outlined below are detailed descriptions of the intramuscular electrode insertion technique, and the steps that are followed to inform and prepare the
subject for the data collection. Specific information regarding the training procedures are outlined in Section E.

1.0 Information and discussion with the participant prior to the session involving intramuscular electrode wires

1.1 Prior to coming to the lab, each potential participant is asked at the time they volunteer if he has an allergy to latex or isopropyl alcohol; if allergic he is informed that he cannot participate in the study.

1.2 Prior to coming into the lab, each potential participant will be asked to fill out a self-report health screening checklist (Appendix G) to assess past health problems as well as present health problems. Participants who report blood clotting disorders, any communicable diseases, respiratory disorders and/or are currently taking blood thinning medication will not be able to participate in the study. Additionally, any subjects with a history of shoulder pain or injuries will be unable to participate.

1.3 Participants are reminded to ask any questions – before, during or after the procedure – whether they relate to the science or the procedure.

1.4 Participants will be made aware that the researchers will adhere to universal precautions to ensure safety during this data collection.

1.5 Participants are advised to wear a sleeveless shirt during experimental set-up and testing. Male participants may choose to go shirtless if that is their preference.

2.0 Preparation of the participant for intramuscular electrode insertion

2.1 The participant will lay prone on a clinical bench and the skin area over the muscle will be shaved and then thoroughly cleaned with isopropyl alcohol.

2.2 All skin in the area surrounding the insertion sites will be cleansed with isopropyl alcohol. Sufficient time (approximately 30 s to 2 min depending on room temperature, humidity and participant skin temperature) will be given for the isopropyl alcohol to dry (confirmed visually) before needles are inserted. Allowing the isopropyl alcohol to dry will allow for sterilization to occur and will prevent isopropyl alcohol leaking into the insertion site which could cause potential tissue irritation.

3.0 Needle and wire insertion for the intramuscular electromyography

3.1 The total depth into tissue will vary from participant to participant depending on the amount of subcutaneous fat present overlying the muscle. It is expected that the needles will be inserted approximately 1 cm into the supraspinatus and infraspinatus. The needle for the subscapularis will be inserted approximately 3 cm deep.
3.2 General Insertion Techniques:
3.2.1 The participant is asked to relax the muscle of interest (muscle in which the needle will be inserted), as flexing the muscle could result in potential discomfort during insertion.
3.2.2 The skin in the area over the insertion site will be pulled taut so that the needle can easily and quickly puncture the skin. Needles are single-use, radiation sterilized and each is contained within its own sterilized packaging. The researcher will be wearing sterile gloves during the insertions.
3.2.3 Once the needle has punctured the skin, the needle should progress slowly to the final destination within the muscle. Several pauses can be taken at increments of a few millimeters at a time before the needle is progressed further. Slow and paused insertion procedures will decrease discomfort to the participant (Daube & Rubin, 2009). The needle insertion should feel similar to the prick of a needle that would be received at the doctor’s office.
3.2.4 The needle should avoid contact with bone (scapula). If the wire were to hit the bone, this could cause discomfort to the participant (periosteum pain) and the wires could become lodged in the bone and would not record any signal from the muscle of interest. If the needle contacts the bone, both the needle and wires are removed and a new needle is inserted. Visual and auditory electromyography cues guide insertions.
3.2.5 If the participant experiences any burning, tingling or pain (indicating the needle has hit a nerve) the needle is immediately removed, and re-inserted into a slightly different area. It is unlikely that the participant will feel the presence of the wires within their muscle.

3.3 Auditory and Visual Guidance during Insertions:
3.3.1 During needle insertion, the researcher feels different levels of resistance as the needle passes through the skin, subcutaneous fat, fascia connective tissues and muscle.
3.3.2 Before insertion, the electromyographic recordings will appear and sound very noisy (large random spikes and sound like static). If equipment permits auditory recording, insertion activity will be heard (“swish”) and seen as a burst of activation as the needle is first inserted into the muscle. This activity is the electrical response of the muscle to the mechanical damage produced by the movement of the needle (Daube & Rubin, 2009).
3.3.3 After the needle has first punctured the muscle and is progressing into it, a contraction of that muscle will result in contraction activity that will be heard (“swish”) and seen (distinct motor units which appear as large obvious spikes, as seen in Figure 1 and 2). Using the visual-auditory electromyographic guidance during insertion, the depth and location of the needle can be adjusted to proper positioning, and reduce the likelihood of improper placements, and re-insertions.
3.3.4 Proper insertion can then be further verified by:
   i) Contraction of the muscle of interest: Expect large amplitude of electromyographic activity.
   ii) Contraction of surrounding nearby muscle (where the needle could mistakenly be inserted): expect very limited activation.
Figure 1: Visual Guidance during Intramuscular Insertion

