Jefferson Office of Human Research
Informed Consent OHR-8
Version Date – FOR OHR USE: 5/22/20

Department: Department of Physical Therapy

Principal Investigator: Christopher Keating

Study Title: Measuring Pain Experience in Individuals with Lateral Elbow Tendinopathy

Lay Title: Measuring Pain in LET

General Information Section

Informed Consent

You are being asked to take part in a research study. Research is different from standard medical care, and is done to learn something new.

Please read on to find out:

- The purpose of this research.
- How this research is different from standard medical care.
- The procedures involved.
- The risks.
- The possible benefits.
- The alternatives to taking part in this research.

You will have the opportunity to discuss this study with the research personnel. Use this information to decide if you want to take part in this research. This process is called informed consent.

Voluntary Participation

You do not have to take part in this research. It is your choice whether or not you want to take part. If you choose not to take part or choose to stop taking part at any time, there will be no penalty or loss of benefits that you would normally get.

Purpose

The purpose of this research is to look at the measurement of pain in tennis elbow patients. We will do this through the use of a tool with two points also known as two point discrimination calipers (TPD), hand grip strength tester (dynamometer), a tool that measures the amount of pressure at the

elbow (pressure algometer), and an electronic app to identify left and right body parts (laterality). In addition, we will have you complete a series of questionnaires that are designed to measure psychological influences on pain. We will look at how these results compare to each other.

How this Research is Different from Standard Medical Care

Currently, two point discrimination (TPD) and Pressure Pain Thresholds (PPT) are tools of choice to look at changes in touch in patients with pain and hand grip strength testing looks at your grip strength. They have been studied in great detail and have been talked about in research articles. TPD and laterality are newer tools, and have not been studied in patients with tennis elbow and a tool that measures pressure are also newer ways for tennis elbow patients to be tested and have not been studied in patients like you.

The use of surveys to help customize treatment is standard care, but new to patients like you.

The research conducted in this study is purely data collection. As a participant in this study, there is no potential for any health benefit or gain as a result of involvement.

Number of Participants

Approximately 70 people will take part in this research in the Philadelphia region.

Duration

You will be in this research study for **ONE 60-minute** session.

Procedures and Risks

It is important that you know the procedures and risks involved in this research. These will be discussed with you and are included in detail later in this form. Review the information carefully when making your decision to take part in this research.

Possible Benefits

You will not benefit from taking part in this research, but other people may be helped by what is learned. Participating in the study will not affect your ability to receive treatment.

Alternatives to Taking Part in this Research

The alternative to being in this study is to not take part.

Costs

There are no anticipated costs to you for participating in this study. This will be discussed in more detail later in this form.

Payment

You will not be paid for taking part in this study. If this research or the information or specimens you provide result in commercial profit, you will not receive any money from that profit.

Ending Study Early

There are a number of reasons you may decide or be asked to stop the study early (example: medical issues). You may also have to stop the study early even if you do not want to. You and the research personnel will discuss the reason if this becomes necessary. If you do leave the study early, you may be asked to complete some of the procedures described in this form.

New Information

New information may come out during this study. You will be given any new information that could change your decision to take part. You may ask to see the information collected about you, but not until the entire study is complete. You will not be given any research results that could affect your health.

<u>Detailed Information Section</u>
Devices

Two point discrimination calipers

- Two point discrimination calipers are a tool with two pointed edges attached to a ruler-like device. The pointed edges are able to be moved to varying distances away from one another in order to test a person's ability to distinguish one touch from two.

Hand-held Dynamometer

- Ergonomic, or fitted and comfortable, hand-held device for objectively quantifying muscle strength.

Pressure Pain Algometer

- Algometers are used to measure and record the amount of sensitivity to pain when pushing on the outer elbow

Smartphone

- An iPhone application will allow for the testing of laterality. You will be asked to select from the images shown whether you see a LEFT or a RIGHT hand or arm.

Procedures

While you are in this study, you will have different procedures, tests and/or evaluations which are described below. Please note that additional tests and procedures may be needed to check on your health condition.

