EXAMINING LUMBOPELVIC-HIP COMPLEX FUNCTION IN PATIENTS USING ULTRASOUND IMAGING

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APPROVAL OF THE DISSERTATION

This dissertation, "Examining Lumbopelvic-Hip Complex Function in Patients using Ultrasound Imaging", has been approved by the Graduate Faculty of the Curry School of Education in partial fulfillment of the requirements for the degree of Doctor of Philosophy.

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ABSTRACT

The lumbopelvic-hip complex is comprised of a variety of muscles, including: both larger, global movers, and smaller, local stabilizers. One of the frequently studied local stabilizers is the transverse abdominis (TrA), which has documented dysfunction in the non-specific low back pain (NSLBP) population. The TrA has also been used as a representative of core function in many of these studies by providing muscle thickness changes and activation. Ultrasound imaging (USI) is commonly used to provide a real-time view of muscle thickness and is reliable in not only static, rested positions, but also during movement in functional tasks. Due to the preparatory nature of TrA contraction prior to movement, its influence on motion at the extremities becomes of great interest to further understanding the role of core stability in individuals with injury, specifically chronic musculoskeletal injury. Core or trunk involvement in other chronic musculoskeletal injuries, such as patellofemoral pain (PFP) have been a focus recently in sports medicine research. Most of the recent studies have only examined core endurance, through plank or bridging tasks, however the examination of the role of local spinal stability prior to movement could develop the understanding of this challenging pathology. *The examination of effects on TrA activity in various positions and plank endurance times following a 4-week impairment-based rehabilitation program addresses both the specific core muscle activity and core endurance aspect aforementioned.* Another muscle group within the lumbopelvic-hip complex that has been linked to PFP are the gluteal muscles due to their role at the hip, pelvis, and distal influences at the

knee. The gluteus medius (Gmed) has been the prime muscle of interest for most researchers due to its known weakness and diminished neuromuscular control in the literature. Gluteus maximus (Gmax) contributes to this overall dysfunction, however its role as a larger, global mover becomes less of a focus in many descriptive and rehabilitation-based studies. An increase in knowledge of how the Gmax and Gmed, collectively and individually, function is important in addressing deficits found in the PFP population. Strength assessment and muscle activation, via electromyography (EMG), are the most common methods of collecting muscle function of the Gmax and Gmed. Though, these methods do not provide a visual of the actual tissue moving real-time and cannot account for spatial or morphological changes of the muscles. USI, as utilized in NSLBP, could serve this role in the PFP population and act as an adjunctive method of muscle activity assessment. Gmed and gluteus minimus ultrasound has been performed in other studies, but with only a healthy population or individuals with hip pathology. These prior studies have also predominantly used M-mode USI, which provides information on onset of muscle motion and timing, but not static images of muscle thickness obtained by the use of B-mode USI. Fascial borders of muscle tissue are necessary to visualize clearly to measure muscle thickness and B-mode imaging has been shown to have the optimal fascial view over M-mode. *The determination of Gmax and Gmed activity following an impairment-based rehabilitation program assessed through USI and EMG serves as a dual approach to muscle activity in a PFP population and allows clinicians to understand not only how the glutes are activating electrically, but*

moving spatially as well. Due to the influence of proximal structures on chronic pathologies involving the lumbopelvic-hip complex, it is important for researchers and clinicians in the sports medicine community to identify a potential common thread between these pathologies. USI is advantageous in the determination of this potential common thread as it allows a non-invasive, real-time, reliable view of this deeper musculature. The relationship between core stability and lower extremity function has been explored recently as well and seems to be relevant to sports medicine and health care professionals, especially in regard to tracking injury occurrence and effects of rehabilitation. Since the TrA is one of the deeper local stabilizers that contracts in a preparatory manner before limb movement, it becomes of increased interest as the probable commonality. *Quantification of TrA activity in individuals with chronic musculoskeletal conditions, including: NSLBP and PFP, and the comparison of those individuals to their healthy counterparts would answer the commonality question.* Just as core endurance has migrated into studies of pathologies beyond just low back pain, more fine motor control at the local level is the logical next step. *Therefore, the overall purpose of this study is to determine lumbopelvic-hip function, through TrA activation, core endurance, Gmax and Gmed activation, following rehabilitation in those with PFP and TrA activity at baseline in those with PFP, NSLBP, as compared to healthy individuals.*

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CORE MUSCLE FUNCTION AND ENDURANCE IN PATIENTS WITH PATELLOFEMORAL PAIN FOLLOWING IMPAIRMENT-BASED REHABILITATION

ABSTRACT

Context: Patellofemoral pain (PFP) is a common knee injury suffered among active individuals and some rehabilitation programs for PFP target hip muscle dysfunction. However, evaluation of core muscle function in this pathology or after rehabilitation is uncommon. **Objective:** To examine effects of a 4-week impairment-based rehabilitation program with a core-focused component. Muscle activity of the transversus abdominis (TrA) in various functional positions and endurance (forward and side plank times) were compared before and after rehabilitation. **Design:** Prospective cohort study. **Setting:** University laboratory. **Patients or Other Participants:** 19 PFP patients (23.7±4.8yrs, 168.7±6.8cm, 69.6±15.1kg, 14F, 5M) completed 12 clinician-supervised rehabilitation sessions over a 4-week period. **Intervention(s):** The rehabilitation program was based on individual patient deficits, measured prior to their first session, and included lower extremity range of motion, strength, core strength, and movement patterns during functional tasks. Patients were progressed based on their specific performance, corresponding with the individual impairment-based model. **Main Outcome Measure(s):** Prior to the first session and following the final session, ultrasound imaging (USI) thickness measures of TrA in 4 positions (tabletop, bipedal stance, unipedal stance, and during a single leg squat (SLS)) and plank times (forward, side) were collected. A traditional activation ratio was calculated for tabletop (abdominal draw in maneuver/resting thickness) and functional activation ratios were used for the unipedal and SLS positions (divided by thickness in quiet bipedal stance). TrA thickness in each position was normalized by dividing by body mass in kilograms. Forward planks and bilateral side planks were timed to failure. Repeated measures ANOVA was utilized to

compare all measures before and after rehabilitation and a secondary analysis was used to compare thickness and activation in each position. **Results:** There was no time main effect for TrA thickness or activation following rehabilitation (p=.37), but a significantly longer plank time was observed (p=.002) after rehabilitation. There was a significant position main effect for rested (p<.001), and contracted thickness for tabletop vs. SLS (p=.003), bipedal vs. SLS rested (p=.006), and unipedal vs. SLS rested thickness (p=.002). The functional activation ratio for SLS was greater than the unipedal ratio (p<.05). A position main effect was observed between front planks and side planks on the non-PFP limb (p<.001) and between side planks on the PFP limb vs. non-PFP limb (p=.001). **Conclusions:** Despite improvements in symptoms following the impairment-based rehabilitation program, the absence of change in core muscle activity over time may indicate varying motor strategies in individuals with patellofemoral pain. The utility of performing core exercises in different positions, not only in tabletop positions, can be helpful to engage the TrA, as evidenced by positional changes. Increased endurance in plank times support the inclusion of a core muscle focus in an impairment-based rehabilitation.

Word Count: 447

Key Words: transverse abdominis, rehabilitation, planks

INTRODUCTION

Patellofemoral pain (PFP) is a common knee injury suffered among active individuals, accounting for 7.3% to 25% of knee pathologies.[1,2] PFP has an unclear etiology, and can be very problematic as the insidious onset of peri- or retropatellar pain has an effect on various activities such as: running, jumping, squatting, prolonged sitting, kneeling, and stair ambulation.[3–6] In most rehabilitation programs for individuals with PFP, hip muscle and/or quadriceps dysfunction has been targeted,[7,8] however the role of more proximal muscles, such as deeper tissue that is part of the lumbopelvic-hip complex, is under-studied. A more recent investigation has included exercises targeting core stability into patellofemoral pain rehabilitation.[9] The traditional approach to rehabilitation has also been challenged with the concept of an impairment-based exercise prescription.[8] Individuals begin the program based on an initial comprehensive evaluation and are progressed based on individual performance.[7] This method more closely mirrors clinical practice as opposed to a single program applied to all individuals suffering from the same broad pathology. Strength, range of motion, and movement patterns during functional tasks are some of the specific findings that dictate the progression of the impairment-based rehabilitation model.[8] This technique addresses the variety of clinical subgroups in PFP and directs the therapeutic exercise focus to specific deficits for each participant or patient.[7,10]

The notion of the proximal link to a distal problem[11,12] has been proposed for hip musculature in the PFP population, although core muscles, especially deeper stabilizers may play a similar role. Patients with PFP that completed a rehabilitation program that

included core exercises along with the traditional hip focus had an earlier resolution pain as well as greater overall strength gains, compared to a knee-only strength plan.[9] However, it is unknown whether changes occur in the deep abdominal stabilizers as exercises are directed to deficits throughout the lower extremity and hip in patients with PFP. Therefore, the assessment of a deeper core stabilizer, such as the transverse abdominis (TrA) may provide a unique account of another proximal link. Core stability has been assessed in a variety of ways in the literature, but most commonly through plank exercises in studies focused on those with PFP.[9] Abdominal muscle activity in isolation and during a specific function, such as a single leg squat (SLS) could provide a more comprehensive assessment of core stability, while plank hold time assesses endurance.[13] Using an approach that encompasses core muscle activity during a specific task in addition to an endurance-focused task is well documented in the low back pain literature.[13,14]

Ultrasound imaging (USI) of the TrA allows clinicians and researchers to view core musculature activity in static and functional positions. This provides a reliable manner to assess spinal stabilizing muscle thickness in tabletop positions and during more functional, gravity-loaded positions. The use of an activation ratio is prevalent in the low back pain literature and compares muscle thickness in a contracted state versus resting to indicate the capacity for the muscle to change during a volitional contraction. When assessing the TrA using USI, the contracted state is during an abdominal draw-in maneuver.[15] This activation ratio provides great insight into muscle activity in a static position and how the individual can target activation or contraction of the TrA, but

becomes difficult to transfer this same ratio to a more functional position. For standing and specifically, single leg stance and single leg squat positions, a functional activation ratio has shown to be more representative of TrA activity beyond a quiet stance condition.[16] This normalization strategy is similar to that of electromyography when normalizing a peak amplitude during an activity or exercise to a quiet stance measure. When individuals have pain and dysfunction during many functional and loaded positions, such as those that provoke pain in patients with PFP,[1,3,17] it is important to have a measure of muscle activity that accounts for the difference in a dynamic versus static condition. Understanding the role of the core musculature and how it may be addressed with an impairment-based model could be beneficial for those with PFP, especially in a subgroup that may have a greater proximal weakness or neuromuscular dysfunction. The inclusion of planks represent the endurance factor and more global activation of lumbopelvic-hip muscles, which could also contribute in the proximal link to the distal problem.[11,13,18] Therefore, the purpose of this study was to examine the effects of a 4-week impairment-based rehabilitation program on TrA muscle thickness in 4 different positions (tabletop, bipedal stance, unipedal stance, single leg squat) and front and side planks, representing a specific function task and endurance task, respectively before and after a 4-week impairment based rehabilitation program in individuals with PFP. We hypothesized that there would be improvements in TrA activation and plank times after the rehabilitation. We also expected position effects to be present in normalized rested thickness, contracted thickness, and TrA activation and may change after rehabilitation for PFP.

METHODS

Study Design and Population

This prospective cohort study was conducted over a 4-week period with 12 supervised rehabilitation sessions. Individuals were determined to have patellofemoral pain by a self-report of an insidious onset of symptoms, presence of a peri- or retropatellar knee pain during at least two of the following functional activities: running, jumping, squatting, prolonged sitting, kneeling, stair ambulation. Participants also had to have experienced their knee pain for more than 3 months, with a pain level of at least 30mm out of 100mm on a visual analog scale. The Anterior Knee Pain Scale was also administered and participants must have attained a score of 85 or less. Individuals were excluded if they had a previous knee surgery, internal derangement, ligamentous instability, other sources of anterior knee pain (i.e. patellar tendinitis), any lower extremity neurological symptoms, muscular abnormalities, or current pregnancy. The sample size determination for this study was made based on previously reported side plank time changes following rehabilitation in a PFP population (MDC: 58.8, SD: 49), using an alpha level set to 0.05, β=0.8, indicating 11 participants in order to achieve adequate statistical power.[18] Additional demographic information including details of patellofemoral pain duration, physical activity, and disability are detailed in Table 1. Institutional Review Board approval was granted for this study and all participants provided informed consent prior to participation. All assessments for this study were obtained at initial baseline prior to rehabilitation and within 48 hours of completion of the 4-week, 12 session rehabilitation program.

Instruments

Muscle thickness measures were taken using a Siemens Acuson Freestyle ultrasound unit (Siemens Medical, Mountain View, CA) with an 8-MHz wireless linear transducer. All tabletop measures were taken with the transducer held by the investigator (LCM) and all bipedal, unipedal, and single leg squat measures were taken with the linear transducer fixed to the lateral abdominal wall with a foam block and elastic Velcro belt as used in prior studies.[16] A stopwatch application on an Apple iPhone 6 (Apple Inc, CA) was used to time plank time-to-failure for all participants.

Rehabilitation Program

A 12-session rehabilitation program was supervised by a certified athletic trainer (ASM) with 7 years of clinical experience over a 4-week period. The baseline data collection session that determined the starting point for all aspects of the rehabilitation program, included: hip and knee range of motion, strength, core strength, and movement patterns in functional tasks.[19] USI of the lateral abdominal wall and plank times (front and side) were collected during this initial assessment as well, but were not used to dictate the progression of the impairment-based model. The current classification of subgroups with the PFP population is based on the presence of weakness in the hip abductors and quadriceps, patellar mobility, foot posture, and lower extremity muscle tightness. The areas assessed in the initial baseline for rehabilitation addressed each of these areas, which allowed for investigators to designate their starting point in the exercise protocol to the supervising clinician. All strengthening exercises originated at a percentage of their maximal strength from that initial collection, while the progression of each exercise was based on individual performance and clinician judgment[7,8] and this same model has been completed in other chronic musculoskeletal condition treatment.[20] The first two weeks of

the 4-week rehabilitation included exercises that all individuals performed, but set and rep progression was still personalized. Some of those exercises included: seated knee flexion and extension, wall squats, isometric hip abduction and external rotation, clam shells, pelvic tilts prone and on a Swiss ball, and single leg balance with eyes open and closed. Functional task movement quality had an increased focus in the exercise protocol in the final two weeks for all participants, regardless of their progression throughout the remainder of the individual impairment model.[19] These specific exercises and functional tasks were meant to target the gluteal muscles, quadriceps, hamstrings, and gastrocnemius, however there were also core strengthening exercises that were a consistent component within the protocol. The abdominal draw-in maneuver was instructed throughout the 4 weeks and was performed while lying supine or prone on a table, as well as while seated on a Swiss ball to increase proprioception and neuromuscular control. Participants reported pain throughout each rehabilitation session in order for the clinician to make necessary adjustments to their progression throughout the exercise sessions.

Ultrasound Imaging

Tabletop Imaging

Participants were placed in a supine hook-lying position with a bolster placed under their knees to ensure a relaxed abdomen. Ultrasound gel was placed on the lateral aspect of the abdominal wall, approximately 10cm lateral to the umbilicus and the transducer was placed on the gel.[21] An image was captured when the apex of the musculotendinous junction of the transverse abdominis, just deep to the external and internal oblique muscles. Images were captured at rest upon exhalation during normal breathing for each

individual. Participants were also instructed to perform an abdominal draw-in maneuver for a contracted image, which was used for the activation ratio in the tabletop position.[15] Three images[22] were captured on the right side of the abdomen, followed by the left side, and images were saved onto the ultrasound unit for later export.

Bipedal Stance Imaging

Upon completion of the tabletop image collection, participants were instructed to stand with their feet shoulder width apart and to look forward, with arms relaxed to their side. The ultrasound transducer was placed in the same position as the tabletop measures, but was fixed to the lateral abdominal wall with a foam block and Velcro elastic belt.[16] Three rested images were taken in the same manner as the tabletop images and were also saved for exporting.

Unipedal Stance Imaging

The unipedal, or single leg stance, images were taken with the transducer within the foam block and belt on the same side as the stance limb. Images were taken on the right and then left sides, again in a series of 3 images per side as the other positions. Participants were instructed if they felt unsteady or if they were going to lose their balance, to put their other foot down on the ground to avoid any falls.

Single Leg Squat Imaging

The final position of image collection was at peak knee flexion during a single leg squat. Transducer and belt placement was the same as the bipedal and unipedal positions. Participants were instructed to perform a single leg squat as far as was comfortable on both limbs, starting with the transducer on the right side of the abdomen and performing a right single leg squat and then repeated on the left, three times each. Images were

captured at peak knee flexion, just as the participant began to ascend to complete the squatting motion.

Front and Side Plank Time-to-Failure

Participants completed front or ventral planks, as well as planks on their right and left sides. These planks were timed to failure in seconds, which was defined as falling out of the testing position or if the participant chose to stop the trial. Individuals were instructed to maintain a body position parallel to the floor without their hips dropping toward the floor. A towel was placed on the floor to avoid participants slipping out of the plank position due to the floor surface only.

Data Processing and Statistical Analysis

Muscle Thickness Normalization

In order to compare muscle thickness pre-and-post rehabilitation within subjects, the rested and contracted ultrasound images were measured and normalized to body mass in kilograms (kg). Muscle thickness was obtained by measuring in millimeters from the inferior portion of the superior TrA fascial border to the superior portion of the inferior fascial border. ImageJ software (National Institutes of Health, Bethesda, MD) was used for all image measurement. This measurement technique has been shown to be reliable in a variety of studies, including images collected in functional, standing positions.[23–25] Once all images were measured, the three thickness measures obtained for each position on the PFP limb side were averaged.[22]

Activation Ratios

To generate the traditional activation ratio (AR), the normalized contracted muscle thickness was divided by the normalized rested muscle thickness in the same position.[15]

The resulting value is unitless and representative of muscle activation beyond the rested thickness, evident in a number greater than 1.0. The functional activation ratio (FAR) uses a different normalization strategy by dividing rested thickness while in a more loaded, functional position by the quiet, baseline position for that task (i.e. unipedal stance divided by bipedal stance). The FAR was used for the unipedal position and for the SLS position with equations represented in Figure 1.

Statistical Analysis

Repeated measures ANOVA was used to observe time and position effects for both the TrA rested and contracted normalized thickness measures (mm/kg), activation ratios, functional activation ratios, and plank times (sec). Mean differences with 95% confidence intervals were also calculated, as well as Cohen's *d* effect sizes to determine magnitude of difference of pre-post measures. After examination of data distribution in front and both side planks, 3 outliers were removed from all plank analyses due to their increased hold times, therefore the sample size consisted of 16 participants. SPSS Statistics version 24.0 (IBM Corp) was used for all statistical analyses.

RESULTS

Table 1 outlines demographic information for the 19 participants with PFP that participated in the study (Age: 23.7±4.8years, Height: 168.7±6.8cm, Mass: 69.6±15.1kg, 14 females, 5 males), including significant improvements in subjective outcomes following rehabilitation in pain and function. No time main effect was found in TrA thickness or activation during the 4-week rehabilitation period (Table 2). A significant time main effect was observed with plank times-to-failure (Table 3) with a large effect

size found with PFP limb plank time, favoring post-rehabilitation (Figure 2). Position main effects were observed (Table 2) between rested, normalized TrA thickness, which was smallest in the tabletop position and increased in thickness progressively into the bipedal, unipedal, and finally the greatest thickness in the SLS position. For contracted thickness, position main effects were present in tabletop vs. SLS (p=.003) and a time-by-position interaction was observed in tabletop vs. SLS (p=.043) and bipedal vs. SLS (p=.008). The SLS FAR was significantly greater than the unipedal FAR (p=.003). Front planks were significantly greater than side planks on the non-PFP limb (p<.001) and there was also a position main effect between planks on the PFP limb and the non-PFP limb hold times (p=.001) (Figure 2). Cohen's d effect sizes with 95% confidence intervals are summarized in Figure 3.

DISCUSSION

Muscle activation of the TrA did not change following the 12 session, 4-week impairment-based rehabilitation program, but side plank times on the PFP and non-PFP limb did increase with moderate to large effect sizes (Figure 2). For the secondary analysis of positional effect on the thickness of the TrA, there was a significant increase in muscle thickness in the SLS position compared to tabletop, bipedal, and unipedal stances at rest (all p<.05) and a greater thickness during SLS than in the tabletop position during a contraction (p=.003). Although there were no time effects observed in these core measures, the incorporation of a more focused measure of a spinal stabilizer, the TrA, and an endurance measure, planks, allows for a more comprehensive way to examine the core.[13] This approach is similar to what has been used in the low back pain population,

which frequently uses a multifactorial assessment strategy to accommodate for the various intrinsic and extrinsic causes of low back pain.[26,27] Similar to low back pain rehabilitation, PFP is multifactorial and rehabilitation encompasses several possibilities where neuromuscular control can enhance stability and stress on the knee either up or down the kinetic chain. Previous research has focused on strength, kinetics, kinematics, and function at the ankle, knee, and hip; while our study aimed to examine the effects at the deep abdominal stabilizers and whether changes could be detected following a generalized rehabilitation program.

USI enables visualization of the muscle and measurement of its changes in various positions during rest compared to when the muscle is contracted. There is support for including a task specific aspect to core assessment and the SLS has been proposed to fill that role in the literature as well.[13] The comprehensive assessment of core stability was present in our study, but the primary intention of study design was to meet the individual patient needs of strength gains, range of motion improvement, increased movement efficiency in functional tasks, and pain management. Although core focused exercises, including the abdominal draw-in maneuver, were included as part of the exercise regimen, these were not the primary focus. Individuals with low back pain have exhibited improvements in muscle activation, but many of those studies utilize ultrasound as a biofeedback tool, not solely for measurement at baseline and following rehabilitation.[28,29] Focused training on activation of the TrA separately from the remainder of the impairment-based program may be necessary in showing change over time or an extended rehabilitation period with that direct core focus amplified. Additionally, using

the initial baseline measures of muscle activity from ultrasound could be another domain to include in the structuring of the impairment-based model.

The lack of change over time from our particular study does not negate the importance of examining the patient with PFP with that same multifactorial strategy. Individuals with PFP are known to fit a variety of clinical subgroups, which served as the foundation for the impairment-based rehabilitation.[7,10] Proximal contribution to PFP has been assessed at the hip,[30–34] distal influence from the foot has been explored,[10,18] and local factors at the knee[30,35,36] are a mainstay in assessing and treating this population. From our results, there was no time effect in TrA activation indicating that an improvement of this muscle in various positions was made by our rehabilitation program, but this allows a shift of focus toward the plank tasks, specifically those performed on the limb affected with PFP. A large effect (Figure 2) was observed with planks performed on that side and is consistent with other findings in those with PFP.[9,18] The magnitude of this effect shows that global core activation can place patients with PFP in a more stable planking or side-bridge position. This positioning or exercise may initially be avoided due to a potential of increased vulnerability of the PFP limb, but with an individual progression, improvements can arise in a 4-week timespan. Three outliers were removed due to their increased plank hold times and all individuals that were removed were male participants. Due to those 3 male plank time effects on the distribution of the remaining data, and since the sample size was already met, they were ultimately excluded. Another study that compared plank times before and after rehabilitation, only included females in their study, which is a commonality among PFP research due to the increased prevalence of

females with PFP.[18] However, males do present with PFP, and we wanted to include both sexes to represent the distribution of the pathology as it has been documented in the greater population.[1,17]

Due to the position effects observed, training in each position could be incorporated to compliment the focused training of the functional tasks in particular. Mirror training was already being performed by the participants and adding an ultrasound biofeedback component could bolster that training. Healthy adults have already shown an improvement in TrA activation over a short biofeedback and individualized training session, including a 5-month retention, which could be very beneficial in the PFP population.[29] The SLS position also had the largest rested and contracted TrA thickness at both the pre-rehabilitation and post time points. This supports the inclusion of a specific task assessment and although a time effect was not present in this particular study, the training of tasks like the SLS are supported in PFP rehabilitation literature.[13] The modulation of the thickness measures in different positions provides a visual of the proximal musculature in a real-time manner and supports the notion that muscle activity should increase to support the body in a preparatory manner, and at the most basic level, a postural support in a loaded position. The core-focused component may not have been as effective due to the task-specific nature of the assessment with a SLS, but training movement quality of a SLS during rehabilitation may have improved movement efficiency in other more distal muscle groups.[19]

The differences in the FAR between the unipedal and SLS positions showed that these individuals with PFP were utilizing their TrA during each of those tasks beyond the activity of a quiet bipedal stance. This is similar to findings that have been shown in healthy people,[16] but has a notable trend toward a decrease in activity following rehab. The significant time-by-position interaction (Table 2) that was observed in the tabletop and bipedal contracted thickness measures also supports the notion of using a functional activation ratio to gain an idea of muscle activity from a raw thickness value. Participants' ability to perform an abdominal draw-in maneuver, which was the basis for the contracted measure, decreased following rehabilitation as evident by the resultant smaller normalized thickness. Due to the other improvements through the larger rehabilitation program, participants may have found another strategy to move efficiently besides increasing TrA activity. Gaining understanding of how the TrA is changing in thickness during a more functional movement is also an important result of our study. Instead of relying on activity during an abdominal draw-in maneuver as many studies in the low back pain literature have done successfully, we were able to answer how much activation those with PFP are able to attain during a single leg stance and squat. Regardless of changes over time, we believe these findings are valuable and provide a novel outlook on core activation to clinicians.

Improvements were found in other areas of the impairment-based model besides TrA activation, but this does suggest that either these individuals did not fit a clinical subgroup that would benefit from a core focused program assessed by muscle activity or simply more time of core stability training was necessary to see greater activation

increases. On the contrary, plank times improved over time, which is consistent with other recent studies[9,18] and continues to support the notion of overall global core endurance as a beneficial exercise for individuals with distal pathologies.[13,37] Individuals with PFP may also utilize a different core motor strategy to complete a SLS that was not captured within the scope of this study. Core stabilization is a complex idea that has many contributing factors and is commonly debated in the literature. However, our study distinctly showed that following our intervention, core endurance, not TrA activation was improved. This is valuable to clinicians and can guide their exercise choices when designing impairment-based plans for patients experiencing PFP.

Limitations

This study was not without limitations and the lack of a time main effect in TrA activity may have been attributed to the length of the rehabilitation program. Even though subjective function and pain outcomes improved during the 12 sessions over 4-weeks, activation changes may take a longer period of time to see a meaningful increase. Most recent rehabilitation programs focused on PFP have been completed over a time period longer than 4 weeks, as in our current study, with most totaling 6-8 weeks of rehabilitaiton[9,18,19] which may have influenced our results. This particular study also included 5 males in its analysis along with the other 14 females. Many PFP studies focus only on females due to the increased prevalence with females, however we felt that the distribution of males in the study closely mirrored the distribution of males with in the reported PFP population, since they have been documented as having PFP 2-10 times more than what is reported of males.[1,17,38]

Conclusions

Increased endurance during planks supports the inclusion of core endurance focus within an impairment-based rehabilitation program for patients with patellofemoral pain, especially in regard to a side plank on the PFP affected limb. The assessment of TrA activity did not reveal an improvement over time, but different positions that include supine hook-lying, as well as bipedal, unipedal stances, and during peak knee flexion of a single leg squat, show incremental increases in thickness directly with the functional position progression, respectively. Incorporation of planks into rehabilitation programs for individuals with PFP and an understanding of TrA activity measures that are novel to this population should be considered by clinicians when assessing and treating PFP.

