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

NCT number: NCT06390085

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Current User: **Gerling, Gregory (gg7h)**

Protocol Number: 6201

IRB of Record: UVA

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

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

Previous IRB-SBS Protocol Number:

Date Approved: **2023-10-25**

This protocol record was electronically approved on 2023-10-25

This protocol record is currently Approved.

Personnel (UVA Only)

Principal Investigator: Gerling, Gregory (gg7h) - Status: Faculty
Department: E0:EN-Eng Sys and Environment
Title: E0:Associate Professor
CITI Training:
2020-06-22 - Conflicts of Interest - Stage 1
2016-05-09 - Conflicts of Interest - Stage 1
2013-11-13 - Conflicts of Interest - Stage 1
2016-05-09 - IRB-HSR RESEARCHER BASIC COURSE
2016-05-09 - IRB-HSR RESEARCHER REFRESHER COURSE
2022-05-31 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS

2019-06-27 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2016-05-09 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2021-12-01 - Undue Foreign Influence: Risks and Mitigations

Contact Person: Gerling, Gregory (gg7h)

Research Team (Sub-Investigators):

Kao, Anika (ak4hz)
Department: S0:EN-Mech/Aero Engr Dept, U1:Engineering Graduate
Title: S0:Graduate Research Student B
CITI Training:
2022-09-28 - Conflicts of Interest - Stage 1
2020-10-08 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2020-08-13 - Responsible Conduct of Research - Basic Course
2022-11-28 - Undue Foreign Influence: Risks and Mitigations

Department Chair: Scherer, William (wts)

non-UVA Research Team (Sub-Investigators)

non-UVA Sub-Investigator: Loghmani, M. Terry
Institution: Indiana University
Position at Institution: Associate Professor of Physical Therapy
Email: mloghman@iu.edu
Phone: 317-278-3463
Training Documentation

View File: citiCompletionReport_3786821_45159808.pdf
date uploaded: 2023-09-25, by: Gerling, Gregory *(gg7h)*
This file is approved.
date approved: 2023-10-25

non-UVA Engaged Institutions (in the United States)

Use this section for non-UVA Institutions which are located in the United States.

Use the International Research section, farther down this page, for non-UVA Institutions located outside of the United States.

Is more than one institution located in the United States (another university, commercial institution, etc.) engaged in this research proposal? Yes

Institution Name: Indiana University

PI at Institution: Loghmani, M. Terry - mloghman@iu.edu, 317-278-3463

IRB Contact at Institution: Johnson, Bethany - bwinnie@iu.edu, 317-278-7831

Institution Type: US Postsecondary Institution

Institution Activities: The activities at this institution duplicate the activities at all of the other institutions involved in this study (including UVA).

Institution Review: This institution will rely on UVA to conduct an IRB review.

Study Overview

Anticipated end date for collecting data: 2024-07-01

Anticipated end date for analyzing data: 2025-01-01

Is this research funded? Yes

Funding Source(s): Federal government, Sub-Contract

Supply all Agency Grant Numbers & Titles currently associated with this protocol:

This is a pilot award, being awarded through a NIH U24 grant held by Duke University. I do not have the grant numbers at this point. Our pilot award title is Optical Measurements of the Skin Surface to Infer Distinctions in Myofascial Tissue Stiffness. Duke University will not be a site where this work will take place, their university is a pass through of the funds from the NIH to UVa.

Do any of the Funding Sources create a Conflict Of Interest for the Principal Investigator, Faculty Sponsor or Research Team (Sub-Investigators) listed on this protocol? No

What is the purpose in conducting this research? How does this study contribute to the advancement of knowledge and why is it worth doing?

