PROTOCOL TITLE: The Effect of Volitional Transversus Abdominis Contraction on Time to Peak Sagittal Ground Reaction Force during Gait in Patients with Knee Osteoarthritis

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The Effect of Volitional Transversus Abdominis Contraction on Time to Peak Sagittal Ground Reaction Force during Gait in Patients with Knee Osteoarthritis

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1.0 Objectives*

1.1 The purpose of this study is to study the effects of core activation on knee joint loading during ambulation in patients with knee osteoarthritis (OA). This study aims to investigate the effects of transversus abdominis (TA) activation during simultaneous kinetic analysis of time to initial peak ground reaction force (T_1) at the heel in the sagittal plane.

The objective of this study is to determine whether patients with knee OA demonstrate changes in T_1 during comfortable gait speeds when actively contracting the TA muscle. In addition, this study will serve as a pilot study in order to perform a post-hoc power analysis for future study on the effects of the independent variable (TA contraction/changes in core stability) on the dependent variable (T_1).

1.2 Null hypothesis: There will be no change in T_1 in patients with knee OA during gait while contracting their TA.

Alternate hypothesis: There will be a decrease in T_1 in patients with knee OA during gait while contracting their TA.

2.0 Background*

2.1 This will be the first study on this topic performed by the investigator. Regarding current knowledge gaps, evidence has shown an influence of core strength measures/stability on lower extremity function. This relationship has been examined very little in patients with knee OA; however, evidence does show a correlation exists. There have been no studies examining the effect of a core strengthening/stability intervention on lower extremity kinetics in patients with knee OA to the PIs knowledge.

2.2 This is the first study examining the effects of TA contraction knee loading during gait in this population.

2.3 Current evidence shows that core activation/stability may play a role in lower extremity kinetics and kinematics. Most research has focused on younger, more athletic individuals. Research on this population has in the past looked at patellofemoral disorders or ligamentous injury. For example, decreased core function has been shown to increase the risk of sustaining anterior cruciate ligament injury. In addition, increased core stability has resulted in decreased knee loading during athletic activities.

There continues to be an overall paucity of research on proper prescription

and dosage of therapeutic exercise for patients with knee OA. Evidence has shown that quadriceps strengthening and aerobic conditioning do lead to decreased disability. Additionally, correlations have been shown between core stability and functional ability as measured via the Western Ontario and McMaster Universities Osteoarthritis Index. Patients with knee OA also exhibit decreased overall core stability as compared to healthy controls. This body of research however does not include any evidence on the effects of a core stability intervention on improving overall function.

Knee OA leads to abnormalities in kinetic loading of the lower extremity during ambulation. An increase in T_1 in this population has been observed when comparing to healthy controls. Separately, studies have shown that in patients with knee OA, knee joint loading can be influenced by intraarticular hyaluronic acid injections, resulting in decreased T_1. Therefore, this study will explore the idea of how activation of a muscle (TA), which plays a large role in core stability, influences kinetic loading (T_1) during ambulation in patients with knee OA.

3.0 Inclusion and Exclusion Criteria*

3.1 The PI will screen potential participants either in person, via medical record review (TherapySource in Rehabilitation Faculty Practice Clinic), or via phone conversation. The PI will also ask other clinicians if they are aware of anyone who may meet the inclusion criteria who may be willing to participate.

3.2 Inclusion criteria for the study will include those with medical diagnosis (providing written evidence from a physician, physician assistant, or nurse practitioner) of knee OA unilaterally or bilaterally. Exclusion criteria for the study will include: bilateral total knee arthroplasty, requirement of an assistive device or assistance with ambulation, spinal diagnoses which contraindicate participation in spinal stabilization activities, and those currently limited by another lower extremity pathology at the time of participation.

3.3 The following populations will be excluded from participation. Adults unable to consent may have difficulty following the cues to activate the TA while ambulating. Pregnancy women and younger individuals do not typically present with knee OA. Prisoners are admitted for treated in the School of Allied Health Professions (SAHP) as they are all served by University Health facilities.