Table 1. Patient demographics (mean ± standard deviation)

	Pre-rehab	Post-rehab
Sex	14 female, 5 male	
Age (years)	23.7±4.8	
Height (cm)	168.7±6.8	
Mass (kg)	69.6±15.1	
Treatment leg	9 right, 10 left	
Duration of PFP (months)	25.2±27.8	
Anterior Knee Pain Scale	76.7±7.7	87.6±6.9*
Activities of Daily Living	78.9±9.6	88.1±5.6*
Godin Leisure Time Questionnaire	196.9±137.3	199.6±121.2
Tegner Activity Scale	5.7±1.7	6.3±1.6
Fear Avoidance Beliefs Questionnaire	13.3±4.7	10.0±4.8*
Lower Extremity Function Scale	81.1±10.3	90.8±5.6*
Global Rating of Change		4.5±1.8

Abbreviations: PFP, Patellofemoral Pain; rehab, rehabilitation
*Significant difference from pre-rehabilitation measure
Alpha level set at $p \leq .05$

Table 2. TrA activity values (mean ± standard deviation)

N=19	Position	Pre-rehab	Post-rehab
Normalized thickness at rest (mm/kg)	Tabletop*	0.068±0.018	0.063±0.015
	Bipedal*	0.074±0.021	0.079±0.018
	Unipedal*	0.074±0.017	0.080±0.020
	SLS	0.088±0.027	0.093±0.025
Normalized thickness contracted (mm/kg)	Tabletop*†	0.099±0.030	0.089±0.017
	Bipedal†	0.109±0.038	0.101±0.026
	Unipedal	0.104±0.039	0.112±0.030
	SLS	0.110±0.031	0.119±0.030
Activation Ratio $\frac{thickness_{cont}}{thickness_{rest}}$	Tabletop	1.544±0.416	1.453±0.365
Functional Activation Ratio $\frac{thickness_{unipedal/SLS}}{thickness_{bipedal\ at\ rest}}$	Unipedal*	1.035±0.215	1.024±0.155
	SLS	1.245±0.380	1.179±0.258

Abbreviations: rehab, rehabilitation; cont, contracted; ADIM, abdominal draw-in maneuver; SLS, single leg squat.
*Significant position main effect, compared to SLS
†Significant time*position interaction, compared to SLS
Alpha level set at $p \leq .05$

Table 3. Plank time-to-failure times (mean ± standard deviation)

N=16	Position	Pre-rehab	Post-rehab
Time-to-failure (seconds)	Front*	109.69±65.26	105.81±49.10
	PFP limb*†	43.69±16.28	57.38±18.79
	Non-PFP limb†	46.19±18.89	58.63±19.38

Abbreviations: rehab, rehabilitation; PFP, patellofemoral pain
*Significant position main effect, Front vs. PFP limb
† Signficant position main effect, PFP vs. Non-PFP limb
Alpha level set at $p \leq .05$

$$AR = \frac{TrA\ thickness_{contracted}}{TrA\ thickness_{rested}}$$

$$FAR = \frac{Rested\ TrA\ thickness_{unipedal}}{Rested\ TrA\ thickness_{bipedal}}$$

Figure 1. Activation ratio equations.[15,16]
Abbreviations: AR, activation ratio; FAR, functional activation ratio; TrA, transverse abdominis.

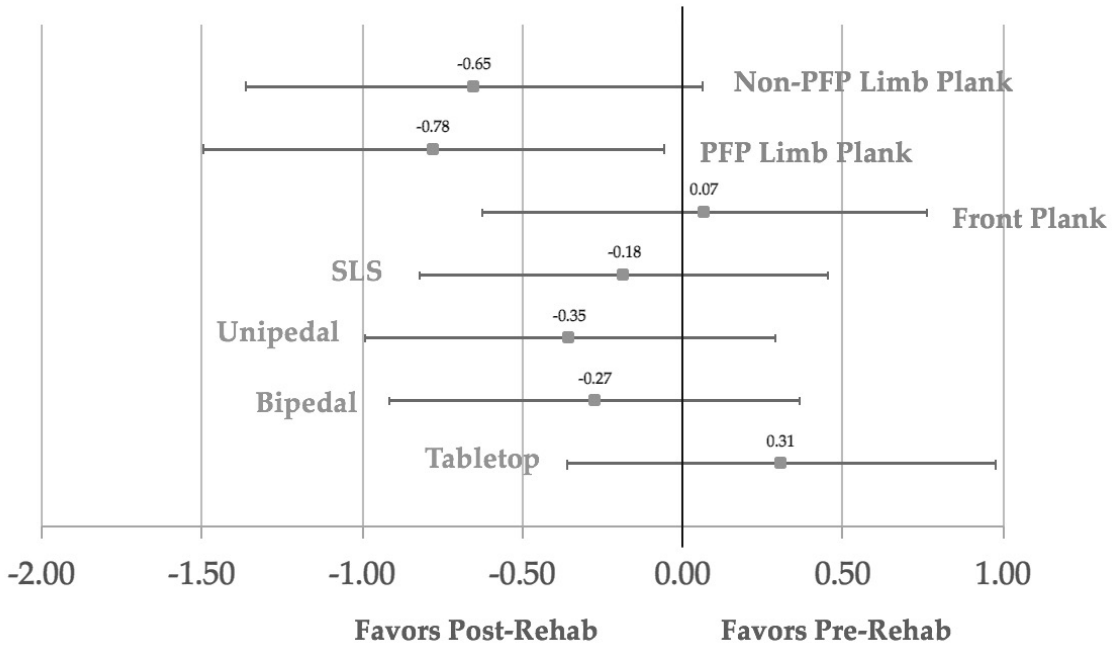

Figure 2. Cohen's *d* effect sizes and 95% confidence intervals for TrA thickness in each position and planks in each direction before and after rehabilitation.
Abbreviations: PFP, patellofemoral pain; rehab, rehabilitation

SECTION II: MANUSCRIPT II

GLUTEAL MUSCLE ACTIVITY CHANGES IN PATIENTS WITH PATELLOFEMORAL PAIN FOLLOWING IMPAIRMENT-BASED REHABILITATION

ABSTRACT

Context: The role of the gluteal muscles, specifically the gluteus maximus (Gmax) and gluteus medius (Gmed), has been explored frequently in individuals with patellofemoral pain (PFP) both before and after rehabilitation. Muscle activation is often evaluated using surface electromyography (EMG) during functional tasks, yet the muscles can be visualized with ultrasound imaging (USI) during these same tasks. Although the measures each contribute to muscle activity, it is not known how those measures are related before and after an impairment-based rehabilitation program. **Objective:** To determine Gmax and Gmed muscle thickness changes using USI & EMG following rehabilitation in PFP patients. **Design:** Prospective cohort study. **Setting:** University laboratory. **Patients or Other Participants:** 19 PFP patients (23.7±4.8yrs, 14F, 5M) completed 12 clinician-supervised rehabilitation sessions over a 4-week period. **Intervention(s):** The rehabilitation program was based on individual patient deficits, measured prior to their first treatment session, in lower extremity range of motion, strength, core strength, and in movement patterns during functional tasks. Patients were progressed based on the aforementioned initial evaluation and individual performance in each domain. **Main Outcome Measure(s):** Prior to the first session and following the final session, USI thickness measures of Gmax and Gmed during side-lying hip abduction with slight extension, in a bipedal stance, unipedal stance, and during a single leg squat (SLS). For the USI measures, Gmax and Gmed thickness was normalized by dividing by participant body mass in kilograms and contracted thickness was divided by rested thickness for side-lying. A functional activation ratio was calculated for unipedal and SLS, by dividing rested thickness in each position by rested bipedal thickness. EMG

was collected at the same pre-and post-rehabilitation time points during a SLS. Peak amplitude during the SLS was normalized to quiet bipedal stance and was used to represent Gmax and Gmed activity. Repeated measures ANOVA was utilized to compare all Gmax and Gmed outcomes before and after rehabilitation. A secondary analysis for position effect was also performed for the ultrasound activity variables and a Pearson's correlation analysis was used to compare USI and EMG during a SLS. **Results:** A significant time main effect was observed for normalized thickness with a decrease for Gmax (p=.009) and increase in rested thickness for Gmed (p<.001). Tabletop thickness in Gmax did not change. Functional activation in the unipedal stance improved for Gmed (p=.040). There was no significant time effect found for EMG activity during the SLS following rehabilitation. There was a time-by-position interaction in the unipedal contracted thickness measure (p=.032). There was no relationship between USI and EMG during the SLS (p>.05). **Conclusions:** Normalized muscle thickness of both the Gmax (decrease) and Gmed (increase) changed in standing, functional positions after 4 weeks of impairment-based rehabilitation. The functional activation of the Gmed improved in the unipedal stance. Gluteal activation and strengthening was a targeted focus within the impairment-based model for all participants regardless of the speed in which they progressed through each domain of the protocol. The proximal musculature should remain a mainstay in PFP rehabilitation, as muscle thickness can be improved in only 12 sessions.

Word Count: 504

Key Words: hip muscles, ultrasound imaging, impairment

INTRODUCTION

A proximal source of patellofemoral pain (PFP) has been proposed by many investigators in the PFP literature with robust results in support of that theory.[11,12,18,39] Weakness and neuromuscular dysfunction of the gluteus maximus (Gmax) and gluteus medius (Gmed) have been found in individuals with PFP.[40] The role of the Gmed in pelvic stabilization, and preventing abduction, internal, and lateral rotation during weight bearing is important for proper movement of the lower extremity, not just the hip. The insufficiency of global movement of hip extension from the Gmax, external rotation, and stabilizing against abduction remains a goal in PFP rehabilitation programs. Its insertion on the iliotibial band may also contribute to strength deficits and aberrant movement. Hip strengthening exercises in rehabilitation protocols have shown improvements in this population,[9,19,41] but how thickness changes occur from similar rehabilitation strategies is not present in the literature. The maintenance of overall pelvic alignment and stability falls on both the Gmax and Gmed, which can become particularly problematic in single leg tasks.[42,43]

Electromyography (EMG) has been used frequently to understand not only amplitude of activation, but timing of activation of the Gmed specifically during functional tasks and exercises.[40,44,45] Results from studies using EMG can identify neuromuscular dysfunction and provide feedback to researchers and clinicians on types of exercises that achieve higher activation than others, however a visualization of muscle thickness, motion, and positioning can provide an adjunct method of understanding muscle function. An increase in thickness does not necessitate an increase in EMG amplitude, especially with a muscle like the Gmed whose eccentric contraction is important in pelvic stabilization during

movement.[46] With dual representations of muscle activity through USI and EMG, this comprehensive outlook on muscle activity fits well with an individualized methodology for treatment as well.

Muscle thickness of the gluteal muscles has been evaluated using ultrasound imaging in both B-mode and M-mode. However, a clear distinction in fascial borders is more evident using B-mode with static image capture at a single time point, as opposed to M-mode which captures tissue motion and onset of muscle activity.[46,47] Gaining more of an understanding of not only how muscles of the lumbopelvic-hip complex are activating, but how they are moving when placed in different positions is very important for those with PFP. The influence of the dysfunction that is well known of the gluteals is apparent through not only range of motion and strength assessments, but also during functional task assessments that focus on quality of movement.[9,18,40,41] Ultrasound imaging provides a real-time view of what is occurring beneath the skin and how the muscles appear in a relaxed, side-lying position as well as during an exercise that is known to target that muscle (i.e. a single leg squat targeting Gmed). Using muscle thickness measures in rested and contracted states to determine activation is a reliable calculation method utilized frequently in healthy individuals and in comparison to the low back pain population when assessing the transverse abdominis and lumbar multifidus, among other muscles in the lumbopelvic-hip complex.[15,23] This form of activation ratio is used when a focused contraction, such as an abdominal draw-in maneuver for the transverse abdominis, is the contraction of interest. However, with larger muscles like the Gmax and Gmed that have a variety of actions, a functional activation ratio may be more

appropriate. The functional activation ratio uses thickness during a functional or dynamic task as the numerator of the ratio and divides that thickness by a quiet stance measure comparable to the starting position most commonly for the respective task.[16] Tracking changes within a chronic musculoskeletal condition, such as PFP, with a method of measurement that offers a visual of muscle activity in both static and dynamic positions would fill a gap in the current body of research.

The application of rehabilitation that is individualized has been proposed for the PFP population and allows for the researcher or clinician to progress individuals based on their personal performance as opposed to a standard protocol applied to everyone with that pathology or participating in a single study.[8] Using an initial baseline comprehensive collection of domains including: range of motion, strength, and movement quality during functional tasks also mirrors clinical practice and results of those studies would have a direct and arguably immediate clinical application. The diversity of clinical subgroups within the greater PFP population has presented a challenge to establishing best practices in assessment and treatment alike[7,10], but an impairment and individualized approach helps to lessen those disparities as well.

Therefore, the purpose of this study was to determine changes in normalized muscle thickness of the Gmax and Gmed in multiple positions, along with peak EMG activity during a SLS, in individuals with patellofemoral pain after undergoing a 12 session, 4-week impairment-based rehabilitation program. We expect a slight increase in Gmax activity and a greater increase in Gmed activity for both USI and EMG measures due to

the prevalence of gluteal targeted exercises in the rehabilitation program. We also anticipate no relationship between USI and EMG measures during the SLS due to their different ways of assessing muscle activity (i.e. spatial/morphological changes vs. electrical changes).

METHODS

Study Design

A prospective cohort study was conducted in a university setting with two collection time points, at baseline and upon completion of a 4-week, 12 session impairment-based rehabilitation protocol. Institutional Review Board approval was obtained prior to initiation of the study and all participants provided informed consent.

Participants

Nineteen participants (age: 23.7±4.8yrs, 14F, 5M) with patellofemoral pain for longer than 3 months (duration of PFP: 25.2±27.8 months) and a score of 85 or less on the Anterior Knee Pain Scale (AKPS: 76.7±7.7) were enrolled and completed 12 sessions of rehabilitation. Additional participant demographics are outlined in Table 1.

Instruments

For ultrasound image capture, an Acuson Freestyle unit was used in B-mode with an 8 MHz linear transducer (Siemens Medical, Mountain View, CA). A medium density foam block with a Velcro elastic belt was used to house the linear transducer in all standing collection positions (Figure 1). All image measurement was completed with ImageJ software (National Institutes of Health, Bethesda, MD). Electromyography was recorded using the Delsys Trigno Wireless system (Delsys Inc., Natick, MA) with wireless

Ag/AgCl bar electrodes adhered to the skin with double-sided adhesive strips for Trigno wireless electrodes (Delsys Inc, Natick, MA). AcqKnowledge 4.2 software (Biopac Systems Inc., Goleta, CA). was used to process all EMG data.

Rehabilitation Program

All 12 sessions of rehabilitation were supervised by a certified athletic trainer (ANM) with 7 years of clinical experience. For range of motion, individuals only received patella joint mobilization and sets of stretching quadriceps, hamstrings, iliotibial band, and gastrocnemius if there was a range of motion deficit found in the initial comprehensive baseline assessment. A progression of short foot exercises was also included if participants mastered the baseline expectations for form and ability to isolate proper movement in these exercises. All other progressions in strength, core stability, and balance were also progressed at the supervising clinician's judgment based on mastery of the starting level. The first two weeks of the program included simpler exercises, such as: 4-direction straight leg raises, wall squats, clam shells, pelvic tilts, and single leg balance. The second and final two weeks increased difficulty, while participants were still advanced at their own pace. The second phase of exercises included some of the same exercises from the first two weeks (straight leg raises, wall squats), but included planks, and single leg squats, lunges, single leg deadlifts, all with mirror training.[8] Gluteal activation is a primary focus in most of the exercises included in the protocol, as they were adapted from an 8-week regimen with a large Gmax and Gmed focus.[19]

Ultrasound Imaging and EMG Collection

During the initial baseline collection, participants were asked to lie on each side on a tabletop to expose both hips, which was always performed on the right side first for all

individuals regardless of side of PFP. Participants were instructed to relax their bottom limb into slight flexion and one investigator with 3 years of experience with musculoskeletal ultrasound (LCM) captured all images. B-mode ultrasound imaging was used for all image capture due to the increased fascial border recognition in this mode.[47] For the rested tabletop measure, participants remained relaxed on the table in the side-lying position with the transducer at 50% distance between the greater trochanter and the mid-point of the iliac crest, in order to visualize both the Gmax and Gmed on-screen.[48,49] Three images were captured on tabletop and then participants were asked to perform a side-lying hip abduction approximately 12 inches off of the table with slight extension with their toes pointing toward the wall they were facing. The contracted image was taken at the maximum abduction point. After tabletop measures, participants were asked to stand and the transducer was then placed in a medium density foam block with an elastic belt fixed to their lateral hip in order to obtain the same visual as the tabletop measures. Depth of image capture on-screen had to be adjusted in some participants due to the shift of tissue in the standing, loaded position. This depth change was adjusted with a pixel conversion later in the measurement phase. Bipedal and unipedal images were then captured, with the transducer on the same side as the limb with PFP, and the unipedal stance was on that same limb. Prior to the SLS image capture, the skin was prepared for placement of EMG electrodes by shaving, abrading, and cleaning the skin with an alcohol pad. The wireless bar electrodes were placed on either side of the transducer, with Gmax halfway between the posterior superior iliac spine and greater trochanter, and the Gmed electrode halfway between the iliac crest midpoint and greater trochanter.[50] Participants then were asked to stand quietly with no movement in order to

obtain a quiet stance recording for EMG and then they completed 3 single leg squats bilaterally with EMG recording through the entire squat cycle and image capture taken at peak knee flexion. Upon completion of all ultrasound image capture in each position and EMG recording during the SLS, participants were dismissed from the initial and baseline collection sessions.

Data Processing and Statistical Analysis

The 3 gluteal images collected in each position on the side of the PFP limb were measured and averaged[51] to generate means for tabletop, bipedal, unipedal, and SLS conditions representative of the baseline and post-rehabilitation time points. Muscle thickness was designated as the distance from the inferior portion of the superior fascial border to the superior portion of the inferior fascial border of the Gmax and then the Gmed inferiorly. The thickest portion visible was the point of measure and was kept consistent in all participants. Distances in mm were measured in ImageJ software (National Institutes of Health, Bethesda, MD) using a pixel conversion based on the depth of image capture to ensure true-to-size measurement on each image. Muscle thickness values (mm) for both muscles were divided by body mass (kg) to normalize the measure and allow for comparison between subjects, using a ratio scaling method.[52] Body mass and Gmax and Gmed thickness measures across positions were related upon initial assessment (Pearson's *r* range: 0.4-0.9). Due to this moderate to strong correlation, the investigators decided upon a body mass normalization strategy for all ultrasound measures (mm/kg). For the tabletop activation ratio, the contracted (abducted) thickness served as the numerator and was divided by the rested thickness while the participant was side-lying. The functional activation ratio in the unipedal stance was calculated by

dividing the thickness during unipedal stance on the limb with PFP by bipedal stance thickness. The same calculation method was used for the SLS functional activation, however unipedal stance thickness was replaced with thickness at peak knee flexion of the SLS.

For EMG data collection, a sampling rate of 2000Hz was used with a band pass filter of 10-500Hz and a root mean square signal set at 50ms. Each SLS trial was normalized to the quiet stance peak amplitude. Peak amplitude during the SLS was determined and became the numerator over the quiet stance amplitude as the denominator. Mean peak amplitudes were exported and processed in AcqKnowledge software.

A repeated measures ANOVA was used to observe main effects for time and position in both muscles. Within subject simple contrasts were performed *post hoc*. Cohen's *d* effect sizes were also generated to determine magnitude of change with 95% confidence intervals. Pearson's *r* correlation coefficients were calculated to assess the presence and strength of relationship between muscle activity of the Gmax and Gmed during a SLS using ultrasound thickness measures and EMG. SPSS Statistics version 24.0 (IBM Corp) was used for the repeated measures ANOVA and Microsoft Excel (Microsoft Office version 15.32) was used for calculating mean differences, standard deviations, and Cohen's *d* effect sizes. Alpha was set *a priori* at $p \leq .05$ for all comparisons.

RESULTS

Participants improved their subjective function following rehabilitation, including a significant increase in Anterior Knee Pain Scale scores (pre-rehab: 76.7±7.7; post-rehab: 87.6±6.9), Activities of Daily Living (pre-rehab: 78.9±9.6; post-rehab: 88.1±5.6), as well as Fear Avoidance Beliefs Questionnaire and Lower Extremity Function Scale scores, which are outlined in Table 1. The mean global rating of change following the 12 sessions of rehabilitation of 4-weeks was 4.5±1.8, which can be interpreted as "moderate" to "quite a bit" better from the start of rehabilitation.[53,54]

Tables 2 and 3 outline Gmax and Gmed activity findings respectively, before and after rehabilitation. A significant decrease in rested and contracted Gmax thickness in all positions except tabletop was found (Table 2) and an increase in all Gmed thickness in all four positions was shown following rehabilitation (Table 3). Gmax thickness significantly decreased over time with strong effect sizes, in the bipedal (*d*=.74; 95% CI: 0.09, 1.40), unipedal (*d*=.84; 95% CI: 0.17, 1.50), and SLS positions (*d*=.75; 95% CI: 0.09, 1.40). A significant increase in normalized thickness was observed in Gmed over time with strong effect sizes, in tabletop (*d*=-1.61; 95% CI: -1.85, -0.47), bipedal (*d*=-0.80; 95% CI: -1.46, -0.14), unipedal (*d*=-1.42; 95% CI: -2.13, -0.71), and SLS positions (*d*=-1.06; 95% CI: -1.73, -0.38). There were no significant position main effects observed for the Gmax or the Gmed normalized thickness measures (Tables 2 and 3). There was a single significant time-by-position interaction present in the unipedal stance for contracted thickness of the Gmax. The only change in activation, tabletop or functional activation ratios, was an increase in unipedal functional activation for Gmed (Table 3).

EMG during a single leg squat for Gmax (d=0.17, CI: -0.47, 0.81) and Gmed (d=0.38, CI: -0.26, 1.02) did not change following rehabilitation (p>.05). There were no significant correlations present between Gmax and Gmed thickness and EMG peak activity during a SLS (range of r-values: 0.18-0.44, all p>.05).

DISCUSSION

This study was able to reveal significant changes in both the Gmax (p=.009) and Gmed (p<.001) with a decrease and increase in normalized muscle thickness (rested and contracted), respectively, over 12 sessions of rehabilitation. The single change in functional activation was a decrease in the unipedal stance for Gmed, indicating that the Gmed was not as thick during single leg stance compared to a double leg stance following rehabilitation. Change of thickness over a 4-week period could be attributed to focused training in the impairment-based model, whether those changes increased or decreased thickness. An alteration of strategy or efficiency of movement could be the contributing factors in this particular study. Large effect sizes were also shown for each significant finding, indicating a large magnitude of difference either before or after rehabilitation for Gmax and Gmed (Figures 4 and 5). Each participant received individualized progression throughout each phase of the exercises that had a targeted focus toward Gmed especially, due to its prevalence of study in the PFP body of literature.[8,9,11,39] The decrease in Gmax thickness could be due to participants increasing efficiency of movement throughout their supervised exercise performance. A reliance on larger, global movers, such as the Gmax, would not become as necessary as they became

more effective at utilizing the Gmed and other local stabilizers.[44] The participants would be expected to have an increase in Gmed thickness in loaded, standing positions due to the increase of those types of exercises in the second phase of the rehab protocol, which included mirror training of single leg tasks. This also supports that although there were no position effects in either muscle, Gmed thickness during a SLS was the largest value of all other positions (Table 3).

Similar findings in the low back pain population have been shown with a change in thickness for the transverse abdominis and lumbar multifidus with focused training on those muscles.[55] The timing effects of rehabilitation have been explored in the non-specific low back pain population[56] as well and our current study allows for a potential connection between temporal changes in thickness and its relationship to subjective function changes in another chronic musculoskeletal condition, PFP. The insidious onset, episodic nature of pain, and U-shaped curve representing too much activity causing pain and too little activity also causing pain are shared characteristics of both non-specific low back pain sufferers and those with PFP. The time main effect with targeted rehab exercises present in our study mirrors changes seen in core musculature in the low back pain literature as well, which we believe supports the use of ultrasound imaging and muscle thickness evaluation in PFP. The application of an activation ratio[15] using the normalized thickness measures to determine change in thickness during a contraction targeted at a specific muscle over a relaxed thickness allows improved understanding of spatial activity of the Gmax and Gmed due to their size and difficulty in visualizing the same regions of the muscle on-screen throughout a contraction or movement. This

normalization strategy, ratio or isometric scaling, has also been used in various ways with the low back pain population with success in making comparisons.[52,57] Our use of a within subjects comparison for this particular study also warranted a normalization strategy that was individual specific and body mass revealed the greatest correlation to thickness measures, therefore became the natural choice.

The absence of a significant correlation between the percent activation of the Gmax and Gmed during the SLS using USI and EMG supported the notion that these two methods of measurement are informing us in different ways about muscle activity. Although the relationships were not found to be statistically significant, there was a weak to moderate relationship (r=0.18-0.44) (Figure 7). The strongest relationship was found in the post-rehabilitation measures of Gmed activity, which had the p-value closest to .05, with a value of .06, indicating an approach toward significance. All of the correlation values were positive, indicating that as EMG activity increases beyond quiet stance, USI indicated an increase in thickness during the SLS beyond quiet stance, except for the pre-rehabilitation Gmax measures. The pre-rehabilitation Gmax USI to EMG relationship had an r-value of -0.18, which is a very weak relationship and lacked statistical significance and proved to be negligible. The determination of the relationships between USI and EMG was very important to assist in our understanding of these two measurement modes. EMG activity could have been fairly high during the SLS task without a large increase in thickness or percent activity beyond quiet from an USI perspective. USI and EMG have been used in conjunction in timing of activation studies, using M-mode ultrasound examining the motion of tissues with onset of activation measures from EMG.[47] This type

of assessment using these tools may be more relatable as opposed to our method in the current study.

The larger randomized control trial in which this study was nested, also saw a significant increase in Gmax and Gmed strength as assessed by hand-held dynamometer, as well as an increase in hip abduction range of motion. The increased strength of the Gmed could support the increase of thickness when normalized to body mass indicating a hypertrophic effect of the impairment-based progression of exercises. Although Gmax strength increased, the shifting of using other muscles for postural support and most notably in a single limb stance or squat could explain the decrease in thickness in both unloaded and loaded positions.

Ultrasound imaging and comparison of muscle thickness changes has not been completed before and after rehabilitation in Gmax and Gmed in this population to our knowledge. Using an approach to assess morphology of the gluteals is a clinically applicable method of muscle assessment that is lacking the current PFP literature. Future research should assess muscle thickness in a wider variety of positions and exercises to track changes in thickness based on different demands placed on the entire body, not isolated to a single limb stance or squat.

Limitations

This study was not without limitations and only focused on two of the documented dysfunctional muscles within the patellofemoral pain population with a unique assessment strategy. The positions utilized for measurement may not have tasked the

individual enough to ascertain a position effect, i.e. unipedal stance vs. single leg squat. Images were only captured at a single time point and may not represent complete muscle activity. We chose to capture muscle thickness at peak knee flexion in the SLS to visualize muscle thickness just as they were beginning to ascend. The entire squat cycle could be assessed to determine how the muscles change as the demands on hip control alter throughout the descent and ascent of a SLS. Additionally, even though the impairment-based rehabilitation approach showed improvement in subjective function, the length of the program may need to be lengthened in order for significant changes in measures, such as EMG peak activity. Other studies have focused on timing of EMG or peak amplitude normalized to a maximal voluntary isometric contraction as opposed to peak amplitude normalized to a quiet measure. This difference in our approach to EMG processing and data interpretation could have affected the subsequent results of no changes following rehabilitation. Future studies could address timing of muscle activation using EMG and sync the electrical activation with timing of contraction onset with M-mode ultrasound imaging, which has been done in healthy individuals and with other hip pathologies, but not in those with PFP after treatment.[58]

Conclusions

A 12 session, 4-week impairment-based rehabilitation showed a significant increase in Gmed muscle thickness and a decrease in Gmax thickness by ultrasound image evaluation. Although a thickness change occurred over time, there were no differences in either muscle based on body positioning, side-lying on a table versus standing and functional positions. There was also no significant change in peak activation of Gmax and Gmed activity as measured by EMG during a single leg squat. Overall, the

rehabilitation protocol based on personal progressions showed significant changes over time in both Gmax and Gmed.