About half the U.S. adult population suffers from chronic neuromusculoskeletal pain. While its evaluation and treatment are often addressed using soft tissue manipulation (STM), its efficacy is mostly based upon clinician judgement. Robust biomarkers are needed to quantify the effects of STM on patient outcomes. Among noninvasive methods to quantify the mechanics of myofascial tissue, most are limited to small (<10 mm2), localized regions of interest. In contrast, we propose to develop an approach to optically measure a larger (~100 cm2) field of deformation at the skin surface simultaneously as force is applied. We will derive biomarkers based on skin lateral mobility, compression, and distraction to infer distinctions in myofascial tissue stiffness. Specifically, we will deploy multiple cameras to track ink speckles whose fields of stretch deformation are resolved with digital image correlation. A preliminary system has been developed and evaluated in differentiating bilateral distinctions of the cervicothoracic region in a small group of participants, as a licensed clinician performs STM. These preliminary results indicate that the optically derived surface biomarkers can differentiate bilateral differences in skin mobility, with trend directions in deformation similar to measurements with an instrumented force probe. These findings suggest skin surface measurements are capable of inferring underlying myofascial tissue stiffness, although further confirmation requires a larger, more diverse group of participants. With the preliminary ability to differentiate tissue bilaterally, our next step is to collect sufficient data to prove we can differentiate tissue changes before and after STM intervention, in a larger cohort of participants, and refine system engineering requirements to apply for an NIH R21 or R01 award.

What will participants do in this study? Please provide an overall summary of the study plan. Where and when it will be conducted? What do you hope to learn from these activities? If the study has more than one phase, clearly map out the different phases. You will be required to describe the study components in more detail in later sections but use this paragraph to help your IRB reviewer to understand the general outline of the study. Other sections in the protocol form can be seen below.

The study will last a duration of about an hour, and take place on a single day. It will be conducted in a lab room of the PI, which is isolated from others in the space. We will recruit 30 participants. We hope to recruit people who show no tension in the upper back, others with moderate tension, and yet others tension to a greater degree. We will assign participants to a group based on the screening question, administered via Qualtrics, which will be asked of them upon their response to our email advertisement. We are attempting to screen so as to attain a balance in number of participants between the groups. Once a participant is selected to participate, we will invite them and have them sign the consent form. After this, they will complete a demographic questionnaire, administered verbally. Then, they will change into the clothing (e.g., sports bra, halter top, or swimming suit, etc.) that they were asked to bring in order to expose their upper back/neck region. This will take place in a separate, isolated room within the laboratory space, and we will provide them also with a gown for added privacy. 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. Next, the actual study procedures include that the proctors will apply a non-toxic, washable ink to the skin of the participant's upper back, in a square about 10 by 10 centimeters. This is easily washed off at the study’s conclusion. Once the ink is applied, we will ask the participant to lie down on a massage table. An experienced, trained, and licensed physical therapist will perform an assessment manually, where they will compress their fingers into the skin, as well as

stretch the skin laterally. The assessment is not anticipated to cause any pain to the skin. We will ask the participant to self-reported pain level using the questions from the study assessment. With a set of off-the-shelf cameras above the participant's back, we will record the movements of the fingers of the clinician as well as the participant's skin movements. The reason we use the ink is that it makes it easier for us to track the skin movements in high-resolution video. We will not record audio, and we will not record any images of any part of the participant other than the area defined in ink on the back. Once the clinician performs this assessment, on both left and right sides, she/he will perform a soft tissue massage intervention where she/he will use moderate massaging and compression. Following this intervention, we will perform a final assessment manually, as done when the study began. The cameras will send data to a laptop which then uploads data to a UVA Sharepoint server. Risk are minor and include that perhaps someone's skin could be irritated by the washable ink or the soap when washing it off. The participants would be compensated with a $25 gift card.

Is this study topic relevant to cancer risk factors, prevention, cancer treatment, or survivorship (e.g., pain, financial toxicity, etc.), or will the study purposefully include participants currently or previously diagnosed with cancer, or their caregivers?
No

(optional) **Study Overview file upload**: Below you have the option to upload additional files to help the Board better understand your study. You are not required to provide any additional explanation beyond completing the text boxes provided in this Study Overview section; however, for example, if you are using a new technology or a complicated process that would be more easily demonstrated with an image or video, you can upload the file here.