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)

- Pregnant women
- Prisoners

4.0 Study-Wide Number of Subjects*: NA

5.0 Study-Wide Recruitment Methods*: NA

6.0 Multi-Site Research*: NA

7.0 Study Timelines*

7.1 Each participant will only be required to participate for one session, lasting about 1 hour. This does not included the informed consent process requiring approximately 30 minutes of their time prior to participation. Approximately 5 months will be required to enroll all participants. It is the PI's goal to complete primary data analysis no more than 3 months after data collection is complete, so total estimated study time is 8 months.

8.0 Study Endpoints*

8.1 The primary study endpoint will be the cessation of data collection and the participants' active participation in the research program. The Secondary endpoint will be the completion of data analysis, which concludes the management of PHI.

8.2 Primary (exposure to any physical risk) and secondary (management of PHI) safety endpoints are synonymous with the study endpoints mentioned in 8.1.

9.0 Procedures Involved*

9.1 This project serves as pilot study for future investigation on the role of core stabilization on gait kinetics in patients with knee OA. Therefore the sample size will be small. Post-hoc power analysis will inform the PI about requirements for participant recruitment needs for future investigations.

9.2 After informed consent is completed, participants will be scheduled for a session in the Motion Analysis Laboratory in the SAHP. Patients will have already been asked to wear close fitting, exercise appropriate clothing to allow marker placement, and prevent marker blocking during motion analysis. Data collection will begin by collecting the following anthropometric data: body weight (pounds, converted to kilograms) via a scale, height (inches, converted to mm) via a tape measure, leg length from ipsilateral anterior superior iliac

spine to ipsilateral medial malleolus bilaterally (cm) via tape measure, and knee and ankle joint widths (cm) via a caliper. After collection of this data is completed and recorded, the PI will place reflective markers on the patient's skin via adhesive tape made for this purpose at the following landmarks bilaterally: ASIS, posterior superior iliac spine, lateral thigh, knee center of rotation, lateral leg, heel, lateral malleolus, and base of the second metatarsal. When this set-up is complete, static calibration of the motion analysis system will take place with the participant standing still in the capture area. When this is complete, the participant will be allowed a 2-minute warm-up by walking back and forth in the capture area. When this is completed the participant will be asked to walk at a comfortable pace across the capture area. Three trials with good force plate contact will be collected. After these three trials are obtained, the patient will lie supine on the mat in the lab, and will be taught how to perform a TA contraction. A Pathway MR-20 biofeedback device (The Prometheus Group, Dover, NH, USA) with two electrodes will be placed just medial to the ASISs on the participant's abdomen. A baseline maximal contraction will be performed supine, and the amplitude of contraction will be considered maximal voluntary isometric contraction (MVIC). The device will be set to provide audible feedback at 50% MVIC. The task will be repeated seated, standing, then ambulating three practice trials on the capture area. The participant will then be instructed to perform an additional three comfortable paced ambulation trials with good force plate contact while contracting the TA enough to cause audible feedback via the biofeedback device. After completing these three trials, the biofeedback device and reflective markers will be removed, and the participant will have completed their active participation in the study.

9.3

Procedure/Test	Rate of Occurrence
Anthropometric Data Collection	1
Reflective Marker Placement	1
Biofeedback Placement	1
TA Contraction Trials with Biofeedback	At least once per body position
Walking Trials without TA Contraction	3
Walking Trials with TA Contraction	3

- Exclusion criteria prevent participation of those who require assistance or assistive devices for ambulation, so safety during ambulation is thus minimized. The adhesive tape used in placement of the reflective markers is intended for placement on skin. In regards to PHI, the PI will be the only investigator involved in recruitment, informed consent, and collection of anthropometric data. All documentation of these aspects of the study will be kept in the PI's office in a drawer, with both the office and drawer able to be locked. The motion analysis data will be stored and analyzed on the computer in the Motion Analysis Laboratory under password protection, with the lab able to be locked.
- A tape measure, body weight scale, Pathway MR-20 biofeedback device (The Prometheus Group, Dover, NH, USA) with two electrodes, and Vicon Vero 2.2 Motion Analysis System will be used.
- Please see that attached Excel worksheet that will be used on data collection.