Table 1. Participant demographics (mean ± standard deviation)

N=19	PFP (pre-rehab)	PFP (post-rehab)
Sex	14 female, 5 male	
Age (years)	23.7±4.8	
Height (cm)	168.7±6.8	
Mass (kg)	69.6±15.1	
Treatment leg	9 right, 10 left	
Duration of PFP (months)	25.2±27.8	
Anterior Knee Pain Scale	76.7±7.7	87.6±6.9*
Activities of Daily Living	78.9±9.6	88.1±5.6*
Godin Leisure Time Questionnaire	196.9±137.3	199.6±121.2
Tegner Activity Scale	5.7±1.7	6.3±1.6
Fear Avoidance Beliefs Questionnaire	13.3±4.7	10.0±4.8*
Lower Extremity Function Scale	81.1±10.3	90.8±5.6*
Global Rating of Change		4.5±1.8

Abbreviations: PFP, Patellofemoral Pain
*Significant difference from pre-rehabilitation measure
Alpha level set at $p \leq .05$

Table 2. Gluteus maximus activity (mean ± standard deviation)

N=19	Position	Pre-rehab	Post-rehab	p-value
Normalized thickness at rest (mm/kg)	Tabletop	0.302±0.119	0.266±0.049	.246
	Bipedal*	0.346±0.120	0.279±0.045	**.033**
	Unipedal*	0.375±0.143	0.283±0.060	**.015**
	SLS*	0.352±0.129	0.275±0.068	**.043**
Normalized thickness contracted (mm/kg)	Tabletop	0.318±0.140	0.261±0.052	.146
	Bipedal*	0.361±0.136	0.277±0.050	**.018**
	Unipedal*†	0.369±0.132	0.299±0.056	**.046**
	SLS	0.344±0.134	0.268±0.067	**.046**
Activation Ratio $\frac{thickness_{cont}}{thickness_{rest}}$	Tabletop	1.044±0.120	0.983±0.111	.144
Functional Activation Ratio $\frac{thickness_{unipedal/SLS}}{thickness_{bipedal\ at\ rest}}$	Unipedal	1.080±0.156	1.027±0.105	.245
	SLS	1.041±0.234	1.010±0.225	.626
Peak EMG activity (normalized to quiet stance)	SLS	1.245±0.380	1.179±0.258	.600

Abbreviations: rehab, rehabilitation; SLS, single leg squat.
*Significant time main effect
†Significant position main effect vs. SLS
Alpha level set at $p \leq .05$

Table 3. Gluteus medius activity (mean ± standard deviation)

N=19	Position	Pre-rehab	Post-rehab	p-value
Normalized thickness (mm/kg)	Tabletop*	0.177±0.079	0.264±0.070	**.003**
	Bipedal*	0.209±0.106	0.274±0.042	**.017**
	Unipedal*	0.182±0.085	0.275±0.038	**<.001**
	SLS*	0.190±0.102	0.277±0.057	**.005**
Normalized thickness contracted (mm/kg)	Tabletop*	0.193±0.096	0.286±0.083	**.007**
	Bipedal*	0.209±0.105	0.274±0.038	**.014**
	Unipedal*	0.203±0.100	0.287±0.039	**.002**
	SLS*	0.187±0.108	0.276±0.068	**.015**
Activation Ratio $\frac{thickness_{cont}}{thickness_{rest}}$	Tabletop	1.080±0.158	1.090±0.170	.816
Functional Activation Ratio $\frac{thickness_{unipedal/SLS}}{thickness_{bipedal\ at\ rest}}$	Unipedal*	0.906±0.167	1.014±0.112	**.040**
	SLS	0.929±0.265	1.026±0.241	.279
Peak EMG activity (normalized to quiet stance)	% activity during SLS	17.516±10.912	13.873±8.119	.251

Abbreviations: rehab, rehabilitation; SLS, single leg squat.
*Significant time main effect
Alpha level set at $p \leq .05$

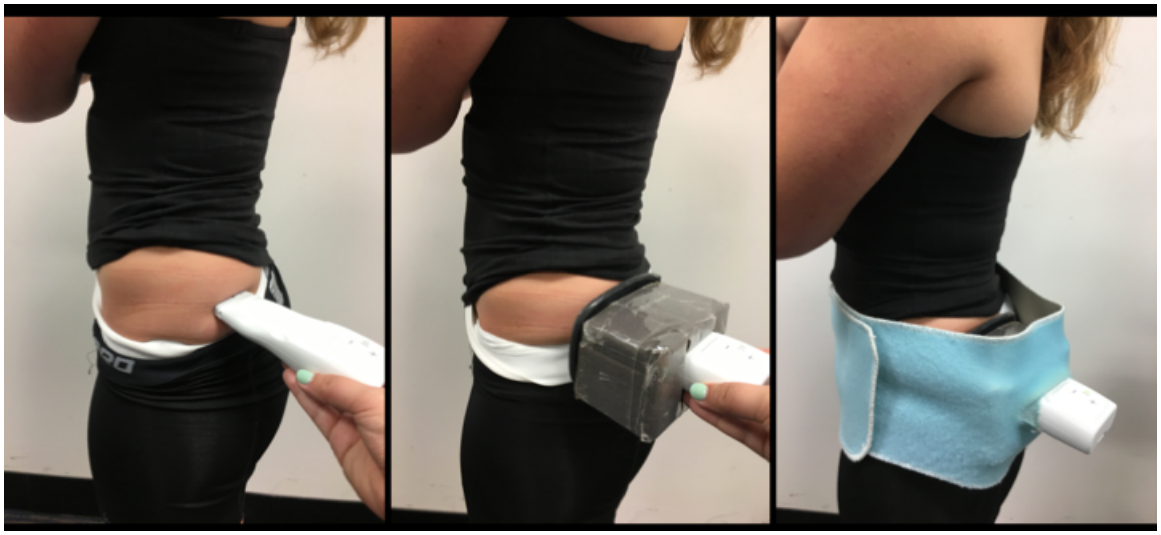

Figure 1. Ultrasound transducer placement with elastic belt and medium density foam block.

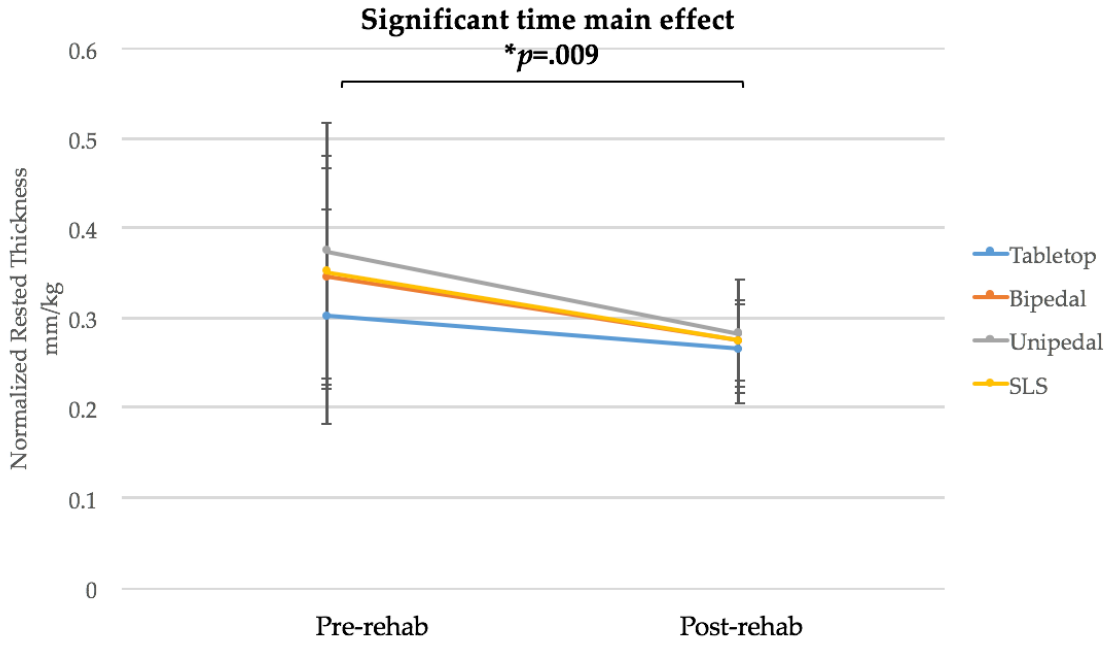

Figure 2. Gluteus maximus normalized thickness in all testing positions before and after rehabilitation.
*Significant time main effect
Alpha level set at $p \leq .05$

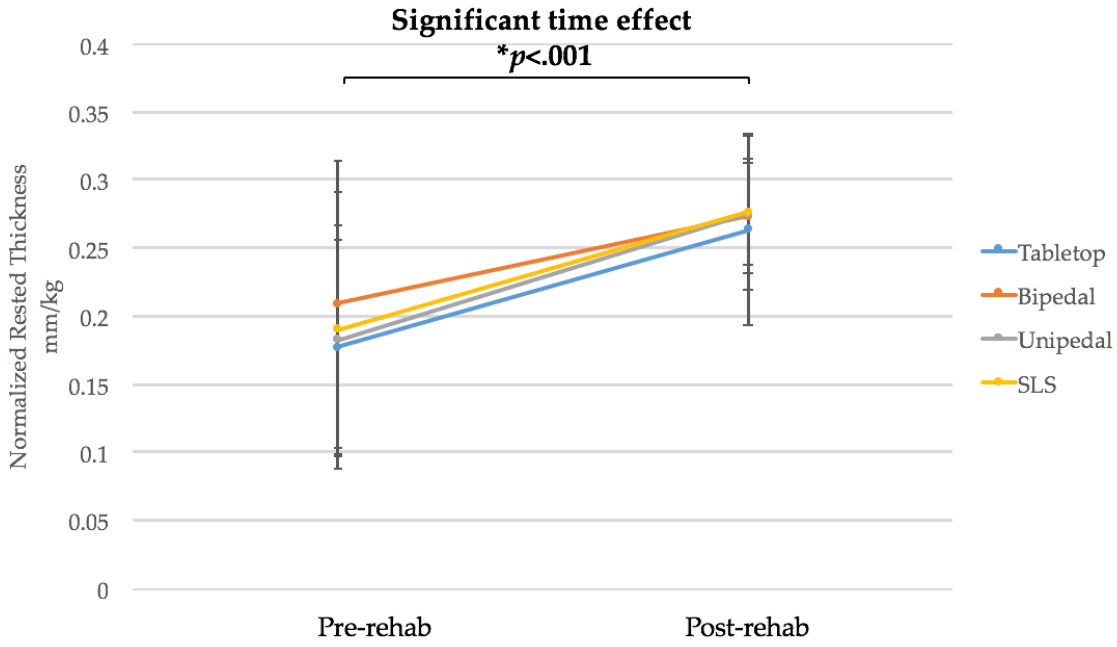

Figure 3. Gluteus medius normalized thickness in all testing positions before and after rehabilitation.
*Significant time main effect
Alpha level set at $p \leq .05$

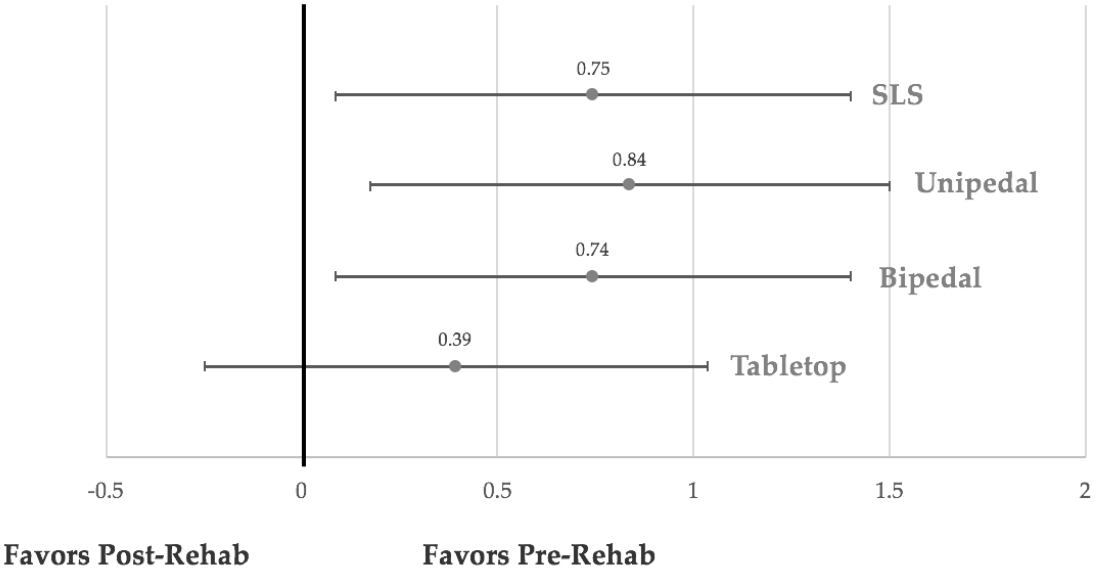

Figure 4. Cohen's *d* effect sizes and 95% confidence intervals for Gmax rested thickness in each position.
Abbreviations: PFP, patellofemoral pain; rehab, rehabilitation.

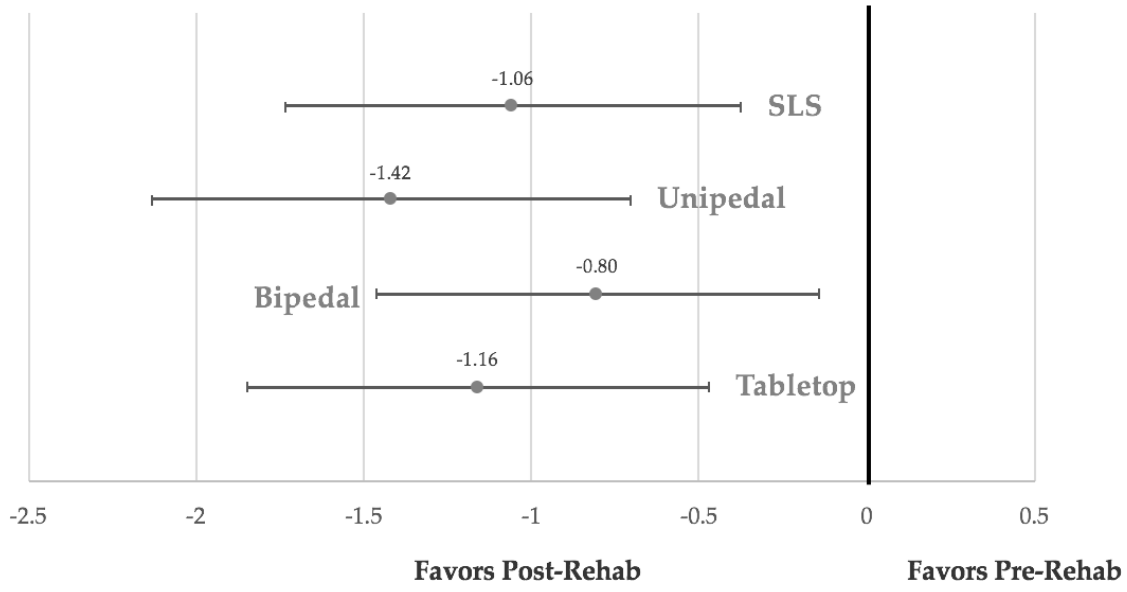

Figure 5. Cohen's *d* effect sizes and 95% confidence intervals for Gmed rested thickness in each position.
Abbreviations: PFP, patellofemoral pain; rehab, rehabilitation.

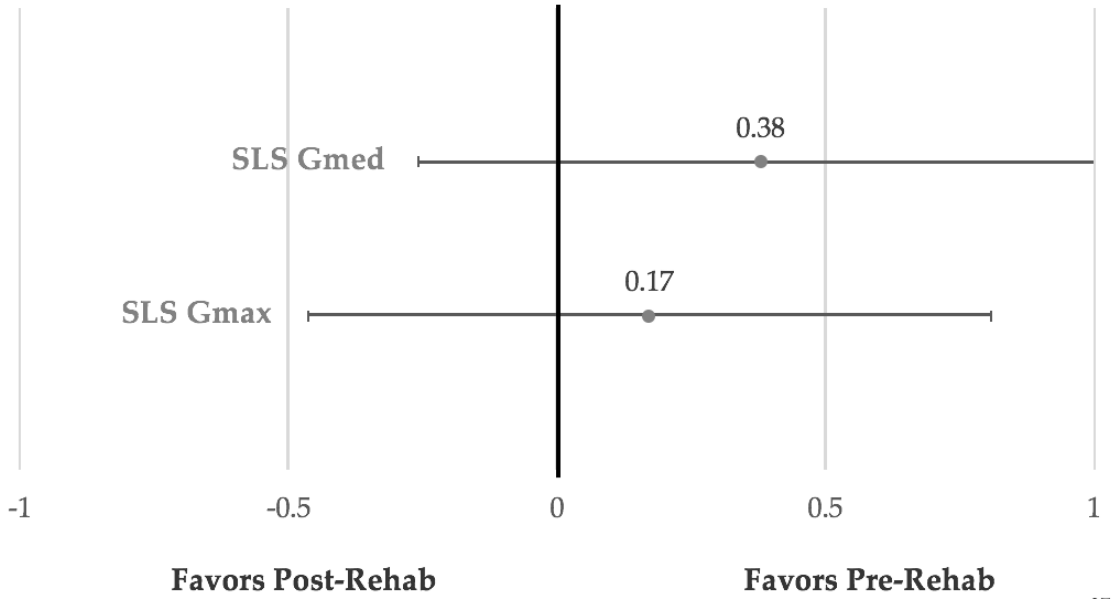

Figure 6. Cohen's *d* effect sizes and 95% confidence intervals for Gmax and Gmed EMG peak activity during a SLS beyond quiet standing.
Abbreviations: PFP, patellofemoral pain; rehab, rehabilitation; SLS, single leg squat.

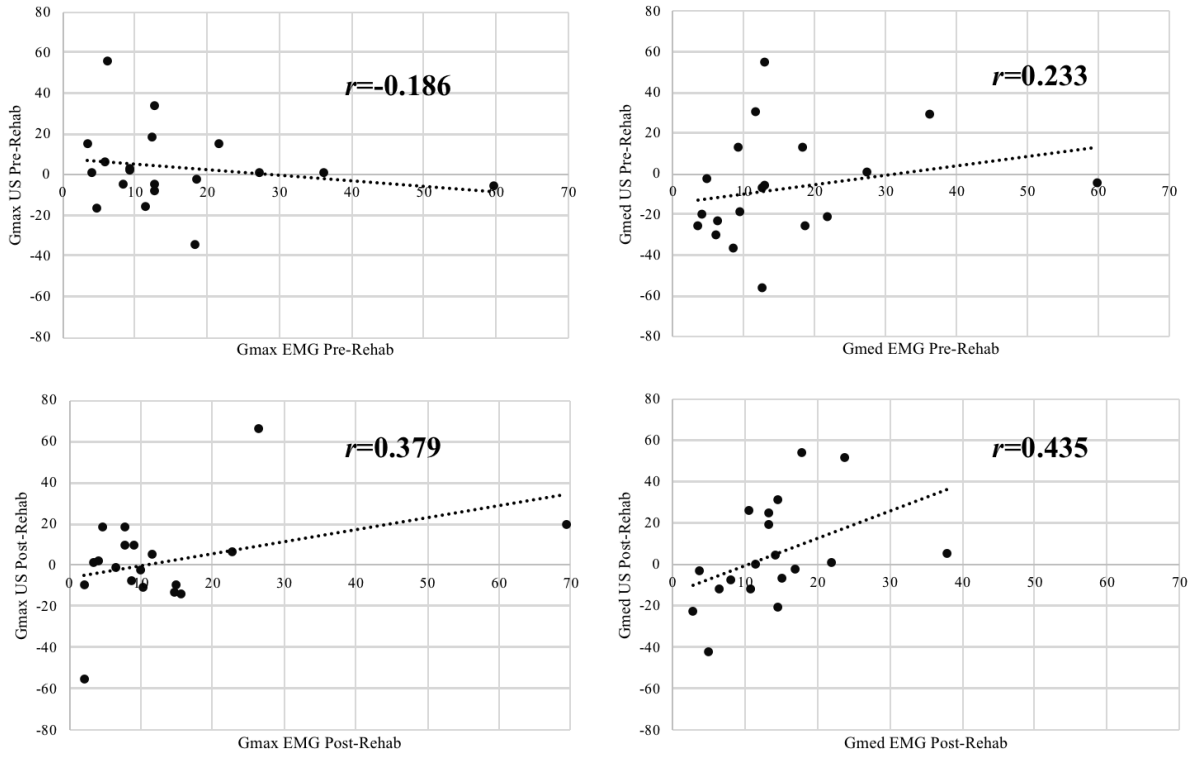

Figure 7. Correlation scatterplots of Gmax (left) and Gmed (right) pre-and-post rehabilitation USI vs. EMG percent muscle activity during SLS beyond quiet stance. Abbreviations: USI, ultrasound imaging; EMG, electromyography; SLS, single leg squat.

SECTION II: MANUSCRIPT III

COMPARISON OF CORE MUSCLE ACTIVITY IN PATIENTS WITH PATELLOFEMORAL PAIN, NON-SPECIFIC LOW BACK PAIN, AND HEALTHY INDIVIDUALS IN STATIC AND DYNAMIC POSITIONS

ABSTRACT

Context: The role of core musculature is important for proximal stability and has been linked to non-specific low back pain (NSLBP), but may have a similar effect on other chronic musculoskeletal pathologies of the lower extremity, such as patellofemoral pain (PFP). The transverse abdominis (TrA) is a spinal and core stabilizing muscle that has been shown to be dysfunctional in those with NSLBP and lack of core stability has been linked to other lower extremity injuries. The link of core stability through TrA characteristics has not been explored in both a NSLBP and PFP population, as compared to their healthy counterparts. **Objective:** To compare differences in TrA activity in various positions in individuals with NSLBP, PFP, and healthy individuals. **Design:** Cross-sectional study. **Setting:** University laboratory. **Patients or Other Participants:** Ninety-nine participants were included in this study. 25 individuals had NSLBP (19F, 6M; age: 22.2±4.2yrs; height: 168.5±7.7cm; mass: 69.2±15.0kg; Tegner: 6.5±2.3), another 24 had PFP (19F, 5M; age: 23.5±4.9yrs; height: 169.7±6.8cm; mass: 68.8±14.5kg; Tegner: 5.8±1.6), and the remaining 50 participants were healthy (38F, 11M; age: 21.1±2.4yrs; height: 165.1±26.3cm; mass: 66.5±14.5kg; Tegner: 6.4±1.6). **Intervention(s):** None. **Main Outcome Measure(s):** USI thickness measures of TrA were collected in a supine, hook-lying position (tabletop), standing (bipedal), in a single leg stance (unipedal), and during a single leg squat (SLS). All thickness values (mm) were normalized by body mass in kilograms. An ANOVA was used to determine effect of position and differences between groups. **Results:** There were no significant group effects or position effects when all 3 groups were compared. When NSLBP and PFP groups were combined, and compared to healthy individuals, there was a significant

group main effect in the unipedal and SLS positions (p=.053, 055) with the injured population having lower TrA thickness in both positions. **Conclusions:** Although there were no significant findings in the comparison of each injured group to the healthy controls, the lower thickness in both of the single leg positions when NSLBP and PFP are combined is meaningful. These groups do appear similarly at the core which could affect clinical focus in rehabilitation for individuals with chronic injuries of the lower extremity.

Word Count: 352

Key Words: core stability, chronic injury, ultrasound imaging

INTRODUCTION

Core stability and its relationship to lower extremity function has been investigated more frequently in the past decade. This has been explored primarily in individuals in the active or athletic population due to the types of injuries they incur due to their activities or sport of choice.[13,14,59–61] However, the injured group that has core dysfunction well established in the literature is the low back pain population, specifically non-specific low back pain (NSLBP) due to the frequency of muscle injury within this subgroup.[62] Other acute and chronic lower extremity injuries have been documented with a relationship to core dysfunction,[59,63] but the focus on improving assessment of the core in all of these groups is paramount. NSLBP sufferers can be challenging for clinicians to assess and treat due to the variety of symptom presentation and pain provocation,[62,64,65] which is similar to patients with patellofemoral pain (PFP).[66,67]

The complex nature of the comprising muscles of the core can make assessment and treatment cumbersome for those with weakness and neuromuscular dysfunction. The lumbopelvic-hip complex is at the center of the core stabilization discussion and can be difficult to evaluate as a whole, which forces investigators and clinicians alike, to choose representative muscles to evaluate. One of the contributing factors to the disparity of the definition of core stability in the sports medicine literature is that there are many methods of measurement used and all termed as representing “core stability”. This is problematic when trying to compare findings from multiple studies or making evidence-based decisions as a clinician with mixed results in the research published. One commonality in the studies looking at lumbopelvic-hip muscle function is that the transverse abdominis

(TrA) is an important spinal stabilizer due to its feed-forward mechanism of contraction that can provide a lot of information in regard to core stability. Due to its location deep to the external and internal oblique muscles, the TrA can be difficult to assess, but ultrasound imaging provides a visual of this deeper musculature. Viewing the TrA using ultrasound imaging has been shown to be reliable and not only in static positions, but in loaded, functional positions as well.[23,24,68] This measurement technique allows for a real-time view of the muscle thickness as the individual is placed in a range of body positions, that can be relaxed and on a tabletop or during a dynamic task.[16] Understanding how the muscle changes when placed under increasing demands can be very helpful to clinicians in addressing those potential deficits in treatment.

Inclusion of a variety of positions during USI assessment of the TrA is also an important consideration when investigators and clinicians, alike, are working to determine if core dysfunction is present. The reliance on what muscle function looks like in only a static, supine position is leaving out a large piece of the neuromuscular dysfunction puzzle that challenges those treating patients with these concerns. USI has been used to show differences in not only the positions, but in normalization methods for the resulting thickness measures from USI. Even in healthy people, modulations in muscle activity were found based on position.[16] The measurement of muscle activity in tabletop, static positions and more dynamic, gravity-loaded positions allow for investigators to obtain a comprehensive outlook on activation. Using a task, such as the single leg squat, which is used frequently for risk screening,[42,69,70] allows for an in-depth view of real-time muscle

function in a position that has a greater chance to mirror pain-provoking activities for people with NSLBP and PFP as opposed to simply lying on a table.

Assessment and rehabilitation are classically challenging for these injuries as well, therefore a common ground for improved assessment, through a visual method (i.e. musculoskeletal ultrasound imaging) would be impactful for clinicians. A common modifiable dysfunction between chronic musculoskeletal conditions may be present at the core level, as shown by TrA activity. Therefore, the purpose of this study was to compare TrA activity in two different chronic musculoskeletal conditions, NSLBP and PFP, to healthy individuals. A secondary purpose was to compare TrA activity in a variety of positions, ranging from static or relaxed, to standing, functional positions. We hypothesized that healthy participants would have greater TrA activation than both of the injured groups, with people with NSLBP displaying the lowest TrA activity of all groups. We also expected greater activation in the more functional positions as compared to static, relaxed measures.

METHODS

Study Design

This was a cross-sectional study conducted in a university laboratory setting. TrA activity was measured using ultrasound imaging at a single time point as a representative of core function in four different positions: tabletop (supine, hook-lying), bipedal stance, unipedal stance, and at peak knee flexion of a single leg squat.

Participants

Ninety-nine individuals participated in this study and 50 of those participants were considered healthy due to having no history of low back pain, knee pain or surgery, or other lower extremity injury in the past year from time of collection. Those with NSLBP were included if they had a self-reported history of 3 episodes of low back pain within the past 3 years of 5 episodes of pain in their lifetime, in which a painful episode caused an alteration in activity or function.[21,71] Participating individuals with PFP self-reported at least 3 months of peri- or retropatellar pain, with an insidious onset and no history of other knee surgery or injury. The PFP group also had pain with at least 3 of the following activities: prolonged sitting, squatting, jumping, running, kneeling, or stair ambulation. For all groups, individuals were excluded if they reported current pregnancy, neurological symptoms, or other muscular abnormalities.