Participant Groups

Participant Group Name: Active

Age Range (years): 18-75

Vulnerable populations: no vulnerable population (none)

Maximum number of participants, in this group, expected to enroll over the life of the study: 15

Minimum number of participants, in this group, expected to enroll over the life of the study: 15

Total number of participants, in this group, ever enrolled: 0

Approximate number of participants, in this group, currently enrolled: 0

Future Enrollment: We will enroll participants, in this group, during the next twelve months

Approximate number of participants, in this group, expected to enroll in the next twelve months: 10

Have participants, in this group, withdrawn from the study in the past year? No

Describe the participants in this group.

Spontaneous pain and tenderness. Pain, with possible referred pain, and motor or autonomic symptoms on palpation. Restricted tissue mobility.

Will participants in this group be *compensated* **for taking part in your study?** Yes

Are any of the participants US citizens or US residents? Yes

This question applies only to participants who are US citizens or US residents.
Will participant payments be processed through an account administered by UVA? Yes

Participants are paid using UVA funds issued as: F

F: other form of payment (i.e. cash, gift card, gift) for value $100 or less.
Provide a justification for not issuing payments using UVA issued checks.

It is very straightforward and easier for both proctors and participants to purchase a gift card through Cavalier Computers and direct charge it to a Workday account.

Describe your payment process, including information about the amount participants will be paid and how payment will be issued and delivered to participants.

$25, Visa gift card, hand delivered to participant at conclusion of study day.

Participant Group Name: Latent

Age Range (years): 18-75

Vulnerable populations: no vulnerable population (none)

Maximum number of participants, in this group, expected to enroll over the life of the study: 15

Minimum number of participants, in this group, expected to enroll over the life of the study: 15

Total number of participants, in this group, ever enrolled: 0

Approximate number of participants, in this group, currently enrolled: 0

Future Enrollment: We will enroll participants, in this group, during the next twelve months

Approximate number of participants, in this group, expected to enroll in the next twelve months: 10

Have participants, in this group, withdrawn from the study in the past year? No

Describe the participants in this group.

Tender on palpation, but not spontaneously painful. May cause pain, a local twitch response, or referred pain with stimuli, e.g., compression. Restricted tissue mobility.

Will participants in this group be *compensated* **for taking part in your study?** Yes

Are any of the participants US citizens or US residents? Yes

This question applies only to participants who are US citizens or US residents.
Will participant payments be processed through an account administered by UVA? Yes

Participants are paid using UVA funds issued as: F

F: other form of payment (i.e. cash, gift card, gift) for value $100 or less.
Provide a justification for not issuing payments using UVA issued checks.

It is very straightforward and easier for both proctors and participants to purchase a gift card through Cavalier Computers and direct charge it to a Workday account.

Describe your payment process, including information about the amount participants will be paid and how payment will be issued and delivered to participants.

$25, Visa gift card, hand delivered to participant at conclusion of study day.

Participant Group Name: Normal

Age Range (years): 18-75

Vulnerable populations: no vulnerable population (none)

Maximum number of participants, in this group, expected to enroll over the life of the study: 15

Minimum number of participants, in this group, expected to enroll over the life of the study: 15

Total number of participants, in this group, ever enrolled: 0

Approximate number of participants, in this group, currently enrolled: 0

Future Enrollment: We will enroll participants, in this group, during the next twelve months

Approximate number of participants, in this group, expected to enroll in the next twelve months: 10

Have participants, in this group, withdrawn from the study in the past year? No

Describe the participants in this group.

Non-tender on palpation. No referred symptoms. Full, pain-free motion and function. Unrestricted soft tissue mobility.