9.4 There is no long-term follow up for this study.

9.5 NA

10.0 Data and Specimen Banking*

10.1 Data banking will be performed at the conclusion of this study in order to use for research or post-hoc power analysis. The repository will consist of the digital data collected during the study. Data will be stored for a period of three years, and may only be accessed via password through the computer in the Motion Analysis Laboratory. Only the PI will have access to this data, and will only use the data with additional IRB approval of a new protocol. Anyone else wishing to use the data must first ask the PI permission before initiating a new protocol.

10.2 Data to be stored is the raw digital data (kinetic and kinematic) and analyzed (T_1) collected during motion analysis.

10.3 The PI, or another researcher after first asking permission of the PI, will have to submit an application to the IRB before using the stored data for any research purposes. After IRB approval of a new protocol, the password for the computer will be provided, and the researcher will have access to the raw data only. They will be responsible for any analysis that may be required for new variables.

11.0 Data Management* and Confidentiality

11.1 The three trials without and with TA contraction during ambulation will be analyzed to determine T_1 for each trial. The average of the three trials under each condition will be calculated. Statistical analysis will include a repeated measures, two mean comparison (a paired-samples t-test or Wilcoxon signed rank depending on results of assumption analysis). Statistical analysis will be performed using the most up to date version of SPSS available to the PI.

11.2 The study is serving as a pilot study for post-hoc power analyses of the variables under consideration for future study.

11.3 The computer, which stores and analyses the raw kinetic data, is password protected. Only the PI and the faculty member in charge of the lab have the password. In addition, only the faculty of the SAHP has access to the lab via key entry. All participants will be given a code-identifier, with a key kept in the compliance binder for the study (also containing informed consent documentation). This compliance binder will stay in the PI's office in a locked drawer.

11.4 Once the raw data is saved on the computer, the files will be backed up on a flash drive which will also be kept in a locked drawer in the PI's office.

11.5

- Data will be stored on the computer in the motion lab, and analyzed data will be backed up on a flash drive locked and stored in the PI's office drawer.
- Data will be stored for three years per the data banking procedure noted in section 10.1-10.3.
- See 10.1-10.3 for persons having access to the data.

12.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

12.1 NA; pending the IRB agrees with the PI there is no more than minimal risk to participants in this research protocol.

13.0 Withdrawal of Subjects*

13.1 The PI does not anticipate any circumstances where a participant may wish to withdraw since this study only requires a very short-term in-person participation. However, if after data collection a participant contacts the PI wishing to not be included in any data analysis/publication, their data will be withdrawn from analysis.

13.2 As soon as a participant informs the PI they wish to withdraw, a notation will be made in the compliance binder, and their data will not be analyzed upon data analysis.

13.3 Due to the brief nature of participation and data collection, anyone who withdrawals from the study cannot be used for data analysis.

14.0 Risks to Subjects*

14.1 The only foreseeable discomfort a participant may have is some muscle soreness within 48 hours from the ambulation and TA muscle contractions involved. Also, there is a possibility of the adhesive tape pulling any hair present on the skin when removed.

14.2 NA

14.3 NA

14.4 NA

15.0 Potential Benefits to Subjects*

15.1 There is a possibility of the research concluding that core stabilization may be beneficial to this population. If that is the case, the PI could communicate this to the participants in order for them to use this in their decision making when is comes to rehabilitative interventions they may undergo in the future.

15.2 There is no direct benefit for participation, only indirect for future use by the patient in their future rehabilitative decisions.

16.0 Vulnerable Populations*: NA

17.0 Community-Based Participatory Research*

17.1 NA

18.0 Sharing of Results with Subjects*

18.1 The results of the study will be shared with participants after their participation if they indicate after questioning to the affirmative after data collection is complete. The results will be shared via a mail out from the PI after completion of the study.