Instruments

Ultrasound imaging was performed using a Siemens Acuson Freestyle unit (Siemens Medical, Mountain View, CA) with an 8-MHz linear transducer. For all standing or functional positions, a medium density foam block and elastic Velcro belt were used to fix the transducer to the lateral abdominal wall of each individual.[16] ImageJ software (National Institutes of Health, Bethesda, MD) was used for all image measurement.

Ultrasound Imaging

TrA imaging was completed by placing the linear transducer on the lateral abdominal wall approximately 10cm lateral to the umbilicus while simultaneously visualizing the musculotendinous junction of the TrA with the thoracolumbar fascia.[21,23] For tabletop measures, participants were instructed to lie supine in a hook-lying position with a bolster placed under their knees to allow for slight hip flexion and relaxation of the abdominal

muscles. Ultrasound gel was applied to the lateral abdominal wall and the transducer was placed to visualize the TrA on-screen. Participants were instructed on the abdominal draw-in maneuver for the contracted condition. They were told to draw their umbilicus toward their spine upon exhalation, and once the image was captured, the investigator allowed them to relax their TrA. Three images were taken in each of the rested and contracted conditions while the participants were supine, hook-lying. Upon completion of tabletop images, participants stood with feet shoulder width apart looking straight ahead while the investigator attached the ultrasound transducer to their lateral abdominal wall with the foam block and belt. Three images were captured while participants stood motionless for the bipedal stance measures. Participants then shifted their weight onto the limb, which was the same side as the transducer, with their arms crossed on their chest with hands rested on their shoulders. Another 3 images were saved in this position for the unipedal stance. The final position was the single leg squat, which was performed on the same side/leg in which the participant had the transducer. The participants completed 3 single leg squats and images were saved at peak knee flexion of each squat.[16] All bipedal, unipedal, and SLS measures were completed on the right side of the abdomen and then the transducer and belt were moved to the left side to complete the same sequence in the same order.

Data Processing and Statistical Analysis

Following all image capture, images were exported from the ultrasound unit for measurement using ImageJ software. Muscle thickness was determined by the distance from the inferior portion of the superior fascial border of the TrA, bordering the internal oblique, to the superior portion of the inferior fascial border. Distances were measured in

millimeters and were normalized by dividing each thickness value by body mass in kilograms using a ratio scaling normalization strategy (mm/kg).[52] Thickness measures during the contracted state, abdominal draw-in maneuver, in the tabletop position were used as the numerator in the activation ratio, while the rested tabletop thickness served as the denominator $\left(\frac{TrA\ thickness_{contracted}}{TrA\ thickness_{rested}}\right)$.[15] A functional activation ratio used the thickness during unipedal stance and SLS over the thickness during bipedal stance to represent TrA activity during the final positions of the sequence, unipedal and SLS $\left(\frac{TrA\ thickness_{unipedal/SLS}}{TrA\ thickness_{bipedal}}\right)$.[16] All TrA activity measures, thickness and activation ratios, were compared between all 3 groups, healthy, NSLBP, and PFP, as well as between healthy and the combined injured groups (NSLBP and PFP collectively). ANOVA for group-by-position was utilized for all comparisons using SPSS Statistics software (version 24.0, IBM Inc.). Mean differences and standard deviations were calculated using Microsoft Excel (Version 15.32, Microsoft Office), as well as Cohen's *d* effect sizes and 95% confidence intervals to show magnitude of change.

RESULTS

Table 1 outlines participant demographic information, which was similar between groups for height, mass, and activity level as measured by the Tegner activity scale. The single difference in demographics was from an older PFP group as compared to their healthy counterparts by a difference of 2.4 years (p=.034). TrA activity between all 3 groups is summarized in Table 2 and no significant group differences were found with the NSLBP or PFP group compared to healthy participants, or with NSLBP compared to PFP. When the NSLBP and PFP groups were combined to form a larger, injured group and compared

to healthy individuals (Table 3), the healthy group had significantly greater thickness in the unipedal position (p=.053) and tabletop activation (p=.043) using the standard ratio of contracted thickness divided by rested thickness. TrA thickness during the SLS was approaching significance (p=.055) for an increase in healthy people in comparison to the combined injured group.

DISCUSSION

In our study, we found no differences in TrA activity between the NSLBP, PFP, and healthy groups. However, we did discover differences in normalized thickness during unipedal stance and tabletop activation when the NSLBP and PFP groups were summed to create a unique, injured group to compare to their healthy counterparts. The application of TrA activity from USI to represent core activation in two different chronic musculoskeletal injuries is a novel strategy in improving understanding of these pathologies. TrA thickness and activation is commonly assessed in the NSLBP population and USI has been used not only to assess,[72,73] but also in treatment through biofeedback successfully.[29,74] In recent rehabilitation studies for individuals with PFP, core assessment was included,[9,18] but only by plank or bridge assessment, not using a visual, muscle thickness change approach. Due to the chronic nature of both of these pathologies, we hypothesized that there may be a similar dysfunction present in the more proximal structures. Although there was no difference found between each of the injured groups and the healthy participants, there still may be shared dysfunction, but just not in the clinical subgroups of the individuals with NSLBP and PFP in our study. Both of these pathologies also share multifactorial and complex etiologies,[7,10,26,62] which we believe is

supported by the difference found once these groups are combined and compared to healthy people in our study.

The decrease in thickness for the injured group during the unipedal position (Table 3) indicates that spinal stabilization through the TrA may be compromised when there is an injury either at the low back or even further down the kinetic chain to the knee for the PFP group. Decreased thickness in a single limb stance presents an additional concern that the individual is not stable at a deeper, local level. Active individuals, like the participants in our present study, are likely to move into a position where they must steady themselves on a single limb during activity. Moving into a single limb stance position with a decreased thickness in a key spinal stabilizer that contracts in a preparatory manner prior to movement could be detrimental. It has been documented that the TrA contracts prior to upper extremity movements[75] and is altered in pathological groups during lower extremity movements alike.[73,76]

The most compelling evidence found in our study to suggest a lack of core activity is the significant decrease found in the injured group in the tabletop activation ratio. A decrease of 0.144 or in percentage activation, 14.4% less TrA activation in a tabletop position is somewhat concerning for the injured individuals. Although there was not a training aspect of TrA contraction through the abdominal draw-in maneuver, this was consistent in all groups, as healthy participants did not receive additional instruction on performing the contraction. The inability to contract the TrA in an efficient manner has been shown to be linked to other musculoskeletal dysfunction and poor movement. The convoluted

nature of both NSLBP has also been connected to the presence of other musculoskeletal injuries.[26] The NSLBP participants in this study did not have PFP, and vice versa, but the lack of spinal stabilization in a static, supine position could lead to the occurrence of the other injury or others in the future, especially with participants that are trying to remain active.

Since there were no body mass, height, or physical activity level differences between all of the groups, the injured population proved to be a fairly young and active group. Due to the similar physical activity level, from the Tegner score, differences in core activation could be less distinguishable because of the injured population maintaining a comparable level of activity to the healthy control group. The age difference between the healthy and PFP group was affected by four participants that were age 30, 31, 32, and 37 at the time of the study. The decision was made to keep these participants in our analysis since there was no difference between the PFP and NSLBP groups in any of the TrA activity measures with those older participants included. The age difference and the lack of physical activity level difference cancel one another out essentially when looking at the broad perspective of the overall study results due to the absence of differences. Though the older participants were, at the least, approximately nine years older than the mean age of the healthy group, their physical activity had no statistical difference. This outward contradiction supports the notion that "injured" individuals regardless of age, can still appear like a younger, healthy person who is maintaining a comparable level of physical activity when TrA thickness and activation is assessed.

The usefulness of ultrasound imaging of the TrA has been shown throughout the low back pain literature and despite the lack of difference in most of the assessments in our study, the lack of change may have the greatest clinical implication. The multifactorial nature and enigmatic presentation[62,67] of these chronic musculoskeletal pathologies may be intimidating and cumbersome to clinicians. However, starting to assess for a global tactic in understanding how to improve assessment and treatment for these individuals, which may originate at the core.

Limitations

There were limitations to this study and one of those was the choice of only assessing TrA activity and no other core muscles. However, ultrasound imaging of the TrA is a reliable method in both static and dynamic positions,[23,24,68] and is a commonly utilized method to assess core activation. Future studies should investigate other aspects of core stability in these populations to determine if there are similar deficits. In our study, we averaged the right and left side TrA thickness and activity measures due to finding no difference between sides. Although in NSLBP and PFP, pain can be present on a single side or bilaterally, this should be considered as a separate analysis in future research. More dynamic tasks of increased difficulty, beyond the challenge of the single leg squat, may allow for investigators to identify a greater change in activation if there is a greater disparity present between those with NSLBP or PFP with healthy individuals.

Conclusions

There was no difference in TrA activity when individuals with NSLBP, PFP, and healthy controls were compared, but when NSLBP and PFP were merged into a single pathological group and compared to healthy participants, there was a difference.

Unipedal thickness and tabletop activation with an abdominal draw-in maneuver were lower in people with NSLBP and PFP. These two pathologies presented with a shared core dysfunction, even in participants remaining fairly physically active.

Table 1. Participant demographics (mean ± standard deviation)

	NSLBP (N=25)	PFP (N=24)	Healthy (N=50)	p-value
Sex	19F, 6M	19F, 5M	39F, 11M	
Age (years)	22.2±4.2	23.5±4.9*	21.1±2.4*	**.034**
Height (cm)	168.5±7.7	169.7±6.8	165.1±26.3	.576
Mass (kg)	69.2±15.0	68.8±14.5	66.5±14.5	.707
Side of pain	25 bilateral	9 right, 10 left		
Tegner Activity Scale (current)	6.5±2.3	5.8±1.6	6.4±1.6	.302

Abbreviations: NSLBP, non-specific low back pain; PFP, patellofemoral pain; F, female; M, male; cm, centimeters; kg, kilograms.
*Significant difference between groups
Alpha level set at $p \leq .05$

Table 2. Transverse abdominis activity, differences between 3 groups (mean ± standard deviation)

	Position	NSLBP (n=25)	PFP (n=24)	Healthy (n=50)	p-value
Normalized thickness at rest (mm/kg)	Tabletop	0.060±0.012	0.064±0.012	0.064±0.024	.724
	Bipedal	0.072±0.021	0.072±0.016	0.081±0.032	.274
	Unipedal	0.074±0.012	0.072±0.018	0.084±0.029	.153
	SLS	0.079±0.024	0.087±0.024	0.095±0.035	.127
Normalized thickness contracted (mm/kg)	Tabletop	0.089±0.021	0.098±0.024	0.101±0.036	.266
Activation Ratio $\frac{thickness_{cont}}{thickness_{rest}}$	Tabletop	1.537±0.300	1.486±0.255	1.655±0.407	.113
Functional Activation Ratio $\frac{thickness_{unipedal/SLS}}{thickness_{bipedal\ at\ rest}}$	Unipedal	1.053±0.172	1.068±0.137	1.070±0.149	.886
	SLS	1.169±0.267	1.241±0.281	1.226±0.233	.557

Abbreviations: NSLBP, non-specific low back pain; PFP, patellofemoral pain; SLS, single leg squat; cont, contracted.
Alpha level set at $p \leq .05$

Table 3. Transverse abdominis activity, differences between 2 groups (mean ± standard deviation)

	Position	Injured (NSLBP+PFP) (n=49)	Healthy (n=50)	p-value
Normalized thickness at rest (mm/kg)	Tabletop	0.062±0.012	0.064±0.024	.687
	Bipedal	0.072±0.019	0.081±0.032	.107
	Unipedal*	0.074±0.017	0.084±0.029	**.053**
	SLS	0.084±0.021	0.095±0.035	.055
Normalized thickness contracted (mm/kg)	Tabletop	0.093±0.023	0.101±0.036	.214
Activation Ratio $\frac{thickness_{cont}}{thickness_{rest}}$	Tabletop*	1.511±0.276	1.655±0.407	**.043**
Functional Activation Ratio $\frac{thickness_{unipedal/SLS}}{thickness_{bipedal\ at\ rest}}$	Unipedal	1.060±0.154	1.070±0.149	.740
	SLS	1.204±0.274	1.226±0.233	.670

Abbreviations: NSLBP, non-specific low back pain; PFP, patellofemoral pain; SLS, single leg squat; cont, contracted.
*Significant group difference
Alpha level set at $p \leq .05$

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SECTION III: APPENDICES

APPENDIX A: The Problem

Statement of the Problem

The lumbopelvic-hip complex is comprised of a variety of muscles, including: both larger, global movers, and smaller, local stabilizers. One of the frequently studied local stabilizers is the transverse abdominis (TrA), which has documented dysfunction in the non-specific low back pain (NSLBP) population.[77–79] The TrA has also been used as a representative of core function in many of these studies by providing muscle thickness changes and activation.[15] Ultrasound imaging (USI) is commonly used to provide a real-time view of muscle thickness and is reliable in not only static, rested positions, but also during movement in functional tasks.[23,68] Due to the preparatory nature of TrA contraction prior to movement, its influence on motion at the extremities becomes of great interest to further understanding to role of core stability in individuals with injury, specifically chronic musculoskeletal injury.[76,80] Core or trunk involvement in other chronic musculoskeletal injuries, such as patellofemoral pain (PFP) have been a focus recently in sports medicine research.[9,18] Most of the recent studies have only examined core endurance, through plank or bridging tasks, however the examination of the role of local spinal stability prior to movement could develop the understanding of this challenging pathology.[9,18,67]

Another muscle group within the lumbopelvic-hip complex that has been linked to PFP are the gluteal muscles due to their role at the hip, pelvis, and distal influences at the knee.[11] The gluteus medius (Gmed) has been the prime muscle of interest for most researchers due to its known weakness and diminished neuromuscular control in the

literature.[11,32,34] Gluteus maximus (Gmax) contributes to this overall dysfunction, however its role as a larger, global mover becomes less of a focus in many descriptive and rehabilitation-based studies. An increase in knowledge of how the Gmax and Gmed, collectively and individually, function is important in addressing deficits found in the PFP population. Strength assessment and muscle activation, via electromyography (EMG), are the most common methods of collecting muscle function of the Gmax and Gmed. Though, these methods do not provide a visual of the actual tissue moving real-time and cannot account for spatial or morphological changes of the muscles. USI, as utilized in NSLBP, could serve this role in the PFP population and act as an adjunctive method of muscle activity assessment. Gmed and gluteus minimus ultrasound has been performed in other studies, but with only a healthy population or individuals with hip pathology.[58] These prior studies have also predominantly used M-mode USI, which provides information on onset of muscle motion and timing, but not static images of muscle thickness obtained by the use of B-mode USI. Fascial borders of muscle tissue are necessary to visualize clearly to measure muscle thickness and B-mode imaging has been shown to have the optimal fascial view over M-mode.[47]

Due to the influence of proximal structures on chronic pathologies involving the lumbopelvic-hip complex, it is important for researchers and clinicians in the sports medicine community to identify a potential common thread between these pathologies. USI is advantageous in the determination of this potential common thread as it allows a non-invasive, real-time, reliable view of this deeper musculature. The relationship between core stability and lower extremity function has been explored recently as well

and seems to be relevant to sports medicine and health care professionals, especially in regard to tracking injury occurrence and effects of rehabilitation.[60] Since the TrA is one of the deeper local stabilizers that contracts in a preparatory manner before limb movement,[80] it becomes of increased interest as the probable commonality. Quantification of TrA activity in individuals with chronic musculoskeletal conditions, including: NSLBP and PFP, and the comparison of those individuals to their healthy counterparts would answer the commonality question. Just as core endurance has migrated into studies of pathologies beyond just low back pain, more fine motor control at the local level is the logical next step. Therefore, the purpose of this study is to determine lumbopelvic-hip function, through TrA activation, core endurance, Gmax and Gmed activation, following rehabilitation in those with PFP and TrA activity at baseline in those with PFP, NSLBP, as compared to healthy individuals.

Research Questions

1. Is lumbopelvic-hip complex function different in patients with patellofemoral pain and non-specific low back pain as compared to their healthy counterparts?
2. Does impairment-based rehabilitation over a 4-week period change transverse abdominis thickness or activation in individuals with patellofemoral pain?
3. Does impairment-based rehabilitation over a 4-week period change hold times for front and side planks in individuals with patellofemoral pain?
4. Does impairment-based rehabilitation over a 4-week period change Gmax or Gmed thickness or activation in individuals with patellofemoral pain?

5. Is there a relationship between Gmax or Gmed activation using ultrasound imaging and Gmax or Gmed activation using electromyography during a single leg squat?

Experimental Hypotheses

1. Healthy individuals will have greater lumbopelvic-hip complex neuromuscular function as compared to individuals with patellofemoral pain and non-specific low back, with non-specific low back having the worst function of all groups.
2. Transverse abdominis thickness and activation will improve over time as individuals with patellofemoral pain become more effective at activating their core.
3. Front and side plank times will increase following rehabilitation, even over a 4-week period we expect an endurance increase.
4. Gmax and Gmed muscles will both improve in activation, but Gmed will show a much greater improvement in activation following impairment-based rehabilitation.
5. There will not be a significant relationship between USI and EMG for the glutes during a single leg squat because they are measuring two different aspects of muscle activity.

Assumptions

- Ultrasound unit will provide high resolution images representative of underlying anatomy that muscle thickness is measurable
- Patellofemoral pain self-reported injury information is correct
- Low back pain truly present in participants as self-reported

- Participants can perform ADIM and gluteal contraction
- Baseline data influencing starting point of impairment-based rehab is representative of where each individual should start progression
- Supervising clinician is progressing appropriately for each individual participant
- Participants are not receiving clinical care or rehabilitation in another location during time of the study

Delimitations

- The subject population was not limited to a single clinical subgroup within the patellofemoral pain population in Manuscripts 1 and 2
- Gluteal contraction may not match the maximal contraction of the glutes in a standing, loaded position
- The subject population was limited to 18+ physically active individuals with non-specific low back pain episodic history (not in active, acute episode >8/10) for NSLBP group in Manuscript 3
- Still images were captured in B-mode during resting and contracted states rather than video recordings
- Measurements not taken real-time immediately following static image capture, images were exported and measured in ImageJ at a later date
- Transducer placement (through adipose and skin) especially for Gmax and Gmed with increased adipose for some individuals
- Anyone with previous experience contracting or who have been through rehabilitation focusing on these muscles

Limitations

- Positions used in study may be pain generating positions for PFP and/or NSLBP participants
- Participants may have experienced pain between sessions or changed levels of pain (although documented, could still affect contraction)
- Time of day in which the images were captured may have affected muscle thickness or contraction
- Food intake timing before image capture may have affected muscle thickness or contraction
- Anatomical variance between participants
    - Lateral abdominal wall fascial borders may be more obliquely oriented in some participants (measured perpendicular to an ideally horizontal fascial line)
    - Amount of adipose beneath the skin above the Gmax superior fascial border may vary, as well as presence of Gmin in some images
- Instrumentation delay for image capture may not capture true thickest point during contraction, especially during single leg squat
- Ability to sustain contraction for image capture may not capture true thickest point during contraction

Operational Definitions

Abdominal draw-in maneuver (ADIM): preferential, focused contracted of the transverse abdominis

Activation ratio (AR): muscle thickness during a contraction divided by that same muscle's thickness at rest, also called "contraction ratio"[15]

Disability: diminished capacity following injury, usually related to activity in the physically active population; evaluation of function should be used to determine[81]

Episode of low back pain: period of time in which pain has started in the low back region, unilateral or bilateral, and has caused a decrease in functionality[71]

Functional activation ratio (FAR): activation ratio with muscle thickness during a task or exercise divided by rested muscle thickness in a quiet stance or equivalent to the task[16]

Impairment-based rehabilitation: rehabilitation based on an initial baseline collection of range of motion, strength, functional task movement efficiency that is progressed based on individual gains[8]

Lateral abdominal wall: external oblique, internal oblique, transverse abdominis

Muscle thickness: oblique or cross-sectional measure of muscle width from fascial border to fascial border

Non-specific low back pain (NSLBP): low back pain that has no diagnosed or known source[62]

Patellofemoral pain (PFP): peri- or retropatellar pain with an insidious onset that causes a change in activity (stair ambulation, jumping, squatting, running, kneeling, prolonged sitting)[3]

Remission (of symptoms): complete absence of symptoms

Resolution (of symptoms): disability is still present, but individual has self-reported as still functional, meaning debilitating pain is absent

Ultrasound imaging (USI): imaging technique using ultrasound to visualize structures within the body, including muscles, neurovascular structures, and organs

Significance of the Study

Understanding the link of a proximal breakdown contributing to distal pathology is a growing interest in sports medicine literature. Quantification of specific muscle function allows for clinicians to target dysfunctional muscle groups. Insight into how individuals with PFP change their proximal muscle activity following an impairment-based rehabilitation that includes an individualized progression with not only quadriceps and knee-focused exercises, but core and movement during functional task emphasis as well. The identification of a potential commonality at proximal musculature for multiple chronic musculoskeletal conditions, NSLBP and PFP, would either highlight an area that clinicians should include in intervention across both pathologies or indicate that a distal focus should be maintained.

APPENDIX B: Literature Review

Lumbopelvic-Hip Complex

The erector spinae, latissimus dorsi, adductors, hip flexor complex, internal and external obliques, transverse abdominis (TrA), lumbar multifidus (LM), gluteus medius (Gmed), gluteus maximus (Gmax), and rectus abdominis are some of the major muscles that makeup the lumbopelvic-hip complex. The complex nature of how these muscles function together for optimal postural control and movement has been widely studied from a variety of approaches. Understanding how the muscles function alone and altogether is very important to determine normal, healthy function, but also what pathological groups look like as well, such as with a low back pain population[62,82,83] or those with patellofemoral pain or other chronic knee pain. The lower-crossed syndrome is another postural presentation of when the complexity of these muscles working together is faulty.

The lumbopelvic-hip complex can also be broken into two categories: local stabilizers and global movers. Some of these muscles are smaller, shorter muscles with less complex pennate and fiber structures and may only cross a small, single joint. Conversely, there are some of the largest muscles in the entire musculoskeletal system that also play very important roles within the lumbopelvic-hip complex and the body as a whole. The TrA and LM are two of the deeper spinal stabilizers that are key contributors to the lumbopelvic-hip complex and have been linked to neuromuscular dysfunction in people with low back pain.[73,78] The Gmax is one of the larger global movers that contributes to lower extremity movement and hip control in combination with the Gmed, which also

provides local stability to the pelvis. The Gmax has been linked to dysfunction with females with low back pain and both of the glutes have overwhelming evidence in the patellofemoral pain literature for weakness and faulty activation during movement and functional tasks.[34,83,84] The neutral zone of the spine is also important to consider when discussing the lumbopelvic-hip complex or "core" as this zone allows for minimal tension in ligaments on those segments, as the activation of the muscles in that area work for efficiently.[85]

Core Stability

Core stability or even the core in general is often misunderstood and labeled in various manners throughout literature. Muscles that are centrally located on the body tend to be considered as contributors to core stabilization, which would also include the lumbopelvic-hip complex in its entirety. Optimal use of these muscles is thought to allow for proximal stability, thereby allowing for optimal movement of the limbs or extremities. There is a local function that must not be ignored as well and has been characterized by the abdominal draw-in maneuver for a targeted or focused contraction of the TrA and the abdominal bracing technique, which has more a global contraction of the larger muscles as well. Positioning of the muscles or the core or lumbopelvic-hip complex and their subsequent recruitment is very important to how the entire body and kinetic chain functions. Evaluation and treatment of these muscles can prove to be challenging for clinicians and researchers due to the layers and multiple contributions for singular members of the complex. Core stability is not only important for postural control and support of the spine, hip, and pelvis, but also has been linked to level of athletic

performance that an athlete is able to obtain. How the segments move together and reliance on the core for stability are important factors to consider and have been explored in the literature, as well as balance and proprioception.[13]

Unfortunately, as aforementioned, there is no consistency at this point in the greater body of literature in this area, in the definition of core stability. An accepted definition was put forth by Kibler et al in 2006, as "the ability to control the position and motion of the trunk over the pelvis and leg to allow optimum production, transfer and control of force and motion to the terminal segment in integrated kinetic chain activities." This definition brings a larger focus and spotlight to athletic function and physical performance, which is pertinent to the sports medicine and athletic training disciplines.[13]

As the lumbopelvic-hip complex and the core overlap and contribute to each other's existence, the appreciation for how each piece works on its own and together becomes of greater interest. This is where a lot of the breakdown in function occurs and longer term neuromuscular dysfunction can either cause or be a side effect of chronic pain and pathology. The lateral abdominal wall, TrA, external and internal obliques, as well as the rectus abdominis more anteriorly create intra-abdominal pressure upon contraction. As these contractions increase that pressure and also create an increased tensile force through the thoracolumbar fascia, a rigid cylinder is formed in which increases spinal stiffness.[86] This idea links back to that proposed by Panjabi, where the thoracolumbar fascia, spine, and abdominal musculature work together like the tent poles and tent material to keep the tent upright and functional. If there is a breakdown or dysfunction in the "tent" then there

can be a collapse of stability.[85] Stability is also tri-planar and requires various patterns of activation from the muscles of the core or lumbopelvic-hip complex.[13] The diaphragm and breathing patterns, if abnormal, can take a toll on this stability in just as an impactful manner as a lack of neuromuscular control and activation.[87]

Non-specific Low Back Pain

Low back pain accounts for a large percentage of all back injuries, of which 23% of those chronic low back pain sufferers have non-specific low back pain (NSLBP).[62] NSLBP is back pain of which there is no diagnosed source of pain.[62,88] This type of low back pain can be especially frustrating to individuals suffering from this condition, to clinicians trying to treat the pathology, and to researchers attempting to understand the condition further. Muscle involvement has been associated with NSLBP and may be one of the primary contributors to the non-specific nature. Episodes of pain, which are painful periods that can be unilateral or bilateral, that affect normal function or activities of daily living.[89,90] Symptoms can be similar or different across episodes, but pain provoking positions or activities are often linked to return of these episodes. Remission of symptoms occurs when the symptoms resolve for a period of time, but ultimately return. Resolution of symptoms occurs when back pain does not return and neuromuscular residual symptoms also have resolved.[91] Those in remission unfortunately still suffer from the neuromuscular deficits. There has been a recent increase in focus in the literature about recurrent low back pain for the remission group, as most of the literature focused on those with active low back pain.[92–94]

NSLBP can be provoked by different activities and there are different approaches to rehabilitation and functional movement assessment as well.[91,95] Low back pain has been previously thought to only affect younger individuals if there was a significant injury present or other spine-related condition, however there is an increase in younger, active individuals that also have NSLBP.[21,25,96] Apart from the usual activities and positions that produce pain, including, occupational sitting, standing and walking, pushing or pulling, bending and twisting, and lifting or carrying[62], participation in exercise or sport can also cause pain.[97–100]

Short and long-term effects

There are both short and long-term effects of NSLBP that have been documented, which have led to further investigation of how these aspects of the pathology lead to episodic return, financial burden, sedentary lifestyle, and a larger public health effect. Short-term effects include: increased pain, decreased function, altered athletic performance, increased potential for recurrent episodes of NSLBP, increased disability,[90,91,95] increased financial burden, aberrant movement patterns, and psychological damage[101–103], which has become more of a focus with the use of cognitive behavioral therapy as a LBP intervention. Disability can be measured by a variety of patient-reported outcome measures, but the Oswestry Disability Index[104] and Roland-Morris Questionnaire are two of the most frequently used in the literature to quantify disability and pain in the LBP population. Longer effects of NSLBP can be more difficult to quantify and to follow with prospective studies when compared to some of the short-term effects, however there is a clear link between the short and long-term effects that create a logical link as to why

NSLBP is such a chronic issue for so many people. Recurrence of painful episodes remains a long-term effect, in addition to increased disability, increased financial burden, and psychological damage which are all short-term effects as well. A decrease to quality of life and longer lasting neuromuscular changes are the long-term effects that have been investigated more recently as measured by patient-reported outcome measure tools and through muscle activity measurement tools, like ultrasound imaging and electromyography.

