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UNIVERSITY OF LIMERICK RESEARCH ETHICS COMMITTEE

RISK ASSESSMENT FORM – PROCEDURES INVOLVING HUMAN SUBJECTS

Title of Procedure	Isometric and Isokinetic Measurement of Muscle Function of the Lower Limb		
Name of Assessors	Prof. P. Jakeman and Peter Francis	Assessment date	10 / 11 / **2011**
Does this procedure already have ethical approval?			**No**
If so, enter ethical number and expiry date		**Approval No:**	
		Date expires: / /	

1	**Please provide a brief description of the procedure**	

1. The subject is pre-screened according to the REC approved study protocol
2. The subject is familiarised with the testing procedures
3. The subjects undertakes a pre-assigned warm-up
4. The subject is secured onto the ConTrex™ Ergometer as per the Standard Operating Procedures(attached)
5. The subject is supervised in the completion of the contraction of the lower limb muscles as per the Standing Operating Procedures
6. The subject is allowed a warm-down period.

2	**Location in which the procedure may take place**		
	√	Project Laboratory (PG034)	

3	**Eligibility of subject(s) to be used**	

	√		UL student (U.G. or P.G.)
	√		University staff or campus personnel
	√		Members of the general public engaged in research projects granted ethical approval.

4	**Potential risks. To be explained <u>before</u> obtaining consent**

√	Minimal discomfort only. Some muscle soreness and potentially joint stiffness for 1-2 day following the test

Risk to the subject:

The procedure is well tolerated in the majority of subjects. The risk to the subject is considered to be minimal. The subject may feel some discomfort. This discomfort may include feelings of muscle soreness and joint stiffness that may persist for 2-3 days following the testing procedure. There may be slight bruising to the calf at the point of attachment of the ergometer arm to the lower limb.

Risk to the experimenter:

The is no perceived risk to the experimenter in the Standard Operating Procedures for this test. The following are precautions specific to this procedure:

1. Care must be taken to avoid accidental disconnection of the ergometer from the mains. All power leads and cables tracking to the instrument must be firmly secured.

5	**Action to be taken in the event of a foreseeable emergency**

Action to be taken with reference to the subject feeling unwell at any stage throughout this procedure:

1. Stop the procedure immediately and, if appropriate, remove the subject from the ergometer
2. Check vital signs airways, breathing and circulation (ABC). Subjects are placed supine with lower limbs raised to improve blood flow and counteract the vasovagal influence. Check blood pressure.
3. Apply CPR if required.
4. First aid personnel would be contacted, and an ambulance would be requested if necessary.
5. The University Medical Centre number is 2534 (9:00 am to 5:00 pm)
6. The University emergency number is 3333

6	**Level of supervision required for procedure**

√	Named researcher who is trained and experienced in the performance of this procedure

7	**Other documentation required for this assessment?**

√	Standard Operating Procedure

Standard Operating Procedure

Measurement of Muscle Function of the Lower Limb

November 2011

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1) Background

Purpose: Isometric and isokinetic dynamometry is used to assess the function of individual muscle groups, more particularly the thigh muscle. This document has been constructed to provide general guidance to study personnel on how to conduct the procedures involved in the repeated measurement of muscle contraction of the muscle of the lower limb, in particular the thigh muscles.

Personnel
For the purpose of this document, a researcher is defined as a member of staff or post-graduate student of the University of Limerick fully trained in the procedures referred to in this document and competent to supervise undergraduate students in the conduct of these procedures.
The researcher is responsible for:

1. The experimental set up, conduct of the test and laboratory area in which the test is conducted.
2. Ensuring the required pre-test checks on the subject approved by the relevant REC are completed and signed off by the principal investigator or person delegated to this task.
3. The calibration and safe working on the ConTrex™ ergometer.
4. The appropriate level of feedback to the subject (if allowed by the research design) and appropriate storage of data (as dictated by relevant REC approval).

2) Con-Trex™ set up and machine calibration.

Purpose: Set up and calibration of the Con-Trex MJ ergometer is required to enter the necessary subject details and set the parameters of the test so it may be carried out in a safe manner.

Procedure:

1) The researcher is responsible for the accurate and safe set up and calibration of the Con-Trex ergometer. This responsibility cannot be delegated.
2) Switch on the computer and log-in to the Con-Trex software.
3) Enter the subject details.
4) Set the length of the test and the position from which the leg will be tested (e.g. knee extensor/flexor , right or left limb)
5) Switch on the Con-Trex machine.
6) Using the controls move the Con-Trex arm straight down until it is at 90° angle with the floor. This point is known as the absolute zero, the point at which gravity is acting straight down.

3) Positioning Subject and setting individual range of motion.

Purpose: The subject must be positioned in the Con-Trex chair which is adjusted to his/her height and anthropometric measurements. Individual range of motion must be determined for accurate positioning of the leg for muscle contraction and for safety reasons to ensure the Con-Trex arm never moves outside of a comfortable range of movement for the subject.