19.0 Setting

19.1 All recruitment, informed consent, data collection, and data analysis will be completed in the SAHP at LSUHSC-Shreveport. Data collection will be performed in the Motion Analysis Laboratory in the SAHP.

20.0 Resources Available

20.1 The PI is a licensed physical therapist specializing in orthopaedics. The PI has training in motion analysis. A professor from another physical therapy at Texas Woman's University (TWU) in Houston will be present to assist with working the Vicon System in order to facilitate data collection and train the PI on data analysis of the raw data. The visiting professor is a tenure associate professor at TWU who has published in the area of motion analysis in PT in the past.

20.2

- The Rehabilitation Faculty Practice Clinic treats many patients with knee OA, and has treated many in the past. There are dozens of potential applicants the PI has access to through the clinic. It is more feasible to recruit this small sample size in a short period of time due to the nature of this particular study.
- The PI has a faculty contract which allows for 30% effort towards research/scholarship. During the time this study is ongoing, 2/3 of this time will be devoted completely to this project.
- The Motion Analysis Laboratory is located on the second floor (room 2-217) in the SAHP. The lab is 700 square feet, and has a Vicon Vero 2.2 (8 camera) motion analysis system with 2 AMTI force plates embedded in the raised platform (8 x 24 ft). There are two desktop monitors connected to the computers used for data collection and analysis for viewing of output and processing.
- The PI is the author of the protocol, and the only full-time investigator.

21.0 Prior Approvals

21.1 NA

22.0 Recruitment Methods

22.1 Participants will be recruited either in person or via phone call. The PI will speak with other clinicians in the Rehab Faculty Clinic as to whether they know any patients who may fit the selection criteria. In addition, the PI will do a chart review in TherapySource in order to find any past patients who fit the criteria. Once someone is identified, the PI will use his or still a current patient in the clinic, the PI will approach him or her in person at his or her next scheduled visit.

22.2 The subjects will be recrtuied from current and past patients in the SAHP Rehab Faculty Clinic.

22.3 TherapySource, the documentation system in the clinic, will be reviewed for patients who fit the criteria, in addition to speaking with other therapists in the clinic.

22.4 NA

22.5 NA

23.0 Local Number of Subjects

23.1 Three to five participants will be recruited for the purposes of this pilot study.

23.2 NA

24.0 Provisions to Protect the Privacy Interests of Subjects

24.1 The participants will only interact with the PI directly during both the informed consent process and in data collection. The visiting professor who will be working the motion system will be present in the room during data collection; however, the PI will be performing all instruction, data collection, and leading the investigation.

24.2 The PI will have already met all the participants during informed consent, and may even be familiar with him from their time receiving treatment in the clinic. In addition, the lab is located two floors above the clinic, and is a private setting, so there is a reduced risk of them being observed by anyone not participating in the research.

24.3 The PI is able to access any information at any time since he is protecting all the hardcopy and digital data. No one else will be able to access the information.

25.0 Compensation for Research-Related Injury

25.1 NA; pending the IRB agrees with the PI there is no more than minimal risk involved.

25.2 NA; pending the IRB agrees with the PI there is no more than minimal risk involved.

26.0 Economic Burden to Subjects

26.1 Other than the cost of transportation, there will be no costs incurred by participation in the study.

27.0 Consent Process

27.1

Informed consent will take place in the Rehabilitation Faculty Practice Clinic in the SAHP.

- Informed consent will take place on a separate day from data collection; therefore, there will be a waiting period between consent and participation.
- Upon presenting to the lab for participation in data collection, the PI will verify verbally with the participant they still wish to participate. It will be the participant's responsibility to contact the PI after participation is complete in order to withdraw from data analysis.
- The PI will be the sole obtainer of informed consent, and will follow SOP.

Non-English Speaking Subjects

- NA; due to the brief nature of the study, the PI will not recruit those who cannot speak and understand English

28.0 Process to Document Consent in Writing

28.1 The PI will be following the SOP of informed consent set by the LSUHSC-Shreveport IRB.

29.0 Drugs or Devices

29.1 NA

29.2 NA