Spinal Stabilization

A lack of spinal stabilization has been found in numerous studies in the low back pain population and has been a primary focus of intervention and rehabilitation programs. Traditional core stabilization programs that include a focus on the abdominal draw-in maneuver and other postural control exercises have been a mainstay in the LBP literature with mixed results.[105–107] The use of clinical predictor rules have been incorporated into the rehabilitation approach to LBP, but have revolved around manipulations and other manual therapy.[108] Biofeedback studies using ultrasound imaging have also found mixed results in the decrease of pain or at least increase in activation of spinal stabilizers focusing on the TrA.[21,29]

Approach to Assessment & Rehabilitation

Pain and disability have both been investigated frequently in the low back pain literature, both individually and together. Other factors have been assessed as well in the low back pain population, but these two domains have become increasingly paid attention to in the

NSLBP realm. Just as the exploration of LBP incidence increasing with age, the changes in pain and disability through various levels of function or exercise are just as important for the younger, more active population.[109] A recent review and proposal of a new method to approach rehabilitation management of low back pain, multiple domains have been proposed as necessary factors to address in rehabilitation.[26] These domains included: nocioceptive pain drivers, nervous system dysfunction drivers, comorbidity drivers, cognitive-emotional drivers, and contextual drivers. Nocioceptive pain drivers include more common or modifiable drivers, like symptom modulation, movement control, mobility and pain, as well as more complex drivers, like non-specific deconditioning and structural stability deficits. Within the nervous system dysfunction drivers, there are modifiable factors of radicular pain patterns, signs of radiculopathy, and signs of myelopathy, in combination with the more complex hyperalgesia, allodynia, and central sensitization. Both of the aforementioned drivers are all pain drivers stemming from body functions and structural deficits, which is where most sports medicine or physical therapy-related studies focus.[105,110,111] The next domain covering personal factors, which drive pain and disability are the comorbidity drivers. Comorbidities included the more modifiable co-occurring painful musculoskeletal pathologies and the more complex co-morbid mental health disorders and sleep disturbances. Cognitive-emotional drivers also lie within this domain and include modifiable negative affect/moor, expectations, pain-related beliefs and cognitions, illness perception, self-efficacy, and coping. The more complex portion of this driver section are pain avoidance behaviors.[26] These can be challenging to assess and document and compare between individuals with an already complex chronic pathology. More recent LBP intervention

studies have included at least a measure of these cognitive-emotional drivers and some even attempted to modify these through cognitive-behavioral and LBP educational therapy.[101–103] The final domain includes environmental factors that drive disability and are labeled the contextual drivers. The more modifiable or common elements include: low return to work expectation, low job satisfaction or high job stress, perception of heavy work, and high occupational demands, with the more complex elements of poor attitudes of employers, family or health care professionals, and low or non-access to care. These can be very challenging to address through intervention and are usually solely documented, if that.[26] Tracking patients through this type of model and charting where the patient is on each domain can assist in assessment and drive intervention and may be utilized more frequently in the literature after this revision of this model.[26]

Patellofemoral Pain

Etiology & Epidemiology

Patellofemoral pain (PFP) is peri- or retro-patellar pain that has an insidious onset which accounts for up to 25% of knee injuries[2], but has been shown more recently to account for approximately 7% of knee injuries.[1] Pain can occur in an episodic pattern[3] and be provoked by a variety of activities or tasks.[39] Due to its unclear etiology, this pathology can be challenging for researchers and clinicians to diagnose and treat. Muscle weakness and neuromuscular dysfunction has become a large area of focus within the patellofemoral pain research and all age groups can be affected by this pathology. Although, there is a higher prevalence of patellofemoral pain in females as compared to their male counterparts.[1,32,34,38] Some of the pain provoking activities that traditionally

plague those with patellofemoral pain are: running, jumping, squatting, prolonged sitting, kneeling, and stair ambulation.[4,38,112] Some of the additional criteria that is not essential to be considered PFP includes: grinding or crepitus from the patellofemoral joint during movements involving knee flexion, tenderness upon palpation of the patellar facet, small effusions, pain during sitting, rising on sitting, or fully extending the knee following sitting. These criteria were decided upon at the 4th International Patellofemoral Pain Research Retreat in Manchester and was disseminated through the 2016 Patellofemoral pain consensus statement.[113] Another key criteria discussed in the definition of PFP was that those that had dislocated their patella or who reported feelings of subluxation should be excluded from all PFP studies or considered as a completely separate subgroup due to their different presentation, risk factors, and treatment approach.[113] Females have also consistently been documented as having a higher incidence of PFP.[1,3,17] In a recent epidemiological study, within most age groups in a large healthcare insurance database, females were reported as having PFP more. In ages below 10 years old, 20-29, and 70+ were the only age groups where females were slightly lower, not statistically significant, but had a lower report of PFP. The greatest incidence of PFP was found in the 30-39, 40-49, and 50-59 age groups as well. This particular epidemiological study published in 2015 reported lower incidence and prevalence as compared to other studies that ranged from 1981-2011. This study included over 2.1 million cases from the large database, which is considerably larger than all of the other published epidemiological studies on PFP.[1,2,4,38]

Associated muscle weakness, dysfunction, and treatment

The presence of quadriceps weakness has been documented thoroughly in the literature in those with PFP and the more proximal muscles, including the Gmax, Gmed, and other lumbopelvic-hip complex muscles have also been shown as dysfunctional and weak.[39,40,114,115] Electromyography has been used traditionally to quantify muscle activity in PFP studies, focusing on the quadriceps and Gmed most frequently, along with strength measures, concentrically, eccentrically, and isometrically.[9,32,34,40] The imbalance of the vastus medialis oblique (VMO) and the vastus lateralis (VL) in the quadriceps group has also been explored as another source of increased patellofemoral joint stress, which could lead to increased pain and decreased function.[116] The interaction of all of these muscles has a great contribution to PFP, although there is still much debate on the clinical subgroups and the best treatment interventions due to its unclear etiology.[67] Regardless of the controversy linked to the pathology, the effect of the proximal muscle weakness has also been linked to increased hip adduction and internal rotation during some of the primary pain-provoking activities for PFP, squatting, stair ambulation, and running.[117] This has been strengthened by the inclusion of more proximal muscle focused rehabilitation interventions. The idea of a "proximal link to a distal problem" was proposed in 2009 and magnified the focus on the gluteal muscles and their contribution to the neuromuscular dysfunction and weakness in those with PFP.[11] Even more recent studies have explored how the traditional quadriceps focused rehabilitation compares to rehabilitation that includes a hip and even core-focus in their program.[9] The core-focused program used planks and core activation in addition to traditional quadriceps and gluteal activation and strengthening exercises. The hip/core program in this large multi-center

randomized trial showed the largest improvement in pain and overall strength gains of the proximal and local muscles assessed.[9] Planks that were timed to failure, front and side plank directions, have been incorporated in recent studies to assess global core function in those with PFP with the idea that those with the chronic condition and increased pain would have more difficulty with core endurance.[9,18]

Beyond the definition of PFP, there have been other aspects of the chronic condition set forth by the consensus statement following the 2016 PFP retreat. The discussion of risk factors that are related to PFP and patellofemoral (PF) osteoarthritis was a part of the statement. Abnormal joint alignment at the PF joint and trochlear groove abnormalities were linked to PF osteoarthritis. Muscle weakness that is already associated with PFP was also linked to PF osteoarthritis, such as: quadriceps weakness, decrease in quadriceps muscle size, force, and strength. For younger individuals that do not have arthritic changes, the gluteal muscles and more proximal muscles in the lumbopelvic-hip complex are linked to a greater degree. Aberrant movement or altered biomechanics were also found in those with PF osteoarthritis as are found in the usual PFP patients as well. Problematic movement during stair ambulation is one example where decreased knee extension moments, quadriceps force, and joint reaction forces at the PF joint were decreased.[118] However, there are also contradictory findings in the literature that have shown no differences in pelvic, hip, or knee kinematics between those with PF osteoarthritis and healthy controls.[119] Gait biomechanics have been explored in this group frequently and continues to be prevalent in the literature, which will provide more evidence to help explain the prevalence, incidence, and factors of PF osteoarthritis.[119]

Impairment-based Rehabilitation

PFP Clinical Subgroups

A classification system for targeted intervention for those suffering from PFP was designated within a large sample of 150 patients over 18 months. Six potential subgroups were found from this study that included adults 18-40 years old that met the usual criteria for those with PFP. The researchers who founded the classification system used a three-phase work program that allowed for creating the classifications, test the feasibility, and finally perform a randomized-control trial to evaluate the cost-effectiveness of the proposed classification framework. The six potential subgroups were broken down from proximal, local, distal, and regional groupings of focus. Hip abduction weakness, quadriceps weakness, patellar hypomobility, patellar hypermobility, foot pronation, lower limb biarticular muscle tightness became the six proposed classifications. These were proposed for their ease of performance in the clinical and research setting and covered previously proposed groupings into one classification system. The tests to determine classification were performed using hand-held dynamometry, performance of a manual patellar glide test, foot posture index, and inclinometry.[7] These classifications create a simpler approach than how complex the etiology of PFP can seem, but may not be all encompassing. Within phase 3 of this larger study, the testing of the system, the majority of participants fell into the hip abductor weakness classification, however there was a great deal of cross-over between some of the classifications.[10] An efficacy study still needs to be completed for this system. There was also different characterization of participants that arose from these classifications. For example, a “strong” group proved to

have greatest length of rectus femoris, low pain scores, males, higher function and quality of life and older. A “weaker”, “tighter” subgroup was shown to have a higher body mass index, Modified Functional Index Questionnaire, Self-completed Leeds Assessment of Neuropathic Symptoms and Signs pain scale, lower physical activity, longest duration of PFP.[10] Creation of these subgroups provides evidence toward an impairment-based rehabilitation model to assess range of motion and strength of proximal, local, and distal muscles, movement during functional tasks, and core stability. Performance of a comprehensive assessment including all of these factors allows for a personalized progression for all PFP sufferers that is more individualized than most intervention programs proposed previously in the literature.[8] An eight-week rehabilitation program proposed by one research group included a similar approach. Exercises that were included were: trunk extensions on a swiss ball, isometric hip abduction/lateral rotation while standing, hip abduction/lateral rotation/extensions, hip extension/lateral rotation in prone, hip abduction/lateral rotation with slight knee and hip flexion while side-lying, pelvic drop while standing, lunges, prone knee flexion, seated knee extensions at 90-45 degrees of knee flexion, single-leg standing on an unstable surface, transverse abdominis and multifidus muscle training, lateral and ventral bridges, hip lateral rotation in closed kinetic chain position, single leg deadlifts and single leg squats. These exercises were all progressed in difficulty every 2-3 weeks over the 8-week period.[19] In an abbreviated 4-week adaptation of this 8-week program, individuals completed 4-way straight leg raises, seated knee flexion and extension, wall squats, isometric hip abduction and external rotation, clam shells, pelvic tilts prone, pelvic tilts on swiss ball, single leg balance with eyes open and closed in the first two weeks. In the final two weeks, the exercises were

advanced with some of the same exercises including: 4-way straight leg raises, seated knee flexion and extensions, wall squats, clam shells, single leg balance with eyes open and closed, along with more advanced exercises: lateral rotation in closed-kinetic chain, step ups, step downs, pelvic drops, planks (anterior and lateral), trunk extension on swiss ball, single leg squats, lunges, and single leg deadlifts with mirror training.[8]

Measurement of Muscle Activity

Ultrasound Imaging

There are a variety of tools available for muscle assessment, however ultrasound imaging (USI) provides a non-invasive, real time view of deeper tissues. Within sports medicine and rehabilitative literature, USI has been utilized to view deeper abdominal structures, as well as spinal stabilizers.[15,120,121] The TrA has become a prime candidate for USI due to its anatomic location and difficulty with assessment through other methods, such as electromyography (EMG). Investigators have shown excellent reliability of USI of the lateral abdominal wall during static, tabletop positions, as well as more dynamic, loaded positions.[23,24,51]

Tabletop, static measurement has been the traditional approach to USI since the patient and transducer are not required to move and therefore an optimal image can be obtained. However, the need for a more functional assessment has arisen with the advancement of technology in ultrasound imaging as well as the need for clinicians and researchers to understand more about pathology of pain in functional positions.[16,68]

Thickness and Activation

Muscle thickness from superior fascial border to inferior fascial border in a B-mode static image is the primary outcome in lateral abdominal wall studies using USI, but must be clearly visible on the image in order for proper measurement.[15] Visualization of the musculotendinous junction is crucial for lateral abdominal wall images when using a linear transducer or a curvilinear transducer, with the transducer placed on the abdominal wall approximately 10cm lateral of the umbilicus.[21]

Measurement of the LM has been shown to have the highest reliability when assessed at the L4-L5 level, with one study as an exception with higher reliability at L5-S1, but can present an issue with optimal muscle thickness visualization.[122,123] Thickness measurements are usually taken in rested and contracted states, such as the abdominal draw-in maneuver for the TrA and LM. Capture of a rested and contracted image allows for use of an activation or preferential activation ratio, which provides more information on muscle activity beyond a rested state.[15] A series of images should also be captured to improve reliability in order to produce a mean of thickness or cross-sectional area, with three images being shown as an acceptable number for the TrA and LM.[22] Gluteal muscle thickness is predominantly discussed in the literature for diagnostic purposes or for ultrasound guided procedures, however there are a few select studies that have investigated gluteus maximus, medius and gluteus minimus thickness in both static and dynamic positions.[47,48,58] M-mode, motion imaging, has been used frequently with the gluteal muscles in conjunction with EMG, in order to show timing of muscle contraction during a variety of tasks in both healthy individuals and those with hip dysfunction.[58] B-

mode and M-mode USI have utility in muscle activity assessment, but must be differentiated if the study goal is to assess muscle activation or thickness changes and whether a time component is needed or not.[47]

Electromyography and its connection to USI and muscle activity

EMG is used to measure electrical muscle activity and can be processed to determine onset of activation, maximal activation, duration of activation, and other timing and magnitude variables with either surface or fine-wire electrodes. Surface electrodes are less invasive, however can have issues with cross-talk or interference of the electrical signal from skin and subcutaneous tissue or adipose. Fine-wire electrodes are invasive and only provide information for a small pin-pointed broadcast area, which forces an assumption of total muscle activity from a single area. Deeper muscle structures can be difficult to measure using surface EMG and USI may be a more appropriate assessment alternative for those muscles.[124] The TrA is an example of a muscle that benefits from the use of fine-wire EMG due to its deeper nature and surface EMG signal can be distorted or misconstrued as oblique muscle activity instead. The gluteus medius is another muscle that lies beneath other tissue that can make surface EMG challenging, but surface assessment allows for increased freedom in tasks that an individual can perform during EMG assessment.[124]

EMG & USI Synchronization

Using EMG and USI simultaneously has been shown to be a more comprehensive outlook on muscle activity, especially for the more challenging muscles that are less

superficial. The Gmed and Gmin have been assessed to show that EMG and USI can show both visual/spatial and electrical onset of muscle activation in different hip-related tasks, such as a hip hitch and step-down task.[58] Custom programming to sync EMG and USI allow for a side-by-side visualization of each type of muscle activity capture[46] and has potential for biofeedback intervention application as well. EMG has also been used an adjunctive method of muscle measurement that is not collected simultaneously, but can be additional information on changes in muscle activity that are present, especially in pathologic populations compared to their healthy counterparts.[46,125,126]

Functional Activation

The traditional activation ratio assessed muscle activity by dividing the contracted muscle thickness by the rested muscle thickness. This method is applicable for tabletop, static positions, but has been shown to not provide the complete picture of muscle activation when capturing B-mode images during a task. The functional activation ratio (fAR) has proposed another method to calculate muscle activity during a task, such as a single leg squat. The numerator becomes the muscle thickness at peak knee flexion of a single leg squat, or other task of choice, and the denominator is muscle thickness during quiet stance, which is similar to a quiet EMG normalization strategy.[16] Even in healthy individuals, functional activation is not present in all people with the TrA during a single leg squat. It has been shown that out of a healthy cohort of 35 individuals with no history of lower extremity injury, surgery, or low back pain, that only 94.29% of those individuals could attain a TrA thickness during an abdominal draw-in maneuver that was thicker or "activated" as compared to rested thickness will supine hook-lying on a

tabletop. This activation further decreases and less of that 35-participant sample is able to attain a thicker TrA muscle while standing with both feet on the floor as well as during a single leg squat. Even when those healthy individuals were asked to perform an abdominal draw-in maneuver and hold that contraction during the single leg squat, there was still a portion of the sample, 17.14% that could not thicken or activate their TrA.[16] This shows that it can be dangerous to assume that all healthy individuals are able to contract and activate all of their muscles "perfectly" or beyond a rested position in the absence of injury history or current pain. Understanding if healthy people can activate their TrA during a functional task is imperative before making that assumption and comparing supposed healthy individuals to a pathologic group.

APPENDIX C: Additional Methods

Table C1. University of Virginia Institutional Review Board Approved Protocol (Manuscripts 1 and 2) (IRB-HSR #17909)

IRB-HSR PROTOCOL

Investigator Agreement

BY SIGNING THIS DOCUMENT, THE INVESTIGATOR CONFIRMS:

1. I am not currently debarred by the US FDA from involvement in clinical research studies.
2. I am not involved in any regulatory or misconduct litigation or investigation by the FDA.
3. That if this study involves any funding or resources from an outside source, or if you will be sharing data outside of UVA prior to publication that you will contact the Dean's office regarding the need for a contract and letter of indemnification. If it is determined that either a contract or letter of indemnification is needed, subjects cannot be enrolled until these documents are complete.
4. The proposed research project will be conducted by me or under my close supervision. It will be conducted in accordance with the protocol submitted to and approved by the IRB including any modifications, amendments or addendums submitted and approved by the IRB throughout the life of the protocol.
5. That no personnel will be allowed to work on this protocol until they have completed the IRB-HSR On-line training and the IRB-HSR has been notified.
6. That all personnel working on this protocol will follow all IRB-HSR Policies and Procedures as stated on the IRB-HSR Website http://www.virginia.edu/vprgs/irb/ and on the School of Medicine Clinical Trials Office Website: http://knowledgelink.healthsystem.virginia.edu/intranet/hes/cto/sops/sop_index.cfm
7. I will ensure that all those delegated tasks relating to this study, whether explicitly or implicitly, are capable through expertise, training, experience or credentialing to undertake those tasks.
8. I confirm that the implications of the study have been discussed with all Departments that might be affected by it and have obtained their agreement for the study to take place.
9. That no subjects will be recruited or entered under the protocol until the Investigator has received the signed IRB-HSR Approval form stating the protocol is open to enrollment
10. That any materials used to recruit subjects will be approved by the IRB-HSR prior to use.
11. That all subjects will sign a copy of the most current consent form that has a non-expired IRB-HSR approval stamp.
12. That any modifications of the protocol or consent form will not be initiated without prior written approval from the IRB-HSR, except when necessary to eliminate immediate hazards to the subjects.

13. Any significant findings that become known in the course of the research that might affect the willingness of subjects to enroll or to continue to take part, will be promptly reported to the IRB.
14. I will report immediately to the IRB any unanticipated problems involving risk to subjects or to others including adverse reactions to biologics, drugs or medical devices.
15. That any serious deviation from the protocol will be reported promptly to the Board in writing.
16. That any data breach will be reported to the IRB, the UVa Corporate Compliance and Privacy Office , UVa Police as applicable.
17. That the continuation status report for this protocol will be completed and returned within the time limit stated on the form.
18. That the IRB-HSR office will be notified within 30 days of a change in the Principal Investigator or of the closure of this study.
19. That a new PI will be assigned if the current PI will not be at UVA for an extended period of time. If the current PI is leaving UVa permanently, a new PI will be assigned PRIOR to the departure of the current PI.
20. All study team members will have access to the current protocol and other applicable documents such as the IRB-HSR Application, consent forms and Investigator Brochures.
21. Signed consent forms and other research records will be retained in a confidential manner. Records will be kept at least 6 years after completion of the study.
22. No data/specimens may be taken from UVa without a signed Material Transfer Agreement between OSP/SOM Grants and Contracts Office and the new institution. Original study files are considered institutional records and may not be transferred to another institution. I will notify my department administration regarding where the originals will be kept at UVa. The material transfer agreement will delineate what copies of data, health information and/or specimens may be taken outside of UVa. It will also approve which HIPAA identifiers may be taken outside of UVa with the health information or specimens.
23. If any member of study team leaves UVa, they are STRONGLY ENCOURAGED to use Exit Checklist found on IRB-HSR website at http://www.virginia.edu/provost/facultyexit.pdf.

The IRB reserves the right to terminate this study at any time if, in its opinion, (1) the risks of further experimentation are prohibitive, or (2) the above agreement is breached.

Investigators Experience

PI: Susan Saliba: tenured faculty at UVa; licensed athletic trainer and physical therapist. Dr. Saliba has been involved in numerous IRB approved human research studies while at UVa, and is an experienced PI. Dr. Saliba is an expert in the field of electrical stimulation and injury recovery.

Subinvestigator: Neal Glaviano– doctoral student at UVa; licensed athletic trainer. Neal has previously been involved in IRB approved human research studies at UVa.

Subinvestigator: Ashley Stern– doctoral student at UVa; licensed athletic trainer. Ashley has previously been involved in IRB approved human research studies at UVa

Subinvestigator: Mark Feger– doctoral candidate at UVa; licensed athletic trainer. Mark has previously been involved in IRB approved human research studies at UVa
Subinvestigator: Grant Norte– doctoral candidate at UVa; licensed athletic trainer. Grant has previously been involved in IRB approved human research studies at UVa
Subinvestigator: L. Colby Mangum- doctoral student at UVa, licensed athletic trainer. Colby has been previously involved in IRB approved research studies at UVa.

Signatures

Principal Investigator

_____	_____	_____
Principal Investigator Signature	Principal Investigator Name Printed	Date

The Principal Investigator signature is ONLY required if this is a new protocol, a 5 year update or a modification changing the Principal Investigator.

Department Chair

BY SIGNING THIS DOCUMENT THE DEPARTMENT CHAIR AGREES:

1. To work with the investigator and with the board as needed, to maintain compliance with this agreement.
2. That the Principal Investigator is qualified to perform this study.
3. That the protocol is scientifically relevant and sound.

_____	_____	_____
Department Chair or Designee Signature	Department Chair or Designee Name Printed	Date

The person signing as the Department Chair cannot be the Principal Investigator or a sub-investigator on this protocol. The Department Chair or Designee signature is ONLY required if this is a new protocol or a modification changing the Principal Investigator.

Brief Summary/Abstract

The purpose of this study is to determine the effect of a 4-week rehabilitation program with or without electrical stimulation treatment on lower extremity kinematics and muscle activation during functional exercises in subjects with a previous history of patellofemoral pain syndrome (PFPS). For this evaluation we will be used the Omnistim 2 ProSport electrical stimulation device with is a marketed medical device currently in use at the University of Virginia. We are using this device per the manufacturer's guidelines in the intended patient population.

Up to 46 subjects with a history of PFPS will be recruited to participate in this project. Subjects will be randomized to receive Patterned Neuromuscular Electrical Stimulation (PENS) OR Sham (sensory) stimulation. These stimulation procedures are described in detail in the Biomedical Research section of this document. It is the effectiveness of the PENS treatment method that is being studied, not the effectiveness of the device.

Subjects in this study will self-refer or respond to recruitment efforts such as flyers. The subjects may or may not have undergone previous rehabilitation programs. Subjects may

decide to seek traditional rehabilitation after or before participation in this study. Subjects may not be participating in a rehabilitation program concurrently with the study.

We hypothesis that those who receive rehabilitation with the electrical stimulation will improve muscle strength, improve patient reported outcomes and improve muscle activation and kinematics during functional tasks, such as squatting, stair ambulation and gait. We hypothesis that by improving muscular activation of the gluteus medius, individuals with a history of PFPS will improve frontal plane kinematics while performing functional tasks when examined by hip adduction, hip, rotation, trunk lean, and knee abduction. We will measure lower extremity kinematics, EMG muscle activation, and muscle thickness measured via ultrasound imaging pre-intervention and post-intervention. Peak knee flexion angle and peak external knee flexion moment will also compared between groups using separate 2 (group: PENS intervention, sham intervention) x 2 (time: pre-intervention, post-intervention) ANOVAs with repeated measures.

Background

1. Provide the scientific background, rationale and relevance of this project.
Patellofemoral pain syndrome is a common orthopedic injury, representing as much as 25% of all knee related injuries seen by clinicians. [1-7] Individuals with PFPS often present with pain under their patellar during a plethora of tasks, ranging from prolonged sitting, running, jumping, kneeling, squatting, and stair usage. [2,3,8-12]

The etiology of PFPS is unknown, with many different contributing factors; such as lower extremity misalignment, abnormal tracking of the patellar, quadriceps weakness and soft tissue tightness. [13] Treatment outcomes for PFPS patients is suboptimal when examining the current research, and it has been proposed it is due to the main factors that may contribute to the condition. However, a recent systematic review identified that 44% of clinicians use empirical evidence from personal past experiences, and only 24% use evidence based approach for their patients. [13]

Current research has suggested that individuals with PFPS have an abnormal neuromuscular control in lower extremity musculature. This poor control has been theorized to increase the frontal plane kinematics during functional tasks that may increase compressive forces placed on the patellofemoral joint and increase an individual's pain. [2-4,13,14]Researchers have examined PFPS subjects and have found poor kinematics during different functional tasks in both females and males with PFPS. [6,7,11,15-17] PFPS patients have been found to have less hip abduction and less hip external rotation that amplifies as the level of difficultly in the tasks increases. [6,13,18,19] These increased risks place the individual in a poor biomechanical position that is exacerbated by the repetitive nature of the common tasks that increase pain in the PFPS population. [11,13,20]

One of the more consistent current findings with PFPS patients is the poor activation of the hip muscles during the aforementioned tasks. The gluteus medius muscle is one of the major lower extremity muscles that is responsible for frontal plane kinematics and has been found to change forces place on the knee during a variety of exercises. [10] It has been

found to contribute to over 60% of total hip abductor cross sectional area and its anterior, middle and posterior fibers all contribute to abduct and medially rotate the lower leg. [21] It has also been found to be active when the base of support is minimal, providing great importance to functional tasks. [21] PFPS patients have been found to have weaker hip adduction due to decreased gluteus medius strength, decreased gluteus medius activation and shorter activation durations during functional tasks compared to healthy controls. [10]

Clinicians have also examined many common therapeutic strengthening exercises to identify the most beneficial strengthening exercises for clinical use to improve gluteus medius strength to improve frontal landing mechanics and neuromuscular control. [21-24] While these interventions have been found to improve strength gains and improve patient outcomes, they do not transition to functional kinematics changes during squats or running tasks. It has been theorized that while the strengthen programs improve the muscle amplitude during contraction, there is no change in the improper firing pattern of the gluteus medius. Therefore, an intervention needs to address the late activation of the gluteus medius muscle while performing the functional tasks to improve lower extremity biomechanics.

Traditional electrical stimulation has been used to address muscle weakness in the rehabilitation setting. It has been shown to have some strength improvements with individuals with PFPS, however one of the limitations to the device is it current setting parameters. [25,26] The electrical stimulation often occurs in a duty cycle of 10 seconds on and 50 seconds of rest, which is neither function or addresses the improper onset of activation seen in the literature. [27,28] Patterned electrical neuromuscular stimulation (PENS) is a new approach to using electrical stimulation to improve muscle-firing patterns. [29] The PENS is precisely time electrical stimulation to the muscles based off of healthy EMG studies to re-educate the muscle to fire properly. [29-31]

The purpose of this study is to see if 4-weeks gluteus muscle rehabilitation program with or without electrical stimulation will have an effect on lower extremity biomechanics and muscle activation of the gluteus medius in patients with a history of PFPS while performing functional tasks.