Procedure:

1) The researcher positions the chair, dynamometer, shin support and safety straps to fit the subject's anthropometric measurements.
2) The researcher positions the dynamometer so its centre is in line with the lateral femoral condoyle of the leg to be tested (normally the dominant leg).

3) The researcher positions the chair so that the subject is sitting with a hip angle of 110° and the back of the knees in line with the front edge of the chair so that the thigh is fully supported.
4) The researcher positions the shin pad 6cm above the lateral malleoli of the leg to be tested (normally the dominant leg).
5) The researcher secures the pelvis, thigh and chest using the restraining straps to prevent extraneous movement.
6) The researcher records all chair and dynamometer positions for future testing of that subject.
7) Using the controls the researcher now passively brings the testing leg up to a straight leg position (anatomical zero) asking for subject feedback in relation to any discomfort.
8) The researcher then selects the straight leg position as the anatomical zero on the computer screen.
9) The researcher then passively sets the subjects range of motion around the knee joint for the specific test, fixed if isometric, ranged if isokinetic.
10) With the subject in a comfortable position s/he is told to relax and let the limb hang loose whilst the ConTrex performs a gravity correction within the set range of motion.

4) Measurement of a maximal voluntary contraction (MVC) and the maximal Rate of Force Development (RFD) for an ISOMETRIC (static, no change in muscle length) contraction.

Purpose: The purpose of performing a maximal voluntary contraction is to determine the peak torque and the rate at which this torque is developed giving an indication of muscle strength.

Procedure:

1) The researcher positions the subjects leg in the required position e.g. for extension of the thigh -60° from anatomical zero.
2) When ready the subject is instructed to extend the leg at 50% and then to 75% of their perceived maximal effort for 5 seconds, providing 1 minute rest between these two contractions. The subject's positioning, security within the chair and preparedness for the maximal test is then checked.
3) The researcher then instructs the subject to exert a maximal contraction as fast and as hard as possible for a period of 3 seconds and to obtain an isometric MVC (Maximal Voluntary Contraction). Verbal encouragement is provided to the subject.
4) After a period of 90 seconds rest the procedure outlined in (3) above is repeated on TWO further occasions.
5) When the test is completed the subject is released and is supported in dismounting from the ergometer. A light cycle exercise is recommended to ease the strain of the leg muscles prior to leaving the laboratory.

5) Measurement of work done to fatigue (IMPULSE) in maintaining a submaximal isometric contraction (fixed %MVC) to exhaustion.

Purpose: Impulse is Force(N) x Time(s). The purpose of performing this test is to determine the capacity to maintain a sustained isometric contraction over time. It is a measure of endurance capacity for static work.

Procedure:

1) The researcher positions the subjects leg in the required position e.g. for extension of the thigh -60° from anatomical zero.

2) The subject is instructed to extend their leg and to maintain the required %MVC as indicated on the screen of the ConTrex ergometer. The subject maintains this for a 5s period and then is allow to relax. The subject's positioning, security within the chair and preparedness for the test is then checked.
3) The researcher then instructs the subject to exert a contraction to the required %MVC and hold this for as long as possible. Feedback is provided from the screen of the ConTrex ergometer. Verbal encouragement is provided to the subject as s/he begins to tire from the activity.
4) The test is terminated when the subject is no longer able to maintain a force within -5% of that required by the test protocol.
5) When complete the subject is released and is supported in dismounting from the ergometer. A light cycle exercise is recommended to ease the strain of the leg muscles prior to leaving the laboratory.

6) Measurement of a maximal torque and power for an ISOKINETIC (same angular velocity) contraction performed either in concentric (muscle shortening) or eccentric (muscle lengthening) mode.

Purpose: The purpose of performing a maximal voluntary contraction is to determine the peak torque and power and the angle at which torque or power occur measured in isokinetic (same speed) contraction. The measurement may also be used to determine the total work done.

Procedures for this test vary according to specific measurements required, but normally:

i. Angular velocities selected for this test are set between 10 and 60 $rad \cdot s^{-1}$.;
ii. Protocols use a combination of extension and/or flexion;
iii. Protocols use a combination of concentric (muscle shortening) and/or eccentric (muscle lengthening) contractions;
iv. Protocols may require up to 50 repeated contraction to be undertaken in one series e.g. to generate a fatigue curve

Procedure:

1) The researcher positions the subject's leg in the required position and sets anatomical zero and the range of motion required for the specific test (for flexion and extension if required)
2) Following a countdown initiated by the ConTrex, the subject is instructed to maximally contract in extension and/or flexion maintaining the rhythm programmed by the researcher. The subject's positioning, security within the chair and preparedness for the test is then checked prior to the next test series.
3) After a period of rest indicated in the specific protocol of the test the procedure outlined in (2) above is repeated for all the angular velocities required (normally between 10 and 60 $rad \cdot s^{-1}$) to complete the test.
4) When complete the subject is released and is supported in dismounting from the ergometer. A light cycle exercise is recommended to ease the strain of the leg muscles prior to leaving the laboratory.