Will participants in this group be *compensated* **for taking part in your study?** Yes

Are any of the participants US citizens or US residents? Yes

This question applies only to participants who are US citizens or US residents.
Will participant payments be processed through an account administered by UVA? Yes

Participants are paid using UVA funds issued as: F

F: other form of payment (i.e. cash, gift card, gift) for value $100 or less.
Provide a justification for not issuing payments using UVA issued checks.

It is very straightforward and easier for both proctors and participants to purchase a gift card through Cavalier Computers and direct charge it to a Workday account.

Describe your payment process, including information about the amount participants will be paid and how payment will be issued and delivered to participants.

$25, Visa gift card, hand delivered to participant at conclusion of study day.

Participant Summary

Participant Group Name: Active

Maximum number of participants, in this group, expected to enroll over the life of the study: 15

Participant Group Name: Latent

Maximum number of participants, in this group, expected to enroll over the life of the study: 15

Participant Group Name: Normal

Maximum number of participants, in this group, expected to enroll over the life of the study: 15

What special experience or knowledge does the Principal Investigator, Faculty Sponsor, and the Research Team (Sub-Investigators) have that will allow them to work productively and respectfully with the participants in this protocol and/or participant data?

The study team will include a non-UVa participant, who is a physical therapist faculty member at Indiana University to complete the hands-on part of the exam. The UVa part of the study team has experience in working with the camera setup and data processing pieces. Additionally, the CITIgroup training module has been completed for IRB-SBS by all participants of the research team carrying out this experiment.

The PI is Gregory Gerling, who serves as Professor of Systems and Information Engineering at the University of Virginia. He has conducted numerous prior human studies related to the sense of touch.

Sub-investigator M. Terry Loghmani serves as Associate Professor of Physical Therapy in the IU School of Health & Human Sciences.

She is a physical therapist, an orthopedic manual therapist, a certified massage therapist and an expert in instrument-assisted soft tissue manipulation. She has conducted prior human studies in a number of domains, and has been working with Gregory Gerling the last year as a part of an NIH U24 effort which seeks to understand mechanistic underpinnings of massage.

Sub-investigator Anika Kao is a 5th year Ph.D. student working with Gregory Gerling. She has conducted prior human studies on light touch discrimination and pleasantness.

What is the relationship between the participants of this study, and the Principal Investigator, Faculty Sponsor, and the Research Team (Sub-Investigators)? Does the Principal Investigator, Faculty Sponsor, or the Research Team (Sub-Investigators) know any of the participants personally or hold any position of authority over the participants (including but not limited to: grading authority, professional authority, etc.)? Do any of the researchers listed on the protocol stand to gain financially from any aspect of this research?

There are no relationships as described above.

Note that the PI will not carry out any participant studies, or have direct access to any identifying information. Therefore, students enrolled in courses taught by the faculty advisor will not be restricted from participation.

Additionally, the participants will not be known beforehand, and no researchers stand to gain anything financially from this research.

Recruitment & Consent

How will participants be approached or contacted for recruitment into the study?

We will contact participants through an email advertisement through the University of Virginia's College of Engineering. There will be no recruitment involving any courses taught by the PI. Upon a participant contacting us, we will follow-up by email to give them the Screening Question, via Qualtrics. This is done to determine who to invite to the study, as we are attempting to acquire roughly equal numbers of participants in the three groups.

If a potential participant does not qualify to be in the study, because, for example, we have too many "normal" participants. We will respond to let them know that they do not qualify. Otherwise, we will let them know that they do qualify and begin to schedule a day and time to participate.

Do participants have any limitations on their ability to *consent* ? No

Describe the limitations on their ability to consent:

What are the consent processes for this study?

> We will have a consent form for participants to sign directly before the experiment. The consent form will be presented by the study proctor. All participants will be able and willing to provide and document their consent.
>
> Students currently taking any course the PI is teaching will not be eligible until completion of the course final (December 7, 2023).