Hypothesis to be Tested

1. Our hypothesis is that those in the PENS group will have improved frontal plane kinematics of the lower extremity when individuals with a history of PFPS perform functional tasks.
2. We hypothesize that those in the PENS group will have improved strength gains when compared to the group who only received strengthening exercises.
3. We hypothesize that those in the PENS group will have greater improvement in patient reported outcomes following the 4-weeks compared to the exercise only group.
4. We hypothesize that ultrasound imaging of the core muscles will improve over a 4-week period that targets lateral hip musculature.

Study Design: Biomedical

1. Will controls be used? Yes

►IF YES, explain the kind of controls to be used.

The control group will be completing the exercise program without electrical stimulation.

2. What is the study design? Pre-test, post-test

3. Does the study involve a placebo? No

Human Participants

Ages: 15-40
Sex: **Both**
Race: **All**

Subjects- see below

1. Provide target # of subjects (at all sites) needed to complete protocol.

32 subjects with patellofemoral pain will complete the entire study. 40 healthy individuals will complete the procedures for the first testing session.

2. Describe expected rate of screen failure/ dropouts/withdrawals from all sites.

We expect a maximum attrition rate of 20%, which would be equivalent to 2 subjects per arm for a total of 4. We also expect up to 10 subjects may drop out due to knee discomfort while performing the functional tests.

3. How many subjects will be enrolled at all sites?

86 subjects. 46 with patellofemoral pain and 40 healthy individuals

4. How many subjects will sign a consent form under this UVa protocol?

86 subjects 46 with patellofemoral pain and 40 healthy individuals

5. Provide an estimated time line for the study.

The estimated time line for this study would be to have 100% enrollment in a year and a half

Inclusion/Exclusion Criteria

1. List the criteria for inclusion

Patellofemoral Pain Group

- Insidious onset of symptoms unrelated to a traumatic event
- Presence of peri- or retro patellar knee pain during at least two of the following functional activities
    - Stair ascent or descent,
    - Running,
    - Kneeling,
    - Squatting,
    - Prolonged sitting,

    - Jumping,
    - Isometric quadriceps contraction
    - Palpation of the medial and or lateral facet of the patella
- Pain for more than 3 months
- 85 or less on Kujala (Anterior Knee Pain Scale) questionnaire
- Pain greater than 3.0 on Visual Analog Scale

Healthy Group

- No current knee pain as measured by the Visual Analog Scale
- 85 of greater on Kujala (Anterior Knee Pain Scale) questionnaire

2. List the criteria for exclusion

Patellofemoral Pain Group and Healthy Group

- Previous knee surgery
- Internal Derangement such as rupture to any of the knee ligaments or an injury to the meniscus
- Ligamentous instability
- Other sources of anterior knee pain
- Neurological Involvement/cognitive impairment
- Any biomedical device
- Muscular abnormalities
- Currently pregnant
- Hypersensitivity to electrical stimulation
- Active infection over the site of the electrode placement (thigh)
- Currently involved in a physician-prescribed rehabilitation program

3. List any restrictions on use of other drugs or treatments. Subjects will be asked to refrain from all pain medication for 4 hours prior to each study session. Pain medications may be resumed at the completion of the session.

Statistical Considerations

1. Is stratification/randomization involved? Yes

►IF YES, describe the stratification/ randomization scheme.

To account for possible gender differences in the subjective assessment of pain, we will randomize a total of 16 females and 16 males to each intervention arm (i.e. PENS, or Sham). To insure that males and females are equally represented in each arm, a stratified permuted block randomization scheme will be utilized. The subjects within gender stratum will be assigned in a 1:1 ratio to the PENS and sham interventions. The sizes of the permuted blocks will vary with block size combinations of 2, 4, 6, and 8 used to generate the 16 assignments per gender stratum. The block randomization will be generated via the software of the SAS PROC PLAN procedure of SAS 9.4 (SAS Institute Inc., Cary NC), and once generated the biostatistician will send the randomization to the study therapists in

a coded format. Randomization assignment key will be sent to the therapists in a password protected Microsoft Excel document.

►**IF YES, who will generate the randomization scheme?**
__X___ UVa Statistician. James Patrie

2. What are the statistical considerations for the protocol?

For both aims in this protocol, the end point is defined as completing data collection for 16 subjects in both the electrical stimulation and low level-electrical stimulation group. Additional alpha will be set as $P \leq 0.05$, with (1-beta) set at 0.80 for all aims.

3. Provide a justification for the sample size used in this protocol.

Power Analyses:

Primary outcome: The baseline to week 4 changes in the single leg squat task pain VAS, and the baseline to week 4 changes in the stair ambulation task pain VAS will represent the two primary outcome variables.

Minimum detectable effect sizes: If 16 subjects per intervention arm complete the 4-week protocol, then we should have at least an 80% chance of detecting the within-arm 4-week changes in pain VAS and the between-arm difference in the 4-week changes in pain VAS listed in Table 1.

Details*:* Three null hypothesis will be tested. Two null hypotheses will focus on the baseline to week 4 change in the pain VAS (within-arm comparisons), while the third null hypothesis will focus on the between-arm difference in the baseline to week 4 change in pain VAS. The later hypothesis will be consider the *pivotal* hypothesis, while the former hypotheses will be considered *secondary*. In column 3 of Table 1, we list the minimum detectable 4-week mean change in pain VAS that would lead 80% of the time to rejecting the null hypothesis that the underlying mean 4-week change in pain VAS is equal to 0. In column 4 of Table 1, we list the minimum between-group difference in the 4-week mean change in pain VAS that would lead 80% of the time to rejecting the null hypothesis that the underlying between-arm difference in the 4-week mean change in pain VAS is equal to 0. *Calculation inputs*: The one sample and the two sample t-test sample size formulas were utilized to obtain the minimum detectable effect sizes listed in columns 3 and 4 of Table 1, respectively. A two-sided alpha level of 0.05 was used as the type I error rate and the standard deviations that were utilized in the calculations are listed in column 2 of Table 1.

Table 1. Within-group and between-group minimum detectable effect sizes.

10	Pain VAS Standard Deviation	Within-Group Minimum Detectable 4-Week Mean Change in Pain VAS	Between-Group Minimum Detectable Difference in the 4-Week Mean Change in Pain VAS

Single Leg Squat	1.48	1.0	1.5
Stair Ambulation	1.66	1.2	1.7

4. What is your plan for primary variable analysis?

The baseline to week 4 changes in the single leg squat task pain VAS and the baseline to week 4 changes in the stair ambulation task pain VAS will represent the two primary outcome variables. Each primary outcome variable will be analyzed by way analysis of covariance (ANCOVA). *Model specification*: Each ANCOVA model will examine three potential sources of outcome variability. The outcome variability explained by the intervention will be the focus of hypothesis testing, while gender and the baseline pain VAS will represent ANCOVA adjustment variables. *Hypothesis testing*: Within each intervention arm, we will test the null hypothesis that the mean 4-week change in the pain VAS is equal to zero. A $p \leq 0.05$ decision rule will be utilized as the null hypothesis rejection criterion. As the pivotal comparison, we will test the null hypothesis that the mean 4-week changes in the pain VAS are the same for the two interventions after adjustment for gender and baseline pain VAS. Again, we will use a $p \leq 0.05$ decision rule as the null hypothesis rejection criterion.

5. What is your plan for secondary variable analysis?

Secondary Pain VAS Analyses*:* Since pain VAS will be assessed at baseline and 3 times per week thereafter for 4 weeks, we will use random coefficient regression (RCR) to model the marginal temporal changes in the leg squat task pain VAS measurements and to model the marginal temporal changes in the stair ambulation task pain VAS measurements. Each RCR model will have two predictor variables. One variable will identify "intervention arm" while the second variable identify "gender". Each RCR model will be specified to allow intervention arm by sex interaction so that the regression coefficients can change from intervention arm to intervention arm and from sex to sex. To account for within-subject pain VAS measurement correlation, the RCR model random effects will be specified in accordance with a *random* intercept and *random* slope RCR model. *Hypothesis testing*: We will used generalized F-tests to test if the average (i.e. marginal) temporal trends in the pain VAS measurements differ from intervention to intervention and from sex to sex. A $p \leq 0.05$ decision rule will be used as the null hypothesis rejection criterion for testing for between-intervention uniformity in the RCR model parameters.

Lower Extremity Strength: The changes in knee extension, knee flexion, hip abduction, and hip external rotation, will be analyzed by ANCOVA and RCR, in a comparable manner as the pain VAS data.

Self-Reported Function: The changes in self assess functions (AKP and ADLs) will be analyzed by ANCOVA and RCR, in a comparable manner as the pain VAS.

Assessment of the Blind: We will use an exact binomial test to determine if the participants were more likely than what would be expected by pure chance to correctly identify the intervention to which they were randomized. We will test the null hypothesis that the underlying probability is equal to 0.05.

6. Have you been working with a statistician in designing this protocol? Yes
IF YES, what is their name? James Patrie

7. Will data from multiple sites be combined during analysis? No

Biomedical Research

1. What will be done in this protocol?

Study Procedures

1) Consent, screening, randomization patient reported outcomes
2) Lower extremity measurements
3) Electromyography
4) Electromagnetic tracking
5) Functional tasks
6) Ultrasound imaging
7) Rehabilitation Training Sessions (12 sessions)
8) Pedometer Assessment
9) Follow-up questionnaires at 6 months and 12 months

VISIT 1A: CONSENT AND SCREENING (Patellofemoral and healthy group)

Patient Reported Outcomes: Questionnaires: Following obtaining informed consent subjects will be asked to complete subjective outcome measures relating to physical activity, general lower extremity function, and knee related subjective function. The Anterior Knee Pain Scale (AKPS) [14] and the Activities of Daily Living Scale (ADLS) [14] will be able to assess the physical activity level and current limitations in activity due to the presence of patellofemoral pain syndrome. The Tegner activity scale and Godin Leisure Activity Scale will be used to assess how active the participants currently are in their daily activities. The Fear Avoidance Belief Questionnaire will be used to assess how participants believe of fear avoidance due to their knee pain may impact their daily activity. The Medical Questionnaire: Lower Extremity will be used to complete the medical history. The Short Form-12 will be used to assess general health of the participant before and after the intervention. The Lower Extremity Functional Scale will be used to assess participant's physical activity during daily activities

If subject is deemed eligible, the study test and procedure will begin within 7 days following determination of eligibility. In addition the subject will be randomized to PENS or Sham treatment.

VISIT 1 B STUDY TEST AND PROCEDURES: (Patellofemoral and healthy group)

Subjects will have the option of completing all of study. Visit 1 following consent and screening per subject preference if time allows or a separate visit to complete Visit 1B procedures may be scheduled.

LOWER EXTREMITY MEASUREMENTS

Warm up

- Subjects will be provided 5-minutes to warm up on a stationary bike or treadmill.
- Subjects will be provided 5-minutes to stretch any muscles you would like.

Lower Extremity Range of Motion

Range of motion of the hamstring, quadriceps, IT Band, hip adductors and calf will be measured with a goniometer.

Lower Extremity Alignment

Q-Angle: Subject will lay supine on a table with leg fully extended. A goniometer will measure the angle formed by the intersection of the line of application of the quadriceps force (line from anterior superior iliac spine to the center of the patella) and the centerline of the patella tendon (line from center of patella to tibial tubercle)

Tibial Torsion: Subject will be prone with knee flexed to 90 degrees. Researcher will visualize the most prominent aspect of the medial and lateral malleolus with small dots. The angle formed by the axis of the knee (imaginary line) to the axis of the knee (imaginary line that bisects the medial and lateral femoral epicondyle).

Navicular Drop: Subject will stand with feet shoulder width apart. Researcher will place fingers on the subject's ankle to place the subject in subtalar joint neutral position. Subject will flatten and raise their foot until the researcher identified the subtalar joint neutral position and the height of the navicular tuberosity will be measured in relation to the floor. Subject will then relax their foot and the height of the navicular will be measured again. The distance present is the amount of navicular drop the subjects demonstrates within their foot.

ELECTROMYOGRAPHY

Electromyography (EMG) will be recorded with the use of a portable device that clips on the subjects waistband.

- Subjects will be standing upright with socks and shoes off.
- Participants' skin will be shaved, debrided, and cleaned with isopropyl alcohol over the muscle belly of the six muscles where the EMG electrodes will be placed.
- The eight muscles to be recorded are gastrocnemius, quadriceps (at 2 locations), hamstrings, adductor muscle group, and lateral hip muscle, posterior hip muscle and low back.
- Subjects will stand quietly once the electrodes are applied to ensure quiet testing measurements.
- Subjects will perform instructed muscle testing to determine maximal force production of each muscle group.

- Muscle testing will include knee extension, knee flexion, hip adduction, hip abduction, and ankle plantarflexion.

ELECTROMAGNETIC TRACKING SYSTEM

Subjects will be setup for the electromagnetic tracking system, which will be used during functional tasks during the testing session. Gait analysis will be performed using an electromagnetic gait system (Flock of Birds, Ascension Technology Inc., Burlington, VT) and forceplate in our laboratory. Data collected will include kinetic and kinematic variables at the hip, knee, and ankle.

- Participants will be asked to stand upright with shoes and socks off near the electromagnetic unit.
- Participants' skin will be shaved, debrided, and cleaned with isopropyl alcohol in the same fashion as EMG set-up, where each of the sensors will be placed.
- Eight sensors will be placed on the legs and back of participants using double-sided tape and athletic wrap before testing begins. Sensor placement will include the dorsum of the foot, lateral mid-shank, lateral mid-thigh, sacrum, and thorax for each participant in standard fashion.
- Participants will be given a standardized pair of shoes for testing procedures. Participants will be allowed to wear their own shoes if we cannot provide a pair that fits correctly.
- Participants will be given ample time to rest between each task.

FUNCTIONAL TASKS:

Single Leg Squat Testing

- Subjects will be instructed to stand on the force plate with their injured limb in the center.
- Subjects will be instructed to flex the opposite leg to approximately 90 degrees, have their arms crossed their chest and looking ahead.
- Subjects will be asked to squat down as are as possible without losing their balance before returning to the starting position.

Single Leg Step Down Testing

- Subjects will be instructed to stand with both feet on the top of the box.
- Subjects will be instructed to stand on their injured leg and slowly lower their uninjured leg to lightly touch the floor with their heel and return to the starting position.

Stair ascend and descend tasks

- Subjects will be instructed to walk up and down two 40cm steps. Subjects will complete this task 3 times at a self-selected speed. Subjects will be able to keep their hands by their slides and complete the task as they normally would.

Lunge

- Subjects will be standing with both feet, shoulder width apart. Subjects will have hands on their hips and will be instructed to perform 5 lunges on each limb.
- The lunge will require the participant to take a step forward and lower their front leg to approximately 90 degrees of flexion and then return to the starting position.

Jogging task

- Subjects will be positioned on a treadmill and instructed to walk for 5-minutes at a 3.0mph speed.
- Subjects will then perform a 5-minute jog at a speed of 6mph.

Balance Task

- Subjects will stand on their leg with eyes open and eyes closed on a force plate. Subjects will perform this task, which will last 10 seconds, and will be repeated three times each.

Drop Vertical Jump Task

- Following the Balance task, participants will perform the drop-jump task. A 30cm (~12 inch) box will be utilized for the drop-jump tasks. The box will be placed 50% of the participant's height from the center of the force plate. The participant will drop from the box onto the force plate and jump into the air as high as possible. They will receive demonstration and verbal details of the tasks and will be allowed 3 practice trials. Participants will be asked to complete 3 successful drop-jump trials with ample time to rest between trials.

ULTRASOUND IMAGING

Images of the transverse abdominis musculature and gluteus medius will be taken with the Logiqbook XP (GE Healthcare, Waukesha, WI)

Transverse abdominis

- Participants will be placed in the hook-lying position (supine with knee bent approximately 30 degrees and a bolster resting under knees).
- The ultrasound gel will be placed directly on the skin.
- The transducer head will identify the transverse abdominis (TrA) between the ASIS and umbilicus on the anterolateral region of the abdomen. 3 images will be saved.
- The participant will be asked exhale and then draw his or her navel up and towards their spine (abdominal drawing in maneuver). This procedure will be repeated twice more, and a total of 3 images will be saved.
- This procedure (resting & contracted) will be repeated for the opposite side (6 total images).
- The participant will be positioned standing with the feet shoulder width apart and hands to his or her sides.
- Steps 2-5 will be repeated to identify and save images of the patient's TrA while both rested (3 images) and contracted (3 images), and then repeated on the opposite side, yielding 12 images total.

Gluteus medius

- Participants will be sidelying with knee fully straight
- The ultrasound gel will be placed on the lateral hip, directly on the skin
- The transducer head will be placed one half of the distance between the greater trochanter and the iliac crest.
- The participant will relax and three images taken
- The participant will raise their leg into the air and 3 additional images will be taken.
- The following steps will then be repeated on the opposite hip muscles

CORE ENDURANCE ASSESSMENT

- Participants will perform a front and side plank to measure their core endurance before and after the 4-week rehabilitation program. Participants will hold the plank position as long as possible and will be timed with a stopwatch.
- The front plank will require the participant to use their feet and forearms to support their full body weight while keeping their body in a straight line. Participants will hold this position for as long as possible.
- The side plank will be assessed on both sides. The participant will use their left forearm and left foot to support their body on their side. Participants will hold this position, trying to maintain their body in a straight line for as long as possible. Participants will then repeat this on their right forearm and right foot.

VISUAL ANALOG SCALE

- The VAS is a 10-cm length line with the words "no pain" on one end and "unbearable pain" on the other end. The subject will make a vertical mark on the amount of pain they are experiencing. The distance is measured from the left to the subject's mark of the extent of pain in centimeters for the pain score. Subjects will complete the VAS after the single leg squat test, single leg step down task, stair task, lunge, and jogging tasks. Participants will also complete the visual analog scale following each treatment session

Pedometer assessment

Patellofemoral Pain Group

Participants will be provided a pedometer (FitBit Charge HR) for the 4-week intervention period in this study. Participants will be instructed to wear it every day during the 4-week period and perform their daily activities they normally partake in. The device will measure the number of steps the participant takes during the 4 weeks to assess if the rehabilitation program allows improved objective daily activity. Following the 4-week study, participants will return the pedometer to the study team.

Healthy Group

Participants will be provided a pedometer (FitBit Charge HR) for a 2-week intervention period in this study. Participants will be instructed to wear it every day during the 2-week period and perform their daily activities they normally partake in. The device will measure the number of steps the participant

takes during the 2 weeks to record daily activity values in healthy individuals to compare to the patellofemoral group. Following the 2-week period, participants will return the pedometer to the study team.

VISITS 2-13 (Treatment sessions 1 to 12) (Patellofemoral group only)

Rehabilitation Treatment Session

Subjects will return to the laboratory for 3 sessions a week for 4 weeks, for a total of 12 sessions. The measurements from the lower extremity measurements and strength measurements from the EMG data will be utilized to create an evidence based rehab program that will include range of motion exercise to the quadriceps, hamstring, adductors, and calf, strengthen exercises to the quadriceps, hamstring, hips muscles and core, and patella mobilizations. This exercise program is based off current recommendations for a targeted rehab plan of care based off the individual restrictions and complaints, suggested by Selfe et al.[47] Subjects will be divided into two groups for the intervention of electrical stimulation prior to each session. Both groups will have identical set-up to the PENS unit, as described below.

The subjects will be divided into a motor group which will use a strong muscle twitch setting, while the other group will be in a subsensory group which will be at a level low enough that no sensory response should be felt by the participant.

Group assignment is not revealed to the randomized subject. Subjects in both groups are told they may or may not feel the stimulation when it is applied.

Patterned Neuromuscular Electrical Stimulation (PENS) OR Sham

PENS is an asymmetrical biphasic square wave that occurs at a frequency of 50Hz, a phase duration at 70 microseconds, and a stimulus train of 200 milliseconds. The amplitude will be increased gradually to increase from a barely visible twitch to a strong activation of the muscles, however it will not be strong enough to cause a tetanus contraction seen in other electrical stimulation devices. The amplitude will vary with each individual since muscle mass and body size will influence the amount needed before a motor contraction occurs.

Subjects will receive a 15 minutes PENS treatment using the Omnistim 2 ProSport electrical stimulation device or a 15-minute sham treatment to the gluteus medius muscle determined by randomization . A third party researcher, to maintain blinding to the treatment team and primary investigator, will apply this treatment. This individual has been trained by the company on proper use of the PENS device and has read the operational manual before any testing has occurred. For both groups, four 3x5cm self-adhesive electrodes will be placed on the lower leg (quadriceps, hamstring, adductor and abductor muscles) of every subject. The individual will sit on a treatment table quietly for the entire duration of the treatment.

- The true PENS group will have the amplitude increased until a motor contraction is visible to the trained treatment team member. Once this is visible the research team member will hit the ‘start’ button and the treatment will occur for 15-minutes and then at the conclusion of the treatment will stop.

- The sham stimulation group will receive a low-level electrical stimulation. This group will have an amplitude increased to 1mA, which is the lowest level available for the device, and the 'start' button will also be pressed for a 15-minute treatment as well.

FINAL STUDY VISIT 14 - STUDY TEST AND PROCEDURES: (Patellofemoral group only)

Both groups will return to the lab approximately 48-72 hours after their final treatment session. Participants will perform the same testing procedures that were completed on the first session. This will include lower extremity measurements, electromyography testing, electromagnetic tracking system with functional tasks, ultrasound images and VAS scores. . The Global Rating of Change (GROC) will be used at the end of the rehabilitation program. The GROC is a likert scale that participants will complete following the 4-week rehabilitation program to assess the perceived change in knee pain levels.

This will take no longer than 2 hours.

Follow-up questionnaires at 6 months and 12 months

Participants will be contacted via US mail or phone call to complete patient reported questionnaires at 6 and 12 months of the conclusion of their participation in the study. The patient reported questionnaires that will be utilized will be the visual analog scale, anterior knee pain scale, fear avoidance belief questionnaire, Godin-leisure and lower extremity functional scale.

2. List the procedures, in bullet form, that will be done for research as stipulated in this protocol.

All study interventions including the rehabilitation visits.

3. Will you be using data/specimens in this study that were collected previously, with the use of a research consent form, from another research study? No

4. Will any of the procedures listed in item # 2 have the potential to identify an incidental finding?

No

5. Do any of the procedures listed above, under question # 2, utilize any imaging procedures?

Yes

IF YES, list procedures:

Real-time ultrasound will be used to measure the transverse abdominals musculature. Images of the transverse abdominis musculature will be taken with the Logiqbook XP (GE Healthcare, Waukesha, WI)

1. Participants will be placed in the hook-lying position (supine with knee bent approximately 30 degrees and a bolster resting under knees).
2. The ultrasound gel will be placed directly on the skin.

3. The transducer head will identify the transverse abdominis (TrA) between the ASIS and umbilicus on the anterolateral region of the abdomen. 3 images will be saved.
4. The participant will be asked exhale and then draw his or her navel up and towards their spine (abdominal drawing in maneuver). This procedure will be repeated twice more, and a total of 3 images will be saved.
5. This procedure (resting & contracted) will be repeated for the opposite side (6 total images).
6. The participant will be positioned standing with the feet shoulder width apart and hands to his or her sides.
7. Steps 2-5 will be repeated to identify and save images of the patient's TrA while both rested (3 images) and contracted (3 images), and then repeated on the opposite side, yielding 12 images total.

__**X**___This imaging research examination utilizes the same imaging techniques, equipment, scanning sequences that would be used if the subject were to have the imaging performed for clinical care. There exists the potential for the discovery of clinically significant incidental findings.

►If checked, answer the following:

Will the images be read by a licensed radiologist and the reading placed in the subject's medical record?

No

►IF NO: The PI takes full responsibility for the identification of incidental findings:

- The PI will have all incidental findings reviewed by a radiologist who will advise the PI regarding clinical significance.
- The PI will inform the subjects verbally of all incidental findings that are of clinical significance or are of questionable significance**.**
- A follow-up letter describing the finding should be provided t**o t**he subject with instructions to either show the letter to their PC or if the subject has **no** PCP, the subject should be instructed to make an appointment at UVa or at the Free Clinic.

6. Will you be using viable embryos?

No

7. Will you be using embryonic stem cells?

No

8. Are any aspects of the study kept secret from the participants?

No

9. Is any deception used in the study?

No

10. If this protocol involves study treatment, explain how a subject will be transitioned from study treatment when they have completed their participation in the study.

No

Data and Safety Monitoring Plan

This study has been deemed minimal risk. Because this study poses minimal risk to the subject, **adverse events will only be collected or recorded if a causal relationship to the study intervention is suspected.** If any adverse event is considered serious and unexpected, the event must be reported to the IRB-HSR within 7 days from the time the study team receives knowledge of the event.

1. Definitions

1.1 How will you define adverse events (AE)?

Do not change this answer

An adverse event will be considered any undesirable sign, symptom or medical condition considered **related to the intervention**. Medical condition/diseases present before starting the intervention will be considered adverse events only if they worsen after starting the study and that worsening is considered to be related to the study intervention. An adverse event is also any undesirable and unintended effect of research occurring in human subjects as a result of the collection of identifiable private information under the research.

1.2 How will you define an unanticipated problem?

Do not change this answer

An unanticipated problem is any issue that involves increased risk(s) to participants or others. This means issues or problems that cause the subject or others to be placed at greater risk than previously identified, even if the subject or others do not incur actual harm. For example if a subject's confidentiality is compromised resulting in serious negative social, legal or economic ramifications, an unanticipated problem would need to be reported. (e.g serious loss of social status, loss of job, interpersonal conflict.)

1.3 What is the definition of a protocol violation?

Do not change this answer

A protocol violation is defined as any change, deviation, or departure from the study design or procedures of research project that is NOT approved by the IRB-HSR prior to its initiation or implementation**.** Protocol violations may be major or minor violations.

Noncompliance can be a protocol violation OR deviation from standard operating procedures, Good Clinical Practices (GCPs), federal, state or local regulation**s.** Noncompliance may be serious or continuing

Additional Information: see the IRB-HSR website at http://www.virginia.edu/vpr/irb/HSR_docs/Forms/Protocol_Violations_%20Enrollment_Exceptions_Instructions.doc

1.4 What is the definition of a data breach?

Do not change this answer

A data breach is defined in the HITECH Act (43 USC 17932) as an unauthorized acquisition, access, or use of protected health information (PHI) that compromises the security or privacy of such information.
Additional Information may be found on the IRB-HSR Website: Data Breach

2. What risks are expected due to the intervention in this protocol?

Expected Risks related to study participation	**Pick One**
Privacy Risk	
There is a small risk that breaches of privacy and/or confidentiality might occur. The risk of violation of subject privacy and confidentiality is minimal due to the requirements of the privacy plan in this protocol.	Occurs rarely
Risk from electrodes	
• Possible mild, transient skin irritation from electrodes	Occurs infrequently
Risk from additional physical activity during rehab sessions	
• Possible joint or muscle soreness due to electrical stimulation and functional activities	Occurs infrequently
Risk from electrical stimulation	
• Possible discomfort during the administration of the electrical stimulation	Occurs infrequently

3. When will recording and reporting of unanticipated problems/adverse events begin?

__X___After subject signs consent

4. When will the recording/reporting of unanticipated problems/adverse events end?

__X___30 days post intervention

5. What is your plan for safety monitoring?

Safety monitoring and aggregate review of adverse events, unanticipated problems, protocol violations and any data breach will be performed by the PI and IRB-HSR through continuation review at least annually.

