Intramuscular Heating Rates of a Chattanooga Intelect XT® Therapeutic Ultrasound with a 3 MHz frequency and 1.0 W/cm2 Intensity at Three Depths up to 2.5 cm.

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Intramuscular Heating Rates of a Chattanooga Intelect XT® Therapeutic Ultrasound with a 3 MHz frequency and 1.0 W/cm2 Intensity at Three Depths up to 2.5 cm.

This study is being conducted by:

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Key Information about this study:

The study involves inserting three very small thermocouples (small, flexible thermometers) into the inside of your calf muscle and then performing a therapeutic ultrasound treatment over the back of the calf. Therapeutic ultrasound is a heating machine used to treat injured muscles, tendons, and ligaments. You should only feel slight warmth with the ultrasound treatment. The risks of ultrasound treatment are minimal, however, if any discomfort occurs as a result of the ultrasound treatment, the treatment will be terminated immediately. Thermocouple insertion risks can include pain very similar to receiving a flu shot and you may have residual soreness for 12-24 hours after the session. Typically, subjects who have had this procedure performed on them, report the discomfort between a 1-3 on a 10 point scale. Infection occurring from the thermocouple insertion is also a possible risk. However, all universal precautions regarding cleanliness and sanitation are in practice. If any infection concerns arise following the study, please contact the investigators.

In order to participate in this study, you must be a male or female 18-35 years old. You must also be able to speak and understand English fluently. You will not be able to participate if you have any current lower extremity injury, or any lower extremity injuries within the last 6 months or a previous history of surgery in the lower leg. You will also be excluded if you have any open wounds, skin infections, impaired circulation, peripheral vascular disease, deep vein thrombosis, advanced arthritis, poor thermal regulation, anesthetic areas, neoplasms/tumors, thrombophlebitis or closed infections. Participation will also be terminated if any abnormalities are seen in the muscle as determined by the diagnostic ultrasound or if you have greater than 1 cm of adipose tissue on on your calf as determined by diagnostic ultrasound. Finally, you will be excluded if you have any known allergies or sensitivities to betadine. The study will take approximately 1 hour of your time. You will be compensated $20.00 for your participation in the study. All information will remain confidential and will be stored in a secure location.

Why am I being asked to take part in this study?

The purpose of this study is to determine the rate of tissue temperature increase in the gastrocnemius (calf) muscle of healthy subjects during a 15-minute thermal ultrasound treatment. Temperatures will be measured at 1.0, 1.75, and 2.5 cm depths using the Chattanooga Intelect® Legend XT ultrasound unit. This information will help health care providers (physical therapists, athletic trainers, etc.) to properly perform thermal ultrasound treatments using this unit.

What will I be asked to do?

- After signing this form and asking questions as needed, investigators will instruct you to lie on your stomach with your foot and lower leg off of the table in a comfortable position.
- Investigators will ask you to contract your calf muscle and will place a mark on your leg using a marker. This mark will be the location of the ultrasound treatment.
- The researchers will then prepare additional marks along the side of your leg using the marker and a carpenter's square to accurately place the thermocouples.
- At the location of each thermocouple insertion, the leg will be shaved and cleaned using both betadine and 70% isopropyl alcohol.
- A needle catheter will be inserted into the inner part of your lower left leg and a small flexible, plastic catheter will remain in the tissue.
- The thermocouple will be placed into your lower leg and the catheter will be removed.
- This process will occur three times.
- A template will be placed on your lower leg to maintain a specific area for the ultrasound treatment.
- The ultrasound treatment will be performed on your lower leg.
- At the conclusion of the treatment, the thermocouples will be removed and band-aids will be placed on each thermocouple site.
- You will be instructed on an icing schedule to reduce any discomfort after the study.

Where is the study going to take place, and how long will it take?

This study will take place at the Bentson Bunker Fieldhouse, room 14. It will take approximately 1 hour.

What are the risks and discomforts?