Describe all the procedures, tests, and evaluations that will be done during this study. Include when and how often they will be done. Consider including a schedule of events showing when everything will be done, including the administration/use of drugs/devices.

Procedures: Explain study procedures/methods.

- Screening for Eligibility
    - You will complete a brief verbal quiz to ensure comprehension of the study contents.
- Patient Specific Functional Scale
    - You will identify 3 activities that are most limited and meaningful to them.
    - The subject will rate these activities on an 11-point scale ranging from 0 "unable to perform" to 10 "Able to perform the activity at the same level as before the injury or problem."
- SF-McGill Pain Questionnaire-2 and Numeric Pain Rating Scale (NPRS)
    - You will be asked to rate their pain on a 0-10 scale for 23 different pain descriptors.
- Central Sensitization Inventory
    - The subject will be asked to assess for the presence of a central sensitization state on 25 questions scored in ordinal fashion 0 (never) – 4 (always).
- Multidimensional health locus of control scale form C
    - You rate their opinion or sense that their outcomes are determined by luck, fate, or a random occurrence that controls experiences.
- Pain Catastrophizing Scale
    - You will be asked to assess for the presence of a pain catastrophizing on 13 questions scored in ordinal fashion 0 (not at all) – 4 (all the time).

- Fear Avoidance Belief Questionnaire
    - You will be asked to assess for the presence of fear avoidance behavior.
- Hospital Anxiety and Depression Scale
    - You will be asked to assess for the presence of anxiety or depression on 14 questions scored in 4-point scale.
- Two Point Discrimination
    - Your elbows will be tested with a tool with two points
    - You will be seated in a with elbow resting next to you
    - You will report after each application "one", if one point is felt or "two", if two points are felt.
    - If unsure, you will report one point.
- Pressure Pain Threshold
    - You will be seated with your elbows positioned in a comfortable, relaxed position on the armrest of a chair. The Commander Echo Algometer will be used to assess the amount of pressure that can be applied at the outside elbow before you feel pain.
    - You will be instructed to say when the pain begins by saying "stop."
    - The tester will gradually apply an increasing amount of force until you say "stop." This measure will then be repeated a second time.
- Pain-Free Grip Strength
    - In a seated position with the affected elbow bent to 90º and wrist in a relaxed position, you will be asked to squeeze the Commander Echo Wireless Grip Strength tester as hard as you can until your elbow pain is reproduced.
    - This procedure will be conducted at each rung position until the grip reproduces your pain. Once the point of a painful grip is reached, you can rest for 30 seconds before repeating the grip at that rung a second time.
- Laterality
    - You will be seated and given a handheld device to hold.
    - The subject will be instructed to review the images on the screen and as quickly and as accurately as they can, select whether the upper extremity on the screen is either left or right.

Risks

Taking part in this study involves certain risks. These risks include possible skin damage from the two-point discrimination tool, and the potential of increased pain symptoms due to TPD calipers, hand dynamometer, and pressure algometer during testing. There may also be risks that are not known at this time. If you have any medical issues during this study, call the appropriate number in the contacts section of this form.

Costs

There will be no study related items or services billed to you or your insurance company. However, you may be responsible for other costs such as transportation and missed work. There is no plan to pay you for lost wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition(s). If you receive a bill that you think is wrong, please contact the research personnel. You will be responsible to pay for your travel to and from the study site and other out-of-pocket expenses such as parking.

Research-Related Injury

There is a possibility that you could have research-related injury, which is an illness or an injury that is directly caused by the study device or a study procedure. If you have a research-related injury, we will offer you reasonable and necessary care to treat injuries directly resulting from taking part in this research. Neither Jefferson nor the study will pay for costs associated with treatment of research-related injury or illness. These costs may be billed to your insurance. In addition, you will be responsible for any deductibles and co-payments required under your health plan and for any claims ultimately denied by your health plan. There are no plans for Jefferson to pay you or give you other compensation for the injury. If you think you have been injured as a result of taking part in this research study, tell the research personnel as soon as possible. Please see the contact information in this consent form.