Figure 2: Visual guidance during intramuscular insertion – the appearance of motor units

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**Supraspinatus** (similar to Geiringer, 1999)

**Participant Position:** Prone with arm relaxed at side.

**Localization:** Landmark spine of scapulae, and lay finger along spine. Insert needle 2 fingerbreadths superior to spine, at medial one-third of scapular spine (approximately 2 cm from edge of medial border). Insert needle parallel to skin in direction towards the finger which overlays the spine. Direct needle towards suprascapular fossa to ensure bone is beneath insertion (this will avoid risk of pneumothorax). Needle will pass through middle trapezius before inserting in supraspinatus.

**Test:** Have participant abduct against resistance with arm at side. Expect audio-visual EMG confirmation.

Figures 3 and 4 demonstrate land-marking techniques for supraspinatus intramuscular electrode insertion.

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**Figure 3:** Land-marking technique for supraspinatus insertion on skeletal model
Figure 4: Land-marking technique for supraspinatus insertion

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Infraspinatus (similar to Geiringer, 1999)

Participant Position: Prone with arm relaxed at side.

Localization: Landmark scapular spine, medial and lateral borders and find centre of infraspinatus fossa (halfway between scapular spine and inferior angle, midway between lateral and medial borders). Insert needle into centre of infraspinatus fossa. Needle will pass through middle trapezius before reaching infraspinatus.

Test: Confirm with scapular retraction that the needle is not in middle trapezius (expect little EMG activation). Confirm with external rotation (while arm is at side), that needle is in infraspinatus (expect large EMG activation).

Figures 5 – 7 demonstrate land-marking techniques and insertion for infraspinatus intramuscular electrode insertion.
Figure 5: Land-marking technique for infraspinatus insertion on skeletal model
Figure 6: Land-marking technique for infraspinatus insertion
Subscapularis (similar to Nemeth et al., 1990).

**Patient Position:** Sitting, with arm abducted 90°, elbow flexed 90° and humerus internally rotated. Have an assistant hold the participants’ arm and protract the scapula.

**Localization:** Palpate the inferior angle and lateral border of scapulae. Find midpoint between acromion and inferior angle of scapulae. Researcher will support the scapulae with the palm of their hand, and will indent the skin anterior to scapulae (grabbing the lateral border) at this midpoint. Insert the needle posteriorly into the direction of the subscapular fossa. Since this insertion site is slightly below the axilla, there is minimal risk of complications including pneumothorax, brachial plexus or arterial injury (Nemeth et al., 1990). Ensuring the needle is pointing posteriorly and directed towards the subscapular fossa and in a direction away from the rib cage will ensure there is no risk of pneumothorax.

**Test:** Expect large EMG activation in internal rotation.

Figures 11 and 12 demonstrate land-marking techniques used for insertion of the subscapularis intramuscular electrode through the axilla.
Figure 11: Land-marking techniques of the subscapularis intramuscular electrode through the axilla on a skeletal model
3.5 Protocol immediately following insertions: Firm pressure will be applied to reduce any risk of bleeding and/or bruising. The ends of the fine wires will be looped and taped down to the skin before the participant moves from insertion positioning.

4.0 Fine wire removal

4.1 Fine wires are removed with a quick tug out of the skin in the direction opposite to that in which the needle was inserted. This removal will be painless because each wire is so pliable that the barb straightens out on traction and offers little, if any, palpable resistance (Basmajian, 1985). The area is cleaned with isopropyl alcohol, and a bandage is placed over the area if required due to bleeding.
C. EQUIPMENT

1.0 Preparation of the Researcher, equipment, and supplies

1.1 As the electrodes are radiation sterilized and individually packaged by the company that supplies the needles (Motion Lab Systems, Inc., Louisiana) and sealed with expiration dates, there will not be a safety issue.

1.2 The researcher will wear sterile latex gloves at all times during insertion procedures and adhere to universal precautions. Used gloves will be discarded in the garbage and new latex gloves will be used for each participant.