6. What is your plan for reporting a Unanticipated Problem, Protocol Violation or Data Breach?

Type of Event	**To whom will it be reported:**	*Time Frame for Reporting*	*How reported?*
Unanticipated Problems that are not adverse events or protocol violations This would include a Data Breach.	IRB-HSR	Within 7 calendar days from the time the study team received knowledge of the event.	Unanticipated Problem report form. *http://www.virginia.edu/vprgs/irb/HSR_docs/Forms/Reporting_Requirements-Unanticipated_Problems.doc*
Protocol Violations (*The IRB-HSR only requires that MAJOR violation be reported, unless otherwise required by your sponsor, if applicable.)*	IRB-HSR	Within 7 calendar days from the time the study team received knowledge of the event.	Protocol Violation and Enrollment Exception Reporting Form *http://www.virginia.edu/vprgs/irb/hsr_forms.html* *Go to 3rd bullet from the bottom.*
Data Breach of Protected Health Information	The UVa Corporate Compliance and Privacy Office	As soon as possible and no later than 24 hours from the time the incident is identified.	UVa Corporate Compliance and Privacy Office- Phone 924-9741
	ITC: if breach involves electronic data	As soon as possible and no later than 24 hours from the time the incident is identified.	**ITC:** Information Security Incident Reporting procedure, http://www.itc.virginia.edu/security/reporting.html
	UVa Police if breach includes items that are stolen	IMMEDIATELY.	Police: phone- (434) 924-7166

Payment

What is the difference between compensation and reimbursement?

A reimbursement is used when the subject is paid back for travel expenses such as mileage, lodging, food while traveling. Receipts or mileage must be submitted for a reimbursement.

Compensation is "payment" for things such as time, discomfort, inconvenience.

Total possible compensation should reflect the true value of the total possible dollar amount per participant for one year involvement in the study whether it be cash, check, gift card, goods, etc. or a combination of these items.

Retention "Gifts"- gifts may be given to a subject periodically during the study to remind them they are in the study. Sponsors may provide such items as water bottles, birthday cards etc. to the subject. NOTE: Cash or gift cards are NOT allowed as retention items.

1. **Are subjects being reimbursed for travel expenses** (receipts /mileage required)**?**
   Answer/Response: No

2. **Are subjects compensated for being in this study?**
   Answer/Response: YES, those in the patellofemoral group will be compensated. Those in the control group will not be compensated

►IF YES, answer the following questions (2a-2d).

2a. What is the maximum TOTAL compensation to be given over the duration of the protocol?
Answer/Response: $40.00 will be given to the patellofemoral group

2b. Explain compensation to be given.
Answer/Response: $40.00 at the end of the study

2c. Is payment pro-rated?
e.g. some compensation is given even if subjects do not complete the entire study
Answer/Response: No

If No, explain why payment cannot be pro-rated.
Answer/Response: Waiting until the end to pay subjects may encourage study completion, although it is a small amount of money and is not considered coercive. They are receiving physical therapy free of charge during the study which may also encourage retention.

2d. Is money paid from UVa or State funds (including grant funds) or will items such as gift cards be distributed through UVa?
Answer/Response: Yes

►IF YES, answer the following questions [2d(i)-2d(ii)].

2d(i). How will the researcher compensate the subjects?
_x____ Check issued to participant via UVA Oracle or State system

2d(ii). Which category/ categories best describes the process of compensation?
_x____ All compensation will be made via check issued to participant via UVA Oracle or State system

The preferred method

Risk/ Benefit Analysis

1. What are the potential benefits for the participant as well as benefits which may accrue to society in general, as a result of this study?
Subjects may benefit from having 4 weeks of rehabilitation provided at no cost. There are no potential benefits to the subjects related to the stimulation/sham stimulation provided. However, the current study will add to the body of knowledge regarding the nature of muscle activation and lower extremity kinematics before and after an electrical stimulation treatment in individuals with a history of patellofemoral pain syndrome.

2. Do the anticipated benefits justify asking subjects to undertake the risks?
There is minimal benefit and minimal risk to subjects. Although there is a potential to benefit research and society, and possibly the care of patients that are rehabilitating musculoskeletal injuries, risk of mild, local, transient skin irritation and/or numbness and temporary, mild muscle soreness may occur following the testing. The risk – benefit ratio is acceptable.

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APPENDIX: Legal/Regulatory

Recruitment

The following procedures will be followed:

- Finders fees will not be paid to an individual as they are not allowed by UVa Policy.
- All recruitment materials will be approved by the IRB-HSR prior to use. They will be submitted to the IRB after the IRB-HSR has assigned an IRB-HSR # to the protocol.
- Only those individuals listed as personnel on this protocol will recruit and or conduct the consenting process with potential subjects.

Retention Incentives

Any item used by the sponsor/ study team to provide incentive to a subject to remain in the study, other than compensation identified in the Payment section, will be submitted to the IRB for review prior to use. The IRB-HSR will provide the study team with a Receipt Acknowledgement for their records. Retention incentive items are such things as water bottles, small tote bags, birthday cards etc. Cash and gift cards are not allowed as retention incentives.

Clinical Privileges

The following procedures will be followed:

- Investigators who are members of the clinical staff at the University of Virginia Medical Center must have the appropriate credentials and been granted clinical privileges to perform specific clinical procedures whether those procedures are experimental or standard.
- The IRB cannot grant clinical privileges.
- Performing procedures which are outside the scope of the clinical privileges that have been granted may result in denial of insurance coverage should claims of negligence or malpractice arise.
- Personnel on this protocol will have the appropriate credentials and clinical privileges in place before performing any procedures required by this protocol.
- Contact the Clinical Staff Office- 924-9055 or 924-8778 for further information.

Sharing of Data/Specimens

Data and specimens collected under an IRB approved protocol are the property of the University of Virginia. You must have "permission" to share data/ specimens outside of UVa other than for a grant application and or publication. This "permission" may come in the form of a contract with the sponsor or a material transfer agreement (MTA) with others. A contract/ MTA is needed to share the data outside of UVa even if the data includes no HIPAA identifiers and no code that could link the data back to a HIPAA identifier.

- No data will be shared outside of UVa, beyond using data for a grant application and or publication, without a signed contract/MTA approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.
- No specimens will be shared outside of UVa without a signed contract/MTA approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.

Prisoners

If the original protocol/ IRB application stated that no prisoners would be enrolled in this study and subsequently a subject becomes a prisoner, the study team must notify the IRB immediately. The study team and IRB will need to determine if the subject will remain in the study. If the subject will remain in the study, the protocol will have to be re-reviewed with the input of a prisoner advocate. The prisoner advocate will also have to be involved in the review of future continuations, modifications or any other reporting such as protocol violations or adverse events.

Prisoner- Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.
For additional information see the OHRP website at
http://www.hhs.gov/ohrp/policy/populations/index.html

Compensation in Case of Injury
If a subject requests compensation for an injury, the study team should notify the IRB-HSR (924-9634/2439847) the UVa Health System Patient Relations Department (924-8315). As a proactive courtesy, the study team may also notify UVa Health System Patient Safety and Risk Management (924-5595).

On request, the study team should provide the Risk Management Office with the following information/documents:

- Subject Name and Medical Record Number
- Research medical records
- Research consent form
- Adverse event report to IRB
- Any letter from IRB to OHRP

Subject Complaints
During a research study, the study team may receive complaints from a subject. If the study team is uncertain how to respond to a complaint, or is unable to resolve it with the subject, the study team may contact the IRB-HSR (924-9634/243-9847), the UVa Health System Patient Relations Department (924-8315).

Request for Research Records from Search Warrant or Subpoena
If the study team receives a request for research records from a search warrant or subpoena, they should notify UVa Health Information Services at 924-5136. It is important to notify them if information from the study is protected by a Certificate of Confidentiality.

APPENDIX: FDA Verification of Approval

1. **What is the name of the approved drug, device or biologic?**
   Omnistim Electrical Muscle Stimulator

2. **What document have you provided to confirm FDA approval?**
   See Paperwork included with this submission.

3. **Is the study required by the FDA?**
   No

4. **Is the study initiated by an investigator and not a commercial company?**
   Yes

5. Is the study retrospective?

No

6. Does the study involve research on a drug/ device in an already approved population/ condition?

The device received FDA clearance for traditional physical medicine use, such as pain reduction, edema treatment, muscle re-education, and muscle strengthening programs.

7. Does the study involve research only on a drug and NOT on a device?

No

APPENDIX: Recruitment

Recruitment includes identifying, review of records to determine eligibility or any contact to determine a potential subjects interest in the study.
*The UVa HIPAA covered entity is composed of the UVa VP Office of Research, the Health System, School of Medicine, School of Nursing, Nutrition Services (Morrisons), the Sheila C. Johnson Center, the Exercise and Sports Injury Laboratory and the Exercise Physiology Laboratory.

1. How do you plan to <u>identify</u> potential subjects?

- To "identify" a potential subject refers to steps you plan to take to determine which individuals would qualify to participate in your study. This does NOT include steps to actually contact those individuals.
- If your study involves more than one group of subjects (e.g. controls and cases or subjects and caregivers) note below which groups are being identified by the given method.

a.__X__ Chart Review/ Clinic Schedule Review/ Database Review from a database established for health care operations (departmental clinical database) or an Improvement Project (*e.g. Performance Improvement, Practice Improvement, Quality Improvement*).

<u>If you plan to obtain data from the UVa Enterprise Data Warehouse (EDW) please see option b below.</u>

<u>DHHS:</u> Study team requests Waiver of Consent to identify potential subjects.
<u>HIPAA:</u> Allowed under Preparatory to Research if PHI to be accessed.
<u>IMPORTANT</u>
Keep in mind that PHI in the medical record may only be accessed by individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:
--a UVa student working in the UVa HIPAA Covered Entity*
--a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*

b__ _ Review of a database that was established to keep data to be used for future research such as the CDR, departmental research database or use of data from a separate current active research protocol.

<u>If you plan to obtain data from the UVa Enterprise Data Warehouse (EDW) you are required to submit your request to the CDR. The CDR staff will work with the EDW to obtain the data you need.</u>

<u>DHHS:</u> Study team requests Waiver of Consent to identify potential subjects.
<u>HIPAA:</u> Allowed under Preparatory to Research if PHI to be accessed.
<u>IMPORTANT</u>

Keep in mind that PHI in the medical record may only be accessed by individuals who work under the UVa HIPAA covered entity; which means they who meet one of the following criteria:
--a UVa student working in the UVa HIPAA Covered Entity*
--a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*

The information from which you are obtaining potential subjects must also have an IRB protocol approval. If this item is checked, enter the IRB # below.

IRB# __

If obtaining information from the Clinical Data Repository (CDR) insert IRB # 10797

c. ____ Patients UVa health care provider supplies the UVa study team with the patients contact information without patients' knowledge.

DHHS: Study team requests Waiver of Consent to identify potential subjects.
HIPAA: Allowed under Preparatory to Research if PHI will be shared by the health care provider.
IMPORTANT
Keep in mind that PHI may only be given to individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:
--a UVa student working in the UVa HIPAA Covered Entity*
--a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*

d. __X__ Patient obtains information about the study from their health care provider. The patient contacts the study team if interested in participating. (Health care provider may or may not also be the a member of the study team)

DHHS: NA
HIPAA: Allowed under Health Care Operations
If this choice is checked, check 3d-INDIRECT CONTACT below.

e. __X__ Potential subjects will not be directly identified. They will respond to an advertisement such as a flyer, brochure etc.

If this choice is checked, check 3d- INDIRECT CONTACT below.
DHHS & HIPAA: NA

f. _____ Potential subjects have previously signed a consent to have their name in a registry/database to be contacted for future studies of this type.

IRB# of registry/ database: _____

DHHS & HIPAA: NA

g. ____ Other: Specify Answer/Response:

If item # a, b or c is checked above and if this protocol involves the use of protected health information do you confirm the following to be true?

- The use or disclosure is sought solely to review protected health information as necessary to prepare the research protocol or other similar preparatory purposes.
- No PHI will be removed from the UVa covered entity.
- The PHI that the researcher seeks to use or access is necessary for the research purposes.

Answer/Response: Yes

2. How will potential subjects be contacted?

To "contact" a potential subjects refers to the initial contact you plan to take to reach a potential subject to determine if they would be interested in participating in your study. This may include direct contact by such methods as by letter, phone, email or in-person or indirect contact such as the use of flyers, radio ads etc.
If your study involves more than one group of subjects (e.g. controls and cases or subjects and caregivers) note below which groups are being contacted by the given method.

a.__X__Direct contact of potential subjects by the study team via letter, phone, direct e-mail. Members of study team ARE NOT health care providers of patients. Information will not be collected from psychotherapy notes.

Note: Letter, phone, direct email scripts must be approved by IRB prior to use. See IRB-HSR Website for templates.
DHHS/HIPAA: Study team requests a Waiver of Consent and Waiver of HIPAA Authorization to contact potential subjects.
IMPORTANT:
Keep in mind that if PHI was collected during the identification phase that contact with potential subjects may only be performed by individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:

- a UVa student working in the UVa HIPAA Covered Entity*
- a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*

b.____Potential subjects will be approached while at UVa Hospital or Health Clinic by a person who is NOT a member of their health care team. Information will not be collected from psychotherapy notes.

DHHS & HIPAA: Study team requests a Waiver of Consent and a Waiver of HIPAA Authorization to contact potential subjects.
IMPORTANT:
Keep in mind that contacting individuals in a clinical setting may only be performed by individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:
a UVa student working in the UVa HIPAA Covered Entity*
a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*
You should share the following information with the potential subject:

- Your name
- Who you are: physician, nurse etc. at the University of Virginia.
- Why you want to speak with them

- Ask if you have their permission to explain the study to them
- If asked about how you obtained their information use one of the following as an option for response.
    - DO NOT USE THIS RESPONSE UNLESS YOU HAVE OBTAINED PERMISSION FROM THEIR UVa PHYSICIAN: Your doctor, Dr. insert name wanted you to be aware of this research study and gave us permission to contact you.
    - We obtained your information from your medical records at UVa.
    - Federal regulations allow the UVa Health System to release your information to researchers at UVa, so that we may contact you regarding studies you may be interested in participating. We want to assure you that we will keep your information confidential.
- IF THE PERSON SEEMS ANGRY, HESITANT OR UPSET, THANK THEM FOR THEIR TIME AND DO NOT ENROLL THEM IN THE STUDY. YOU MAY ALSO REFER THEM TO THE IRB-HSR AT 924-9634.

c.__X__Direct contact of potential subjects by the study team by approaching in person at UVa or via letter, phone, direct e-mail. Members of study team contacting potential subjects ARE health care providers of patients.

If you are not approaching them in person but using a letter, phone call or direct email please note that the letter, phone, direct email scripts must be approved by IRB prior to use.
See IRB-HSR Website for templates.
DHHS: Study team requests a Waiver of Consent to contact potential subjects
HIPAA: Allowed under Health Care Operations.

d.__X__ Indirect contact (flyer, brochure, TV, broadcast emails, patient provided info about the study from their health care provider and either the patient contacts study team or gives their healthcare provider permission for the study team to contact them.)

The indirect method used (flyer, brochure, TV, broadcast emails) must be approved by the IRB prior to use. The IRB does not need to review any type of script to use when the potential subject responds to the indirect method.
DHHS & HIPAA: NA

e. ____ Potential subjects are not patients. The study does not include obtaining subjects health information. Subjects will be contacted directly via email, phone, letter or presentation in group setting with consent then obtained individually in a private setting.

If you are not approaching them in person but using a letter, phone call or direct email please note that the letter, phone, direct email scripts must be approved by IRB prior to use.
See IRB-HSR Website for templates.
DHHS: Study team requests a Waiver of Consent to contact potential subjects.
HIPPA: NA

3. **Will any additional information be obtained from a potential subject during "prescreening"?**
   Yes. Pre-screening questions may be asked during a phone call, or the time of visit 1 prior to obtaining informed consent. The letter will also contain contact information for those interested in the study.

IF YES, submit any documents that will be used to collect pre-screening information so that the IRB may confirm what questions will be asked. NOTE: To comply with HIPAA regulations only the minimum necessary information may be collected at this time. This means that only questions pertaining to the Inclusion and Exclusion Criteria may be asked.

IF YES, DHHS: study team requests a Waiver of Documentation of Consent for Pre-screening questions. HIPPA: HIPAA does not apply if: --no PHI is collected or --if PHI is collected from a potential subject by an individual from a department that is not part of the HIPAA covered entity. HIPAA does apply if the collection occurs by individuals* who work in a department that is part of the HIPAA covered entity. In this case the collection will be covered under Health Care Operations/ These individuals are those that meet one of the following criteria: --a UVa student working in the UVa HIPAA Covered Entity* --a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*

IF YES, Will any of the questions involve health information?
YES Health information may be involved to determine eligibility to participate in the study

IF YES, will you collect HIPAA identifiers with the health information?

NO

4. **Do you plan to ask the subjects to do anything, other than answering questions, for the study prior to signing a consent?** No

5. **How will the consenting process take place with either the prospective subject, the subject's legally authorized representative or parent/legal guardian of a minor (if applicable)?**
   The IRB-HSR approved consent form will be provided to the potential subjects and parents/guardian of a potential subject by mail with an IRB approved recruitment letter or be given to them in person at UVa.
   Parent/guardian and all potential subjects will be interviewed in a quiet and private place and may have family or friends with them if they choose. The person obtaining consent will summarize the consent form verbally, asking open ended questions to determine if the potential subject and their parent/guardian understands what is being covered in the consent form. Questions might include:

- Would you summarize for me what you believe will be done to you if you are in this study?
- Would you benefit from this study?
- What do you feel are the risks of being in this study?

All potential subjects and their parents/guardian (if applicable) will be given an opportunity to ask questions. Their level of understanding will dictate how much time will be spent covering each item. Additional sessions may take place if they have any additional questions to help them fully understand all of the elements of the study. Once all of their questions have been answered the parent/guardian will be asked to sign the consent if they have decided their child will participate.

The child will then be asked if they wish to participate and if so will give assent. The person obtaining consent/assent will sign the form and all subjects and their parents/guardian (if applicable) will be given a copy of the signed form(s). Study procedures will then begin.

6. Will subjects sign a consent form for any part of the study? Yes

7. Will the study procedures be started the same day the subject is recruited for the study? No

8. Is there the potential to recruit economically or educationally disadvantaged subjects, or other vulnerable subjects such as students or employees? No

9. Do you need to perform a "dry run" of any procedure outlined in this protocol? No

APPENDIX: Participation of Children

In the state of Virginia a person under the age of 18 is considered a child.

1. Explain why this research topic is relevant to children.
Patellofemoral pain syndrome is a common condition that young adults and adolescent experience during functional tasks. It has been found that among 15 year olds, the incidence of this condition were 10%. Others have found a prevalence of 30% in students between 13-19 years old. Due to the increase in sedentary activity in the older population, there is belief that the prevalence of PFPS within this age group is related to frequency of youth playing sports. Tasks such as jumping, cutting, running, and pivoting which are activities that increase painful responses with those diagnoses with PFPS and why a younger population is important to include within this study.

2. Is the knowledge being sought in this study already available for children or is it currently being acquired through another ongoing study?
It has been found that symptoms of PFPS restrict physical activity of adolescents, since PFPS is typically labeled an activity limiting condition. The limited activities can have an influence on health benefits that regular exercise provides. This study is looking at

using an intervention to improve the factors that have been found in this population and been found to contribute to an increase in symptoms.

3. Provide data that is available in adults in order that the IRB may judge the potential risk in children. If there is no adult data available, provide reasons why not. If this information is available in a sponsor's protocol, you may reference the section # here and not duplicate the information.
Previous research has examined the influence of glut strength in individuals with patellofemoral pain syndrome in the aforementioned functional activities.[21-24] There has been data collected in these methods (step down and single leg squat) for hundreds of individuals between adolescents and adults, males and females, with and without PFPS as well as in other pathologies such as anterior cruciate ligaments, during functional return to play after injuries, and as a screening method to identify higher risked individuals. [1-3,6,9,12,19,21,32-38] There is minimal risk when performing the functional tasks since they are in a slow and controlled manner. The electrical stimulation treatment is a common therapeutic modality that is used in physical therapy clinics, athletic training rooms, hospitals, and other rehabilitation facilities. It is delivered in a low voltage and a short phase duration that it is beneficial to improve strength improvements before and following injury/surgery. It has also been used to improve functional tasks, such as using it in conjunction with athletes performing vertical jumps, running, sprinting, and biking. The risks are minimal for both the adult and adolescent population.

4. **Is the potential subject population likely to include wards of the state or children who are more at risk for becoming a ward of the state?** Yes

   4a. Is the research is this protocol related to the childs' status as a ward of the state? No

   4b. Is the research to be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards? Yes

   4c. Are you aware of the following requirement?
   If the consent form contains a signature line for both parents the study team will notify the IRB immediately, if at any time during the course of the research, it becomes known that a potential subject is a ward of the state or that a child already enrolled in this protocol becomes a ward of the state.
   Yes

5. **Does this study involve a placebo arm?**
   Yes

   ►IF YES, does the placebo arm pose minimal risk to the subject? Yes

   ►IF YES, explain why the placebo arm in this study is minimal risk.
   The placebo arm will be the lowest level of stimulus that the machine can deliver. This will be a sub-sensory level and the subject will not feel anything

or cause any risk besides the potential for skin irritation due to the electrodes as listed above.

6. Will UVa researchers conduct the study outside the state of Virginia? No

APPENDIX: Privacy Plan for Studies With Consent

1. Answer the questions below (1A-1F) to describe the plan to protect the data from improper use and disclosure.

1A. How will data be collected?

1A(1)._X____ Collection of data onto an individual-use device (e.g. smart phone app, tablet, laptop)

If checked answer the following questions:

- What kind of device is it (e.g. laptop, tablet, desktop computer)? _Desktop computer____
- Who manages / supports the device (e.g., Health Systems Computing Services (HS/CS), Information Technology Services (ITS), self)? __Self___
- How long with the data remain on the device before it is downloaded to a server managed by HS/CS, ITS or SON SECUREnet? _____
- Will anyone other than study team members have access to the data on the device? __No___
- Will data be downloaded to UVa in an encrypted secure manner such as the use of SFTP or HTTPS? _____
- Are any backups made of the information on the device? _Yes____
- After information is downloaded will you delete all UVa subject data from the device? _____
- Does the owner of the device (e.g. phone service provider/ app developer) have any rights to use or access the data either individually or in aggregate?

1A(2.)_____ Collection of data via web-based format (e.g. online consent, online surveys) via a Non- UVa Secure Server (e.g. HS/CS, ITS or SON SECUREnet)

See 1A(6) below for an exception.

1A(3)._____ Directly to a server managed by the principal investigator's department or school that is configured to store data regulated by HIPAA or highly sensitive data.
If checked, please provide the name of the server: _____

1A(4)._____ Directly to a Health Systems Computing Services (HS/CS), or School of Nursing SECUREnet with I Key managed server that is configured to store data regulated by HIPAA.
If checked, please provide the name of the server: _____
NOTE: for HS/CS must have HSCS in the URL of the server name .

1A(5)._____ Directly to an Information Technology Services (ITS) managed server that is configured to store data regulated by HIPAA.
If checked, please provide the name of the server: _____

NOTE: must have ITS in the URL of the server name.

1A(6)._____ Directly to a server managed by the sponsor or CRO in which the data will be sent and stored in an encrypted fashion (e.g. must be shared and stored via Secure FX, Secure FTP, HTTPS, PGP)

1.A(7).__X___ Paper

►If you checked any of the items 1A(1) through 1A(3) will the data include any of the HIPAA identifiers listed below? ANWER QUESTION IN TABLE BELOW

YES	NO	HIPAA Identifier
	X	1. Name
	X	2.Postal address information, other than town or city, state, and zip code
	X	3. Age or Date of Birth if over the age of 89
	X	4. Telephone numbers
	X	5. Fax numbers
	X	6. Electronic mail addresses
	X	7. Social Security number
	X	8. Medical Record number
	X	9. Health plan beneficiary numbers
	X	10. Account numbers
	X	11. Certificate/license numbers
	X	12. Vehicle identifiers and serial numbers, including license plate numbers
	X	13. Device identifiers and serial numbers
	X	14 Web Universal Resource Locators (URLs)
	X	15. Internet Protocol (IP) address numbers
	X	16. Biometric identifiers, including finger and voice prints
	X	17. Full face photographic images and any comparable images
	x	18. Any other unique identifying number, characteristic, code that is derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security #, mother's maiden name, first 3 letters of last name.)
	x	19. Any other information that could be used alone or in combination with other information to identify an individual.

INSTRUCTIONS: If any item above is checked, the study team must verify with the UVa Office of Information Security, Policy & Records Office (ISPRO) that adequate security is in place to collect highly sensitive data. www.virginia.edu/ispro Email: IT-Security@Virginia.edu
Submit ISPRO approval with new protocol submission.

1B. How will data be stored?

__X___ Data, which may include health information or other highly sensitive data will NOT be stored with any HIPAA identifier except date(s). This means:

- Documents such as case report forms will have NO HIPAA identifiers except dates (e.g. no initials or medical record #)
- HIPAA identifiers, except dates will be stored in a different place than the health information/specimens. A code such as subject # 1 will be used to link the identity of the individual (HIPAA identifiers) with the persons health information.

EXAMPLE: The HIPAA identifiers with the code (e.g.- John Doe=subject #1) will be stored in one location (computer drive, paper file, memory stick, CD) and the health information (diagnosis, radiology results) will be stored in a different location (different computer drive, paper file in a different file cabinet, memory stick).

1C. Will specimens be stored by the UVa study team? No

1D. Will any of the data be stored electronically? Yes

►IF YES, will it include storage of any health information or other sensitive data?
No, data will be unidentified and will not contain sensitive data.

►IF YES, will the data include any of the HIPAA identifiers listed below?
ANWER QUESTION IN TABLE BELOW

YES	NO	HIPAA Identifier
	X	1. Name
	X	2.Postal address information, other than town or city, state, and zip code
	X	3.Age or Date of Birth if over the age of 89
	X	4. Telephone numbers
	X	5. Fax numbers
	X	6. Electronic mail addresses
	X	7. Social Security number
	X	8. Medical Record number
	X	9. Health plan beneficiary numbers
	X	10. Account numbers
	X	11. Certificate/license numbers
	X	112. Vehicle identifiers and serial numbers, including license plate numbers
	X	13. Device identifiers and serial numbers
	X	14 Web Universal Resource Locators (URLs)
	X	15. Internet Protocol (IP) address numbers
	X	16. Biometric identifiers, including finger and voice prints
	X	17. Full face photographic images and any comparable images
	X	18. Any other unique identifying number, characteristic, code that is derived from or related to information about the (e.g. initials, last 4 digits of Social Security #, mother's maiden name, first 3 letters of last name.)
	X	19. Any other information that could be used alone or in combination with other information to identify an individua (*e.g. rare disease, study team or company has access to the health information and a HIPAA identifier or the key to t*

1E. If you answered YES to any HIPAA identifier above, where will the data be stored?
Answered NO to all HIPAA identifiers above

1F. Will any of the data be collected or stored in hard copy format by the UVa study team (*e.g. on paper***)?**
Yes

►IF YES, where will it be stored?
___X__ questionnaires/ surveys will be stored in a secure area with limited access.
:

1G. The following procedures will also be followed.

• Only investigators for this study and clinicians caring for the patient will have access to the data. They will each use a unique login ID and password that will keep confidential. The password should meet or exceed the standards described on the Information Technology Services (ITS) webpage about *The Importance of Choosing Strong Passwords.*

• Each investigator will sign the University's Electronic Access Agreement forward the signed agreement to the appropriate department as instructed on the form.

If you currently have access to clinical data it is likely that you have already signed this form. You are not required to sign it again.

- UVa University Data Protection Standards will be followed http://www.virginia.edu/informationsecurity/dataprotection.
- If identifiable data is transferred to any other location such as a desktop, laptop, memory stick, CD etc. the researcher must follow the University's "Electronic Storage of Highly Sensitive Data Policy". Additional requirements may be found in the Universities Requirements for Securing Electronic Devices.
- If identifiable health information is taken away from the UVa Health System, Medical Center Policy # 0218 will be followed.
- The data will be securely removed from the server, additional computer(s), and electronic media according to the University's Electronic Data Removal Policy.
- The data will be encrypted or removed if the electronic device is sent outside of UVa for repair according to the University's Electronic Data Removal Policy.
- If PHI will be faxed, researchers will follow the Health System Policy # 0194.
- If PHI will be emailed, researchers will follow the Health System Policy # 0193 and University Data Protection Standards .
- The data may not be analyzed for any other study without additional IRB approval.
- If you are using patient information you must follow Health System Policy # 0021.
- Both data on paper and stored electronically will follow the University's Record Management policy and the Commonwealth statute regarding the Destruction of Public Records.