Disclosure of Financial Interest

Nothing to disclose.

Privacy and Confidentiality: HIPAA Authorization

Information will be collected about you for this study. The information will be seen by the people involved with this research. Steps will be taken to protect your identity. But the information collected about you can never be 100% secure.

HIPAA (Health Insurance Portability and Accountability Act) – This is the law that protects your personal health information.

To do this study, we need to collect, use, and share your personal health information. This form will explain why your information is being collected, what information will be collected, and who will have access to it. By signing, you are giving us permission to use your information as described in this form.

We are committed to respecting your privacy and to keeping your personal health information confidential. Your personal health information includes the information in your health care records and information that can identify you. For example, personal information may include your name, address, phone number, social security number, and medical information. The personal health information that may be collected, used, and shared for this research includes:

- Information from your medical records
- Demographic information such as name, gender, birth date, ethnicity, medical history, and health care providers
- Physical examinations, procedures, tests, labs, your medical conditions, and medications you use
- Information collected about any research related injury
- Information about mental health, sexually transmitted diseases, HIV, AIDS, drug and alcohol use, genetic test results, and other sensitive information

Your personal information will be used by and shared with the following:

- Personnel at Thomas Jefferson University and its affiliates for the purpose of this research
- Institutional Review Boards (ethics committees that review research) including Thomas Jefferson University's IRB.

When your personal information is provided to some of the people listed, it may no longer be protected under the HIPAA privacy law. You can see your health care records at any time. However, generally you will not be able to see your study records or the study results until the study is completed. A copy of this signed form, information about this study, and the results of any study test or procedure may be included in your health records which may be seen by your insurance company and your health care providers.

This authorization does not have an expiration date. Please inform the investigator in writing if you want to end your permission to collect information/samples. Please note that anything already collected will still be used and you may not be able to continue in this study.

The information from this study may be published in scientific journals or presented at scientific meetings, but you will not be personally identified.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Your private information and specimens, with the identifiers removed, could be used for future research studies or distributed to other researchers for future research studies without your additional permission.

Contacts

If you are having a medical emergency, call 911 or go directly to an emergency room. You should let emergency personnel or providers know that you are taking part in this study.

For Questions About:	Person or Office	Contact Information
The Study or Research Related Injury	Main Investigator: Christopher Keating	215-503-1647
If you need to contact someone other than the study personnel about a concern or your rights as a research subject	Jefferson Center City Institutional Review Board (Ethics Committee)	215-503-0203 215-503-8966 215-955-4239

Signatures

Patient/Subject: By signing this form, you are agreeing that:

- You were given the opportunity to read this form.
- All of the information in this form was discussed with you by an investigator or other research personnel to your satisfaction.
- All your questions have been answered to your satisfaction.
- You were not pressured and you voluntarily agree to take part in this research.

_____	_____	
Your Name	Your **Signature**	Date
_____	_____	
Name of Person Obtaining/ Assisting with Consent	Signature of Person Obtaining/ Assisting with Consent	Date

The investigator's signature certifies that the study participant has been provided with a description of the study, study procedures, risks, benefits and alternatives to participation.

Christopher Keating
Name of Investigator _____ Signature of Investigator Date

_____ _____
Name of Witness Signature of Witness Date
(Witness required if the only language the subject speaks and understands is English, but the subject cannot read English, or if the subject is blind or cannot physically sign the consent form.)

☐ **Copy of Signed and Dated Consent Form Given to the Subject/Parent/LAR**

Teach-Back Questions – These questions were reviewed with the patient.

We have gone over a lot of information. I would like to ask you a few questions to make sure I have done a good job explaining the study to you.

1. In your own words, please answer these questions about this study:
    1. Why are we doing this study (what are we trying to learn)?
    2. What things (including tests and procedures) will you have to do in this study?
    3. What are some of the risks of being in this study?
    4. What is the benefit of being in this study?

2. Taking part in this study is voluntary. What does that mean to you?

3. What other questions do you have about this study?