1.3 Sterile single-use hypodermic needles of 5cm or less and 25 gauge or smaller, each contained within an individualized sterile packaging, are inserted through the skin into three muscles of the shoulder. The needle contains two very thin wires (44 gauge) of similar size to a strand of hair. The wires are bent at the end, so that once the needle is removed from the skin, the thin wires will remain in the muscle during testing. The wires extend by approximately 7 cm beyond the surface of the skin. The wire will record the electrical activity of the muscle as the participant performs various movements. Three needles are inserted (one into the supraspinatus, infraspinatus and subscapularis muscles), each needle containing two wires, so a total of six fine wires will remain in the muscle during the testing (approximately 2 hours). Once the desired muscle contractions are completed, the fine wire will be removed from the muscle by pulling on the end of the wire that is lying outside the skin.

1.4 Once the needles are removed from the skin, they will be put directly into a bio-hazardous material sharps container.

1.5 Upon removal from the participant, the wires will also be thrown into a bio-hazardous material container.

D. DESCRIPTION TO STUDY PARTICIPANTS

Information and discussion with the participant, the participant preparation and the description of the insertion technique is outlined sequentially in the protocol (Section B).

E. PERSON(S) RESPONSIBLE FOR IMPLEMENTING STUDY PROTOCOL

Intramuscular electromyography insertions will be performed by Ms. Chopp. Ms. Chopp underwent training using the protocols outlined in the previous version of this SOP, as also described in ORE #18548. Ms. Chopp is a third year doctoral student in Biomechanics, in the Department of Kinesiology at the University of Waterloo under the supervision of Dr. Clark Dickerson. To date, she has safely performed approximately 60 insertions with no adverse reactions from the participants.

The training of Ms. Chopp was provided by Mrs. Rebecca Brookham, a fifth year doctoral student in Biomechanics at the University of Waterloo also under the supervision of Dr. Clark Dickerson. Mrs. Brookham is an expert in performing these insertions in to the rotator cuff muscles. She received specialized training from Dr. Linda
McLean (PhD) from Queen’s University and has since safely performed approximately 450 intramuscular insertions into the rotator cuff muscles. Mrs. Brookham received a delegation to perform this controlled act in July 2010 from Dr. John Moule (MD) and was deemed qualified to provide the same level of training to Ms. Chopp as she had previously received (approval of ORE #18548 received January 8, 2013).

The training procedures adhered to were as follows:

- Mrs. Brookham outlined the safety procedures for skin preparation, needle insertions and safe disposal techniques which were continually reinforced throughout the training regime.
- Mrs. Brookham fully explained the landmarking procedure – demonstrating needle placement on a model skeleton, cadaveric specimens, and on a human participant.
- Mrs. Brookham guided Ms. Chopp through simulated insertions on the model skeleton – adjusting arm and hand placement, needle angle and anticipated insertion depth.
- Mrs. Brookham accompanied Ms. Chopp to the Anatomy lab where needle insertions were practiced both on undissected and dissected cadavers. During this time, many aspects of the insertion procedure were reinforced: angle of the needle, the insertion depth and slow insertion speed. Practice on the cadavers allowed Ms. Chopp to visualize the layers of muscle, skin and subcutaneous tissues that the needle would need to pass through before entering the muscles.
- Ms. Chopp observed Mrs. Brookham perform multiple insertions on human participants during which she reinforced the aforementioned procedure specifics.
- Mrs. Brookham inserted the needles into Ms. Chopp so that Ms. Chopp would be better able to describe the feeling of the insertions to participants.
- Ms. Chopp performed supervised insertions slowly, describing specific details of the procedures back to Mrs. Brookham, at each step of the insertion.
- When Mrs. Brookham was confident that Ms. Chopp no longer needed her supervision inserting the needles, and that the procedure was being performed safely and consistently, Dr. Moule was asked to come observe the insertions.
- On February 6, 2013 Dr. Moule signed the “Delegation of a Controlled Act Form”, allowing Ms. Chopp to insert the needles unsupervised.

Following this delegation, the second phase of the study (outlined in ORE #18548) was performed. Ten male participants were recruited and underwent the described protocol in which 3 intramuscular electrodes were inserted into their rotator cuff muscles. As previously stated, Ms. Chopp has now inserted approximately 60 needles into the rotator cuff muscles with no adverse reactions.

F. RISKS

1. PARTICIPANTS

- There is a risk of discomfort during the insertion of the needle. This discomfort will be similar to the prick of a needle that would be obtained from a doctor’s office. Additional pain may be experienced due to the depth of the insertion, but this pain will only be temporary, as the needle will immediately be removed.
• Risk of infection from the needles is minimal. The skin area will be cleansed with isopropyl alcohol before insertion. The needles and fine wires will be sterile, and the gauge of the needle is so small that the puncture wound will be minimal. Bleeding is not expected.