Will participants be deceived and/or have information withheld from them about the study? No

Will participants be debriefed? No

Recruitment & Consent Tools

Consent or Assent (signature required)
View File: IRB6201InformedConsentAgreement5.docx
date uploaded: 2023-09-27, by: Gerling, Gregory *(gg7h)*
This file is approved.
date approved: 2023-10-25

Recruitment
View File: IRB6201RecruitmentEmail3.docx
date uploaded: 2023-09-27, by: Gerling, Gregory *(gg7h)*
This file is approved.
date approved: 2023-10-25

Recruitment
View File: IRB6201ScreeningQuestion.docx
date uploaded: 2023-09-25, by: Gerling, Gregory *(gg7h)*
This file is approved.
date approved: 2023-10-25

Associate Recruitment & Consent Tools with Participant Groups

Participant Group Name: **Active**
✓ Recruitment & Consent Tool: **IRB6201InformedConsentAgreement5.docx**
✓ Recruitment & Consent Tool: **IRB6201RecruitmentEmail3.docx**
✓ Recruitment & Consent Tool: **IRB6201ScreeningQuestion.docx**

Participant Group Name: **Latent**
✓ Recruitment & Consent Tool: **IRB6201InformedConsentAgreement5.docx**
✓ Recruitment & Consent Tool: **IRB6201RecruitmentEmail3.docx**
✓ Recruitment & Consent Tool: **IRB6201ScreeningQuestion.docx**

Participant Group Name: **Normal**
✓ Recruitment & Consent Tool: **IRB6201InformedConsentAgreement5.docx**
✓ Recruitment & Consent Tool: **IRB6201RecruitmentEmail3.docx**
✓ Recruitment & Consent Tool: **IRB6201ScreeningQuestion.docx**

Data Sources

Data Source Name: Demographic questionaire

When will the data be collected? Data will be collected after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

> Demographics will be collected, post the consent form being signed.

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? No

Are the participant's identifying information included as part of the data at any time? No

How will you receive the data so that the data are not linked to identifying information?

> We will obtain these verbally and store them in a spreadsheet using the numerical identifier for that patient, and stored in a file structure/directory of the same number.

Data Source Name: Imaging data

When will the data be collected? Data will be collected after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

As part of the study, we will videotape the upper part of the participant's back. Someone's face will never be videotaped, nor will we record any audio.

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? Yes

What type(s) of recording device(s) will be used in this data tool? Video

Describe each recording device(s) and provide a justification for using the recording device.

We need the imaging information to capture the deformation patterns of the skin surface of the participant relative to the movements of the clinican's fingers. This is video data, taken at 30 - 100 frames per second. The recording devices is a raspberry PI camera, and we use three of them, aimed at the same point, so as to acquire 3D data from slightly distinct angles, so as to reconstruct the skin surface accurately. The exact model is a monocular camera (12 MP, Raspberry Pi High Quality, UK) with wide angle lenses (6 mm Vilros, Lakewood, NJ, USA) connected to microcontrollers (Raspberry Pi Zero W boards, UK).

Are the participant's identifying information included as part of the data at any time? No

How will you receive the data so that the data are not linked to identifying information?

A number will be assigned to each participant, starting at 1 and following. This number will be added to the signed consent forms. These forms will be stored as noted above. Andy data linking identifying information will be stored securely and separately from the imaging data.

Data Source Name: Verbal pre and post pain assessment

When will the data be collected? Data will be collected after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

Pain levels of the participant at the point of each manual assessment, i.e., before and after the massage intervention. These are to be taken bilaterally. We will associate this data with the imaging data to determine of the level of pain is associated with mechanical deformation cues we observe, e.g., amount of skin strain.

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? No

Are the participant's identifying information included as part of the data at any time? No

How will you receive the data so that the data are not linked to identifying information?

We will obtain these verbally and store them in a spreadsheet using the numerical identifier for that patient, and stored in a file structure/directory of the same number.

Associate Data Sources with Data Sources

If you are you linking the participants in a data set with their content in a different data set, use this section to associate and describe the linked Data Sources.