It is not possible to identify all potential risks in research; however, precautions have been taken to minimize risks. If new findings develop during this research which may change your willingness to participate, we will provide you with this information. Thermocouple insertion risks can include pain very similar to receiving a flu shot and you may have residual soreness for 12-24 hours after the session. Infection occurring from the thermocouple insertion is also a possible risk. However, all universal precautions regarding cleanliness and sanitation are in practice. If any infection concerns arise following the study, please contact the investigators.

The risks of ultrasound treatment are minimal, however, if any discomfort occurs as a result of the ultrasound treatment, the treatment will be terminated immediately. If you are known to have any allergy or skin reaction to betadine, you may not participate in this study. If you are unaware and a reaction does occur, your participation will be ended.

What are the expected benefits of this research?

Therapeutic thermal ultrasound is frequently used by athletic trainers, physical therapists, and other health care professionals to heat tendons, ligaments and muscles to assist in healing and preventing injury. Currently, not much is known about the amount of heat produced by individual ultrasound units. Due to this, clinicians may not be able to perform the proper treatments. This study will provide these health care professionals with knowledge regarding this specific ultrasound unit so that it can be used to heat tissues to an appropriate level.

Do I have to take part in this study?

Your participation in this research is your choice. If you decide to participate in the study, you may change your mind and stop participating at any time without penalty or loss of benefits to which you are already entitled.

What are the alternatives to being in this study?

Instead of being in this research, you may choose not to participate.

Who will have access to my information?

We will keep private all research records that identify you. Your information will be combined with information from other people taking part in the study. When we write about the study, we will write about the combined information that we have gathered. We may publish the results of the study; however, we will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing you gave us information, or what that information is. For example, your name will be kept separate from your research records and these two things will be stored in different places under lock and key. If you withdraw before the research is over, your information will be removed at your request, and we will not collect additional information about you.

Can my participation in the study end early?

You have the option to withdraw from the study at any time. If any discomfort occurs from the ultrasound treatment or if the thermocouple insertion causes significant discomfort to you, you may leave the study and discontinue participation at any time. Researchers may remove you from the study

if any skin reactions occur from the betadine or other material used in the study or if you have greater than 1 cm adipose tissue on your calf as determined using diagnostic ultrasound.

Will I receive any compensation for participating in the study?

At the end of the data collection period you will be given $20.00 for your participation. In order to be compensated you must be free of any exclusion criteria. If you choose to leave the study early after it has begun, you will still be compensated the full $20.00.

What happens if I am injured because of the study?

If you are injured during this study, you should contact Dr. Kara Gange at 701.231.5777 or kara.gange@ndsu.edu. If needed, she may refer you to NDSU Health Services. Treatment for the injury will be available including first aid, emergency treatment, and follow-up care as needed. Payment for this treatment must be provided by you and your third party payer (such as health insurance or Medicaid). This does not mean that you are releasing or waiving any legal right you might have against the researcher or NDSU as a results of you participation in this research.

What if I have questions?

Before you decide whether you'd like to participate in this study, please ask any questions that come to mind now. Later, if you have questions about the study, you can contact Dr. Kara Gange at (701) 231-5777 or kara.gange@ndsu.edu or contact Meghan Smith at (701) 793-4746 or meghan.c.smith@ndsu.edu.

What are my rights as a research participant?

You have rights as a research participant. All research with human participants is reviewed by a committee called the *Institutional Review Board (IRB)* which works to protect your rights and welfare. If you have questions about your rights, an unresolved question, a concern or complaint about this research you may contact the IRB office at 701.231.8995, toll-free at 855-800-6717 or via email (ndsu.irb@ndsu.edu).

Documentation of Informed Consent:

You are freely making a decision whether to be in this research study. Signing this form means that

1. you have read and understood this consent form
2. you have had your questions answered, and
3. you have decided to be in the study.

You will be given a copy of this consent form to keep.

Your signature _____ Date _____

Your printed name	Date
Signature of researcher explaining study	Date
Printed name of researcher explaining study	