• There is a minimal risk of pneumothorax (puncturing of a lung), and/or brachial plexus or arterial injuries with the improper insertion of subscapular intramuscular electrode. This would only occur if the needle was placed in an improper location and pointing in an improper direction. Since the insertion techniques involve landmarking and ascertaining the scapula bone is directly underneath the direction in which the needle is inserted, the needle will only hit the bone. The needle would have to be pointing in a very wrong direction to miss the scapulae and go through the rib cage to puncture a lung. The insertion techniques used are standardized and designed to specifically avoid this problem, therefore this risk is extremely minimal. However, on occurrence of this incident, CPR and first aid certified researchers would provide necessary first aid to stabilize the participant while waiting for the 9-1-1 response teams. In addition, participants will be provided with an emergency wallet card (Appendix H) that includes both emergency contact numbers and a description of the procedure to be provided to emergency medical personnel at the local emergency room. This wallet card will include the address and phone numbers of a hospital and urgent care center in the Hamilton area, in the event that participants experience an adverse event following the study. The emergency room is open 24 hours a day, 7 days a week.

• A minimal risk of accidental breakage of the wire inside the muscle: Basmajian (1985) assures readers that in their use of intramuscular EMG, they had no accidental breakage in many thousand of uses, and nor would they be disturbed if they had because the fine wire is innocuous (harmless). The tiny gauge of these dull wires and composition of nickel alloy cause these wires to be innocuous, so that the occurrence of a breakage is not disturbing as it would not be harmful to their body. The wires are not degradable. It is likely that the wire would eventually work itself out of their body, as most foreign objects do (such as a wood splinter), however, on the occurrence of this incident, participants would be recommended to follow up with their physician.

• To ensure the confidentiality of each participant, they will be assigned a 3-letter identification code. Only the investigators will have access to this code. All personal health information and records will be stored in accordance with the University of Waterloo policies governing restricted information. All data will be stored indefinitely on computer hard drives (password protected and encrypted - http://ist.uwaterloo.ca/security/encryption/) and/or digital storage media (locked in the investigator’s filing cabinet). A separate consent will be requested in order to use photographs for teaching, for scientific presentations, or in publications of this work. Any identifiable information will be blocked out on the photograph so that participants cannot be identified.

2. RESEARCHERS
There are no known risks to the researchers implementing the protocol as a result of the protocol itself, or the equipment.

G. SAFEGUARDS/SAFETY PROCEDURES

1. PARTICIPANTS

- The cleansing of the skin with isopropyl alcohol, and the use of small sterile needles will reduce the risk of infection. All of the equipment is sterilized and single use.

- The placement of electrodes by trained personnel (Ms. Chopp) using standardized insertion techniques along with palpation and visual insertional guidance, will reduce the risk of improper placement of indwelling needle electrodes, thus reducing the risk of puncturing a lung or injury to an artery or nerve.

2. RESEARCHERS

- Researchers will adhere to universal precautions to ensure the safety of both themselves and the participants.

- Ms. Chopp will always be accompanied by a secondary researcher who will provide assistance with the insertions; specifically bringing the bio-hazardous material sharps container to Ms. Chopp for immediate disposal of the needle.

H. REFERENCES (if applicable)


I. REVISION HISTORY

SOP created on: 05/01/2011 and Ethics Clearance Received on: Date unknown, however, ORE # 16391 and 17289 were approved using this SOP

Revised on: 11/09/2012 and Ethics Clearance Received on: 03/01/2013 (Conditional Approval)

Revised on: 04/01/2013 and Ethics Clearance Received on: 08/01/2013 (ORE # 18548)

Revised on: 1/08/2013 and Ethics Clearance Received on: 06/09/2013 (Conditional Approval)

Revised on: 09/09/2013 and Ethics Clearance Received on: 16/09/2013

SOP created by:
Rebecca Brookham, PhD Candidate, Dept. of Kinesiology, University of Waterloo
Jaclyn Chopp, PhD Candidate, Dept. of Kinesiology, University of Waterloo

Signature:

Date:

[ X ] I acknowledge that as the principal investigator/faculty supervisor I am responsible for updating this SOP and notifying the ORE through a modification form (Form 104) if any of the procedures as outlined above change or require revision.