Data Source Name: **Demographic questionaire**
(not associated with other Data Source)

Data Source Name: **Imaging data**
(not associated with other Data Source)

Data Source Name: **Verbal pre and post pain assessment**
(not associated with other Data Source)

Associate Data Sources with Participant Groups

Participant Group Name: **Active**
✓ Data Source Name: **Imaging data**
✓ Data Source Name: **Verbal pre and post pain assessment**

Participant Group Name: **Latent**
✓ Data Source Name: **Imaging data**
✓ Data Source Name: **Verbal pre and post pain assessment**

Participant Group Name: **Normal**
✓ Data Source Name: **Imaging data**
✓ Data Source Name: **Verbal pre and post pain assessment**

Data Sources Upload

Instrument
View File: IRB6201DemographicSurvey.docx
date uploaded: 2023-09-25, by: Gerling, Gregory *(gg7h)*
This file is approved.
date approved: 2023-10-25

Instrument
View File: IRB6201StudyAssessment1.docx
date uploaded: 2023-09-25, by: Gerling, Gregory *(gg7h)*
This file is approved.
date approved: 2023-10-25

Permission to Access Data Source and Participant Group

Are there any rules or restrictions to access Data Sources and/or Participant Groups? No

Permissions and/or Agreements

Data Reports & Storage

How will data/materials be stored? What measures will be taken to secure these data during collection and analysis? If the data includes recordings, what will be done with the recordings (including if/when the recordings will be destroyed)? Describe the long-term plan for maintaining the data when the active research phase is completed. Please note that you may need additional "material release" consent forms if you are using recordings for purposes beyond the study.

Data and materials will be stored on a private, password-protected, local computer, before being uploaded to a UVA Sharepoint server. The files storing raw data from the study are stored within a password-protected folder; whereas the folder containing all identifying information will be stored in a separate password-protected folder. This machine is kept in a private laboratory which requires UVA ID Access to enter.

Study data will be stored locally and securely until aggregated and processed. Identifying information will be destroyed following completion of data analysis.

How will data/materials be reported for this study? Will the results be reported in aggregate or will individual data be discussed?

In general, the data will be aggregated per each of the study groups. That said, it could be that there are observed to be particular participants who are outliners and their data maybe highlighted.

If a participant decides to withdraw from the study, how will you handle their data?

Within 24-hours of a request to withdraw from the study, all data related to that participant will be destroyed.

Do you plan to publish your raw data after the study is completed *(i.e. open-access or open source publishing)*? Yes

Will other parties (i.e. other corporations, institutions, researchers) have access to or retain a copy of the data? Yes

International Research

Risks & Benefits

Is loss of confidentiality and/or privacy a risk to participants? No

Describe any remaining potential risks to participants. For example, are any of your participants or participant groups "risk-sensitive"? Include information about the probability of harm (i.e. how likely it is that harm will occur). What will be done to reduce risk to participants? If something unexpected involving risk happens, how will you handle it?

There is a very small chance that the ink applied, or the soap used in washing it away, might irritate a participant's skin. We are videotape recording the upper part of the back. We are not recording faces or any audio. There is a very small chance that someone could be recognized by geometric features on their back.

Are there direct benefits to the participants in this study? No

Describe the overall benefit of this study.

There is no direct benefit to the participant. The overall benefit of the study is to further our understanding of if we can image the skin surface deformation patterns which might be associated with underlying myofasical stiffness. Such knowledge could benefit those who present musculoskeletal pain in the future.

Continuation

Are you applying for a continuation of your protocol's approval? No

Modification

Does this protocol version include any changes that were made to the previously approved protocol (protocol form, consent documents, etc)? *Minor edits are considered changes!* No

Unexpected Adverse Events

Did a negative event associated with the research occur and does it meet one of the following conditions:

is not described as a possibility in the previously approved protocol OR;

did not occur within the parameter described (i.e. an increase in frequency or severity)?

No