

Title: Optical Measurements of the Skin Surface to Infer Distinctions in Myofascial Tissue Stiffness

NCT number: NCT06390085

Date: February 3rd, 2023

Informed Consent Agreement

Key information:

- In this study, we will be imaging the skin movements of surface tissue on your back. A clinician will perform assessment and intervention procedures manually, using manual and light movements of stretch and compression.
- Your name and/or identity will not be tied to the information we gather.
- You may withdraw from this study at any time.
- You will be compensated with a \$25 gift card upon completion.
- This study will require approximately 1 hour of your time.

Purpose of the Study: About half the U.S. adult population suffers from chronic neuromusculoskeletal pain. We are making optical measurements at the skin surface to decipher the stiffness of underlying myofascial tissue. We want to see if these measurements can differentiate stiffness between one side of the body and another, and before and after brief massage meant to relax the tissue.

What We'll Do: This study includes a demographic questionnaire, self-report on level of pain, application of ink to the skin, manual clinical assessments, and a massage intervention. The study will take place entirely in Olsson 002. All information collected will be recorded using a randomized ID number, with no ties to you.

1. Upon your arrival for the study, you will be asked to read, review, and sign this informed consent agreement.
2. Next, you will be asked verbally to complete a demographic questionnaire.
3. The study team will verbally ask you to rate your current level of pain.
4. You have been asked to bring clothes (e.g., sports bra, halter top, or swimming suit, etc.) to expose your upper back/neck region, and you will change into those in a room isolated to yourself and within the overall laboratory space. A gown will also be provided for additional privacy.
5. Two researchers will be in the room during the session, with the gender of the researchers taken into account per participant. For example, for a male participant, we plan to have a male researcher present during the session along with the female physical therapist. For a female participant, we plan to have both the female physical therapist and a female researcher present.
6. The study team will apply non-toxic, washable ink to your back in two 10 by 10 cm areas near the shoulder blades on either side of the body.
7. You will lie flat on a massage table.
8. A camera system will record the movements of the fingers of the physical therapist, along with the movements of the skin. We will videotape the upper part of your back. Your face will never be videotaped. We will not record any audio.
9. The physical therapist will conduct standard assessment procedures for about 2 minutes per side of the body, where she compresses and slightly stretches the skin tissue.
10. A soft tissue intervention, or massage, lasting about 15 minutes will take place in your upper back/neck region.
11. Another assessment like that prior will be performed.
12. You will again be verbally asked about your current level of pain.

Time Required: The study will last approximately 1 hour.

Risks: There is a very small chance that the ink applied might irritate your skin.

Benefits: There are no direct benefits to you for participating in this research study. The outcomes of the study may help us, in the future, to develop practical and cost beneficial ways to monitor the treatment progression of persons over time.

Confidentiality: The information that you give in the study will be handled confidentially. Your information will be assigned a code number. The list connecting your name to this code will be kept in a locked file. When the study is completed and the data have been analyzed, this list will be destroyed. Your name will not be used in any report.

Voluntary Participation: Your participation in the study is completely voluntary. Your decision to participate will have no effect on grades or school services.

Right to Withdraw: You have the right to withdraw from the study at any time; however, withdrawing from the study will result in loss of compensation.

How to Withdraw: If you wish to withdraw from the study, tell the researcher at any point in the study and all testing will end immediately. If you would like to withdraw after your materials have been submitted, please contact Gregory Gerling. Withdrawing will not affect your grades or school services. There is no penalty for withdrawing.

Compensation: You will be compensated with a gift card for \$25.

Data Usage Beyond this Study: Anonymized data will be made available to other researchers in the science and engineering community, given your permission on this consent form. Your signature on this form grants permission for your data to be used for research by others in the field.

Contact Information:

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To obtain more information about the study, ask questions about the research procedures, express concerns about your participation, or report illness, injury or other problems, please contact:

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UVA IRB-SBS #6201 - Optical Measurements of the Skin Surface to Infer Distinctions in Myofascial Tissue Stiffness

Website: <https://research.virginia.edu/irb-sbs>

Website for Research Participants: <https://research.virginia.edu/research-participants>

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I agree to participate in the research study described above.

Print Name: _____ **Date:** _____

Signature: _____

You will receive a copy of this form for your records.