Summary of Requirements to Comply with UVa Health System, Medical Center and University Policies and Guidance as noted above:

Highly Sensitive Data is:
-personal information that can lead to identity theft if exposed or
-health information that reveals an individual's health condition and/or history of health services use.
Protected Health Information (PHI) a type of Highly Sensitive Data, is health information combined with a HIPAA identifier
Identifiable Health Information under HIPAA regulations is considered to be *Highly Sensitive Data*

A **Limited Data Set** (LDS) under HIPAA regulations is considered to be *Moderately Sensitive Data. The only HIPAA identifiers associated with data: full dates and or postal address information including town or city, state, and zip code.*

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
General Issues	*General Issues*
Discussions in private Do not share with those not on the study team or those who do not have a need to know.	Do not share with those not on the study team or those who do not have a need to know
Password protect	Password protect
Physically secure (lock) hard copies at all times if not directly supervised. If not supervised hard copies must have double protection (e.g. lock on room OR cabinet AND in building requiring swipe card for entrance).	Physically secure (lock) hard copies at all times if not directly supervised.
For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely.	For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely.
Encrypt See encryption solutions guidance. *Files on Health System Network drives are automatically encrypted. If not stored there it is study teams responsibility to make sure data are encrypted.*	
If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVa Purchase order.	If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVa Purchase order.
Store files on a network drive specifically designated for storing this type of data, e.g. high-level security servers managed by Information Technology Services or the "F" and "O" managed by Heath Systems Computing Services. You may access it via a shortcut icon on your desktop, but you are not allowed to take it off line to a local drive such as the desktop of your computer (e.g. C drive) or to an individual Use Device*. May access via VPN	
Do not share with sponsor or other outside group before consent is obtained or the IRB has granted appropriate approvals and contract/ MTA is in place	Do not share with sponsor or other outside group before consent is obtained or the IRB has granted appropriate approvals and contract/ MTA is in place
If collected without consent/ HIPAA authorization will NOT be allowed to leave UVa HIPAA covered entity unless disclosure is approved by the IRB and the disclosure is tracked in EPIC	If collected without consent/ HIPAA authorization will NOT be allowed to leave UVa HIPAA covered entity unless disclosure is approved by the IRB and an MTA is in place prior to sharing of data

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
Individual-Use Device	*Individual-Use Device*
Do not save to individual-use device* without written approval of your Department AND VP or Dean. If approval obtained, data must be password protected and encrypted.	
Do not save an email attachment containing HSD to an individual use device (e.g. smart phone)	
E Mail	*E Mail*
Do not share via email with Outlook Web/ or forward email using other email vendors like Gmail/ Yahoo	
Do not send via email on smart phone unless phone is set up by Health System	
Email may include name, medical record number or Social Security number only if sending email to or from a person with * HS in their email address. *NOTE: VPR & IRB staff do not meet this criteria!*	In addition to sharing LDS, may include initials if persons sending and receiving email work within the UVa HIPAA covered entity.**
FAX	*FAX*
Verify FAX number before faxing	Verify FAX number before faxing
Use Fax Cover Sheet with Confidentiality Statement	Use Fax Cover Sheet with Confidentiality Statement
Verify receiving fax machine is in a restricted access area	Verify receiving fax machine is in a restricted access area
Verify intended recipient is clearly indicated	Verify intended recipient is clearly indicated
Recipient is alerted to the pending transmission and is available to pick it up immediately	Recipient is alerted to the pending transmission and is available to pick it up immediately

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
Electronic Data Collection & Sharing	*Electronic Data Collection & Sharing*
(e.g. smart phone app, electronic consent using tablet etc.) MUST consult with ISPRO or Health System Web Development Office: 434-243-6702 ▪ University Side: IT-Security@virginia.edu ▪ Health System: Web Development Center: Contract must include required security measures.	
May NOT be stored in places like UVaBox, UVaCollab, QuestionPro. May also NOT be stored in non-UVa licensed cloud providers, such as Dropbox, Google Drive, Survey Monkey, etc.	May be stored in places like UVaBox, UVaCollab, QuestionPro. May NOT be stored in non-UVa licensed cloud providers, such as Dropbox, Google Drive, Survey Monkey, etc.
LOST OR STOLEN:	*LOST OR STOLEN:*
Must report in accordance with protocol/ in accordance with the Information Security Incident Reporting Policy (See Privacy Plan section of this protocol)	Must report in accordance with protocol/ in accordance with the Information Security Incident Reporting Policy (See Privacy Plan section of this protocol)

* *Individual Use Device – examples include smart phone, CD, flash (thumb) drive, laptop, C drive of your computer,*
***The UVa HIPAA covered entity is composed of the UVa VP Office of Research, the Health System, School of Medicine, School of Nursing, Nutrition Services (Morrison's), the Sheila C. Johnson Center, the Exercise and Sports Injury Laboratory and the Exercise Physiology Laboratory.*

2. Describe your/central registry's plan to destroy the HIPAA identifiers at the earliest opportunity consistent with the conduct of the research and in accordance with any stipulations in the research sponsor contract and UVa records management guidelines.
__X___ This is a Database Only study. All data including HIPAA identifiers will be destroyed or de-identified per HIPAA regulations (e.g. no HIPAA identifiers will be kept) when this protocol is closed.
Do not check this option if the protocol has a hypothesis.

***3.* Do you confirm that you will not reuse the identifiable data (HIPAA identifiers or health information) or disclose any of this information to any other person or entity except as outlined in this protocol, except as required by law, for authorized oversight of the research study, or use it for other research unless approved by the IRB-HSR?**
Yes

This means that after the study is closed at UVa:

- You cannot contact the subject by any method (you cannot call them, send a letter, talk to them in person about the study, etc.) without additional IRB approval
- You cannot use the data for any research that is not already described in your IRB protocol without additional IRB approval (if you change your hypothesis you must modify your protocol)
- You cannot share your research data with another researcher outside of your study team without additional IRB approval
- Any health information with HIPAA identifiers will be shredded or discarded by using recycling bins for confidential material found in clinic settings. For large item disposal of confidential material contact Environmental Services at 2-4976 or University Recycling at 2-5050.

TABLE A: HIPAA Identifiers (Limited Data Set)

1. Name
2. Postal address information, other than town or city, state, and zip code
3. Age or Date of Birth if over the age of 89
4. Telephone numbers
5 Fax numbers
6. Electronic mail addresses
7. Social Security number
8. Medical Record number
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, code that is derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security #, mother's maiden name, first 3 letters of last name.)

Table C2. University of Virginia Institutional Review Board Approved Consent Form (Manuscripts 1 and 2) (IRB-HSR #17909)

Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Parents' or Guardians' Permission for Your Child to Be in a Research Study

Agreement of a Child to Be in a Research Study

In this form "you" means the child in the study *and* the parent or guardian.

- ✓ If you are the parent or guardian, you are being asked to give permission for your child to be in this study.
- ✓ If you are the child, you are being asked if you agree to be in this study.

In this form "we" means the researchers and staff involved in running this study at the University of Virginia.

Participant's Name_____

Principal Investigator: **Susan Saliba**
Associate Professor, Human Services
203 Memorial Gymnasium
P.O. box 400407
434-243-4033
saf8u@virginia.edu

Sponsor: **Mid-Atlantic Athletic Trainers' Association**

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

Mid-Atlantic Athletic Trainers' Association

Why is this research being done?

The purpose of this study is to determine if rehabilitation with electrical stimulation may improve leg muscle strength during exercise.

You are being asked to be in this study you have a disorder called Patellofemoral Pain (PFP), which in plain language means that you have pain in front of your knees.

The treatment for PFP is physical therapy which is currently not often fully successful. One of the findings with PFPS patients is the poor "activation" or contraction of the hip muscles during movement. The gluteus medius muscle is one of the major lower body muscles that is responsible for movement. If it does not "activate" properly, it is thought to put strain on other parts of the lower body, like knees for example.

Electrical stimulation is sometimes used in physical therapy and doctor offices to help make muscles stronger after they are injured or after surgery. The current method of electrical stimulation treatment shows limited improvement in muscle strength and pain in people with PFP. The reason for this is thought to be because current methods of electrical stimulation do not help with the issue of poor activation of the hip muscles.

This research is being done to test a different method of providing stimulation treatment. The method is called patterned electrical neuromuscular stimulation or PENS. We want to see if there is improvement in muscle strength and knee pain using the PENS method of giving electrical stimulation treatment in people with PFP.

The study involves receiving 4 weeks of rehabilitation for PFP and either PENS or "sham" stimulation (Sham means that you will not receive the actual PENS stimulation but will have a low level stimulation so you won't know if you are getting the real PENS or not). You may or may not feel the electrical stimulation provided regardless of whether you have PENS or Sham. The electrical stimulation, regardless of group assignment, is performed by a person who is trained to give electrical stimulation. The device used to deliver the electrical stimulation is FDA approved for the uses described in this study. There are also questionnaires, tests, measurements and exercise before and after receiving electrical stimulation treatment. The study tests, measurements and exercise are described in detail in this consent form.

Up to 46 people will be in this study at UVA

What will happen if you are in the study?

The test and all procedures and rehabilitation in this study are all being done for research purposes only.

VISIT 1a – CONSENT AND SCREENING (will take approximately 20 minutes to complete):

If you agree to participate, you will sign this consent form before any study related procedures take place.

Before you can start in the study, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible and that it is safe for you to participate. These include completing questionnaires asking about

- your knee pain (Anterior Knee Pain Scale)
- current physical abilities and limitations (Activities of Daily Living Scale or ADLS, Lower Extremity Functional Scale or LEFS, and Short Form-12)
- your activity level (Tegner activity scale and Godin Leisure Activity Scale)
- if fear of pain limit your activity (Fear Avoidance Belief Questionnaire)
- We will also review you Medical history and complete the Medical Questionnaire-Lower extremity form.

If these tests show you are eligible, you will be randomized to either have the PENS stimulation or sham (low-level electrical stimulation

Randomization

- You will be randomly assigned (like the flip of a coin) to 1 of 2 study treatment groups. You have an equal chance of being assigned to any one of the groups.
- Neither you nor the principal investigator or study team can choose which treatment you are assigned. Neither you nor the principal investigator or select study team members will know which study treatment you will get until the study is done. But if the principal investigator needs to know, she can find out.
- The member of the study team who will be delivering electrical stimulation will know what group you are in. This person will not share the information about which group you are in with you or the rest of the study team.

GROUP 1: PENS stimulation (High Level Electrical Stimulation)
GROUP 2: Sham Stimulation **(**Low Level Electrical Stimulation)

VISIT 1 B STUDY TEST AND PROCEDURES: *(*will last about 2 hours)
Once randomized, **you have the option of continuing to complete Visit 1 B procedures below OR if it is not convenient, we will schedule a time for you to complete Visit 1B below.** You should not have any medication for pain for 4 hours before this testing.

Warm up

- You will be provided 5-minutes to warm up on s stationary bike or treadmill.
- You will be provided 5-minutes to stretch any muscles you would like.

Range of Motion s and Lower Extremity Alignment Measure:

- You will have your ankle and knee alignment measured. You will be asked to lay on a table in a comfortable position. Three measures will be recorded.
- You will have your ankle, knee and hip range of motion assessed 3 times in 6 directions. These motions will be pulling your toes towards your body, having your leg raised strength into the air, bending your knee as much as possible, having your hip raised and lowered, and rotating your leg outward.

Strength Measures using Electromyography

- You will have small sensors attached to your skin that will passively record how much your muscles turn on.
- You will strength will be assessed three time in 7 directions. These directions will be straightening or bending your back, knee, hip and ankle to make sure the sensors are over the correct places and are being recorded by the computer.

Functional Tasks using Electromagnetic Tracking System

- You will be attached with sensors placed on the skin, to a tracking system that will help us look at how you move during the "functional tasks" (see below).
- You will perform 7 functional tasks as described below:
    - You will be asked to stand on your bad leg and bend your knee to lower yourself as low to the ground as possible and then return back to the starting position. You will do this 4 more times (5 total)
    - You will stand on a small step, and will reach down as if taking a step down a stair. Once your heel touches the ground you will return to the starting position with both legs on the step. You will repeat this 5 times total
    - You will go up and down two steps continuously. You will repeat this 5 times total.
    - You will complete a lunge task, where you bring one leg out in front of you and lower your body to the ground and then return to the starting position. You will repeat this 5 times total.
    - You will walk and jog on a treadmill for 5 minutes each.
    - You will complete a jumping task from a box that is one foot tall. You will jump off the box onto the ground, and then jump straight into the air as high as possible. You will repeat this 3 times.
    - You will balance on force plate on your bad limb (eyes open and eyes closed) for ten seconds.

Ultrasound Imaging

- You will have up to 12 images of your stomach and 12 images of your outside hip recorded with a real-time ultrasound machine to measure your muscles around your stomach.
    - You will be asked to be on your side with knees bent with a bolster resting under knees.
    - The ultrasound gel will be placed directly on the skin.
    - The head of the ultrasound wand (called a transducer) will be moved around you abdomen to take images.
    - You will be asked exhale and then draw your navel up and towards their spine several times while images are taken.
    - This procedure will be repeated for the opposite side
    - You will then stand with feet shoulder width apart and hands to your sides. You will be asked to exhale and then draw your navel up and towards your spine several times while images are taken.
    - You will then lay on your side with your knee straight.
    - The ultrasound gel will be placed directly on the skin.

- The head of the ultrasound wand (called a transducer) will be moved around your outside hip to take images of the hip muscles.
- You will then raise your leg into the air and additional images will be taken
- The procedures will be repeated for the opposite side

Core Endurance Test

- You will have your core strength measured by timing how long you can hold a plank. A plank is where you use your feet and arms to hold yourself off the ground and keep your body in a straight line. You will have this timed with a stopwatch. You will also repeat this on each side.

Visual Analog Pain Scale:

- This is a 10 point scale we will ask you to complete at different times during the testing above and after each rehabilitation session described below.

Pedometer Assessment:

- You will be given a pedometer (FitBit) to wear on your wrist for 4-weeks. You will bring this device with you during each rehabilitation session to have the battery charged by the staff. The device will measure the number of steps you take over the next month. Following the 4-weeks you will turn it back over to the research team.

You will be asked to return to the lab after at least 2 days to begin the rehabilitation sessions.

VISITS 2-13 (Rehabilitation sessions 1 to 12) (Each will last approximately 1- 1 1/2 hours)

Both groups will be asked to complete 4 weeks of rehabilitation for their knee pain. You will be asked to complete 3 sessions per week for a total of 12 sessions. You will be asked to refrain from pain medication 4 hours before each rehab session.

During your sessions, you will receive the stimulation level to which you were assigned (either PENS or Sham) followed by rehabilitation exercises. Following stimulation, you will complete rehabilitation exercises that are the same as you would receive if your doctor ordered physical therapy. Each session will complete ankle, knee, hip, and trunk motions, strength, balance and functional exercises. Visual analog scale to measure your pain will be recorded following each treatment session. Following each rehabilitation session, you may resume your usual pain medications.

Final Study Visit (Visit 14) Study test and Procedures: (Will last no longer than 2 hours)

Both groups will return to the lab approximately 48-72 hours after their final treatment session. Please refrain from pain medication for 4 hours prior to this session. You will complete the same testing as you did during the screening process and the testing procedures. This will include a warm up, lower extremity measurements, strength, and functional testing. You will also complete a Global Rating of Change scale, which will assess how much your knee pain has changed following the 4-week rehabilitation

program. This session will be complete in one session and will take no longer than 2 hours.

Long-term Survey Follow-Up at 6-months and 12-months after clinic visit (Will last no longer than 10 minutes)
You will be asked to complete some questionnaires. These questionnaires ask about your knee pain, current physical ability, physical activity, and fear of pain limit your activity.

The questionnaires will be mailed to or a member of the research team will contacted you via phone to complete these questionnaires.

What are your/your parent/legal guardian's responsibilities in the study?

You and your parent/legal guardian have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- If you are under 18 years of age, your parent/legal guardian must bring you to each study visit.
- You and your parent/legal guardian must be completely truthful about your health history.
- Follow all instructions given.
- You or your parent/legal guardian should tell the study doctor or study staff about any changes in your health or the way you feel.
- Answer all of the study-related questions completely.
- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over-the-counter), including herbal supplements and vitamins. The study doctor will let you know if you can take these medications.
- Do not take any pain medications 4 hours prior to each session. You many resume pain medications once the sessions are completed

How long will this study take?

Your participation in this study will require 2- testing visits (we can split these as needed) and 12 separate treatment visits over a 4 week time period. Each testing visit will last about 2 hours and each treatment visit will last about 1 hour.

If you want to know about the results before the study is done:

During the study your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you can ask for more information about the study results.

What are the risks of being in this study?

Risks and side effects related to the study include:

Likely

- Possible mild, temporary skin irritation from electrodes.

Less Likely

- Possible mild muscle strain or soreness from testing
- Possible joint discomfort/mild pain after testing
- Possible discomfort during administration of the electrical stimulation (Some people may have hypersensitivity to an electrical stimulus. If you are having any pain or strong discomfort when the stimulus is being applied please let the researcher know immediately.)

Risks and side effects of drop jump task:

- Muscle soreness during or after testing
- Discomfort in the joints of the lower extremity during or after testing
- Potential for knee or ankle injury

Risk for women

Physical therapy programs may or may not pose risk for pregnant women/unborn child depending on the health of the mother. Additionally the effect of electrical stimulation delivered as part of this study is not known in pregnant women or in unborn babies. Therefore, we will not enroll pregnant women in this study or allow anyone who becomes pregnant to remain in the study.

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You may or may not benefit from being in this study. Possible benefits include: compensation of $40 for your time. In addition, information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study for to receive physical therapy using electrical stimulation. Your doctor can prescribe physical therapy and you may receive that therapy wherever you wish. Physical therapy may include various kinds of electrical stimulation.
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Will you be paid for being in this study?

You will receive $40.00 check via mail for completion in this study.

You should get your payment about 2-4 weeks after finishing the. The income may be reported to the IRS as income.

You will not be paid at all if **you** decide not to finish this study. If the study leader says you cannot continue, you will be paid the full amount for the study.

If you owe money to any Virginia state agency, the state can use the money you earn in this study to pay those debts. These state agencies include the UVa Medical Center, VCU Medical Center or a college or university. The money may be withheld to pay back debt for such things as unpaid medical bills, taxes, fines, child support. Even if this happens, the money you earn may be reported to the IRS as taxable income.

Will being in this study cost you any money?

Being in this study will not cost you any money. There is no cost to you or your health insurance for the procedures/tests, which are being done for research purposes. Specifically, the study provides 4 weeks of physical therapy at no cost to you or your insurance. You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include

a) The Principal Investigator is concerned about your health due to increase pain while performing the functional tasks
b) pregnancy .
c) The principal investigator, or the IRB decides to stop the study earlier than anticipated.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

1. Personal information such as name, address and date of birth
2. Social Security number ONLY IF you are being paid to be in this study
3. Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

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

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the researchers listed below to:

- Obtain more information about the study

- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Susan Saliba
Human Services, Curry School of Education
Saf8u@virginia.edu
Telephone: (434)243-4033

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908
Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

SIGNATURES

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult Participant

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent from Adult Participant

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
___ PERSON OBTAINING	___ PERSON OBTAINING	_ DATE

CONSENT (SIGNATURE)	CONSENT (PRINT)

Parental/ Guardian Permission

By signing below you confirm you have the legal authority to sign for this child.

_____ PARENT/GUARDIAN (SIGNATURE)	_____ PARENT/GUARDIAN (PRINT NAME)	_____ DATE

Person Obtaining Parental/Guardian Permission

By signing below you confirm that you have fully explained this study to the parent/guardian, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____ PERSON OBTAINING PARENTAL/ GUARDIAN PERMISSION (SIGNATURE)	_____ PERSON OBTAINING PARENTAL/GUARDIAN PERMISSION (PRINT NAME)	_____ DATE

Assent from Child (age 15 to less than 18)

Consent from the parent/guardian MUST be obtained before approaching the child for their assent.

_____ PARTICIPANT (SIGNATURE)	_____ PARTICIPANT (PRINT)	_____ DATE

Person Obtaining Assent of the Child (age 15 to less than 18 years of age)
Consent from the parent/guardian MUST be obtained before approaching the child for their assent.

By signing below you confirm that the study has been explained to the child (less than 18 years of age), all questions have been answered and the child has voluntarily agreed to participate.

_____ PERSON OBTAINING ASSENT (SIGNATURE)	_____ PERSON OBTAINING ASSENT (PRINT)	_____ DATE

Consent from Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

Please indicate with check box the identified individual(s):

☐ Subject

☐ Parent(s)/Guardian of the subject

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

Table C3. University of Virginia Institutional Review Board Approved Protocol (Manuscript 3) (IRB-HSR #18267)

IRB-HSR PROTOCOL

Investigator Agreement

BY SIGNING THIS DOCUMENT, THE INVESTIGATOR CONFIRMS:

1. I am not currently debarred by the US FDA from involvement in clinical research studies.
2. I am not involved in any regulatory or misconduct litigation or investigation by the FDA.
4. That if this study involves any funding or resources from an outside source, or if you will be sharing data outside of UVA prior to publication that you will contact the Dean's office regarding the need for a contract and letter of indemnification. If it is determined that either a contract or letter of indemnification is needed, subjects cannot be enrolled until these documents are complete.
5. The proposed research project will be conducted by me or under my close supervision. It will be conducted in accordance with the protocol submitted to and approved by the IRB including any modifications, amendments or addendums submitted and approved by the IRB throughout the life of the protocol.
6. That no personnel will be allowed to work on this protocol until they have completed the IRB-HSR On-line training and the IRB-HSR has been notified.
7. That all personnel working on this protocol will follow all IRB-HSR Policies and Procedures as stated on the IRB-HSR Website http://www.virginia.edu/vprgs/irb/ and on the School of Medicine Clinical Trials Office Website: http://knowledgelink.healthsystem.virginia.edu/intranet/hes/cto/sops/sop_index.cfm
8. I will ensure that all those delegated tasks relating to this study, whether explicitly or implicitly, are capable through expertise, training , experience or credentialing to undertake those tasks.
9. I confirm that the implications of the study have been discussed with all Departments that might be affected by it and have obtained their agreement for the study to take place.
10. That no subjects will be recruited or entered under the protocol until the Investigator has received the signed IRB-HSR Approval form stating the protocol is open to enrollment
11. That any materials used to recruit subjects will be approved by the IRB-HSR prior to use.
12. That all subjects will sign a copy of the most current consent form that has a non-expired IRB-HSR approval stamp.
13. That any modifications of the protocol or consent form will not be initiated without prior written approval from the IRB-HSR, except when necessary to eliminate immediate hazards to the subjects.

14. Any significant findings that become known in the course of the research that might affect the willingness of subjects to enroll or to continue to take part, will be promptly reported to the IRB.
15. I will report immediately to the IRB any unanticipated problems involving risk to subjects or to others including adverse reactions to biologics, drugs or medical devices.
16. That any serious deviation from the protocol will be reported promptly to the Board in writing.
17. That any data breach will be reported to the IRB, the UVa Corporate Compliance and Privacy Office , UVa Police as applicable.
18. That the continuation status report for this protocol will be completed and returned within the time limit stated on the form.
19. That the IRB-HSR office will be notified within 30 days of a change in the Principal Investigator or of the closure of this study.
20. That a new PI will be assigned if the current PI will not be at UVA for an extended period of time. If the current PI is leaving UVa permanently, a new PI will be assigned PRIOR to the departure of the current PI.
21. All study team members will have access to the current protocol and other applicable documents such as the IRB-HSR Application, consent forms and Investigator Brochures.
22. Signed consent forms and other research records will be retained in a confidential manner. Records will be kept at least 6 years after completion of the study.
23. No data/specimens may be taken from UVa without a signed Material Transfer Agreement between OSP/SOM Grants and Contracts Office and the new institution. Original study files are considered institutional records and may not be transferred to another institution. I will notify my department administration regarding where the originals will be kept at UVa. The material transfer agreement will delineate what copies of data, health information and/or specimens may be taken outside of UVa. It will also approve which HIPAA identifiers may be taken outside of UVa with the health information or specimens.
24. If any member of study team leaves UVa, they are STRONGLY ENCOURAGED to use Exit Checklist found on IRB-HSR website at http://www.virginia.edu/provost/facultyexit.pdf.

The IRB reserves the right to terminate this study at any time if, in its opinion, (1) the risks of further experimentation are prohibitive, or (2) the above agreement is breached.

Investigators Experience

Dr. Susan Saliba, PhD, M.P.T., ATC

Dr. Saliba is a certified athletic trainer and physical therapist with over 20 years of clinical experience. She has been the primary investigator for numerous studies through the University of Virginia's IRB-HSR, with a strong research interest therapeutic modalities, interventions and applications administered to improve physical performance.

Study Coordinator I – L. Colby Mangum, M.Ed, ATC

Ms. Mangum is a graduate assistant in the PhD program in Sports Medicine at the University of Virginia. Ms. Mangum's research focus is in area of core stability and its relationship to lower extremity biomechanics and function as related joint injury. Ms. Mangum has participated in and conducted descriptive and outcome studies while completing thesis requirements at the University of Virginia.

Signatures

Principal Investigator

_____	_____	_____
Principal Investigator Signature	Principal Investigator Name Printed	Date

The Principal Investigator signature is ONLY required if this is a new protocol, a 5 year update or a modification changing the Principal Investigator.

Department Chair

BY SIGNING THIS DOCUMENT THE DEPARTMENT CHAIR AGREES:

4. To work with the investigator and with the board as needed, to maintain compliance with this agreement.
5. That the Principal Investigator is qualified to perform this study.
6. That the protocol is scientifically relevant and sound.

_____	_____	_____
Department Chair or Designee Signature	Department Chair or Designee Name Printed	Date

The person signing as the Department Chair cannot be the Principal Investigator or a sub-investigator on this protocol.
The Department Chair or Designee signature is ONLY required if this is a new protocol or a modification changing the Principal Investigator.

Brief Summary/Abstract

The purpose of this study is to examine the muscle thickness via diagnostic ultrasound imaging and activation characteristics via surface electromyography (EMG) of the gluteal muscles in healthy, active adults and active adults that have a history or are currently experiencing low back pain. Participants that are recreationally active will be recruited to participate in this study. The primary goal of this study is to determine the gluteus medius and gluteus maximus activation in these active individuals through 2 methods of measurement (ultrasound and EMG) in various positions/movements that are used in clinical rehabilitation to target the gluteals. Our hypothesis is that healthy individuals will be able to activate their gluteals during these functional movements and that individual with low back pain may have difficult activating their gluteal muscles as compared to the healthy controls.

The secondary purpose of this study is to examine muscle thickness through diagnostic ultrasound imaging and activation characteristics through surface electromyography (EMG) attached to the skin of the gluteal muscles in healthy, active adults and in adults with chronic ankle instability. Participants that are recreationally active will be recruited to participate in this study. The goal of this study is to determine gluteus maximus and gluteus medius activity through these ultrasound and EMG during a treadmill walking task. Our hypothesis is that healthy individuals will demonstrate increased gluteal muscle activity during the stance phases of gait to stabilize the pelvis in the frontal plane as compared to individuals with chronic ankle instability.

Background

Low back, hip, knee, and ankle injuries are common among active individuals and likely are treated by non-weight-bearing and/or weight-bearing exercises when the individual has moved to the stage of therapeutic exercise as treatment. [1-3] Hip abductor exercises are a main component of these exercise programs. [3] The gluteal muscles are thought to be the target muscles of many of these exercises. [1,3-9] However, it can be difficult to determine if the gluteus medius and gluteus maximus are actually being utilized by these individuals. [3] The transverse abdominis and lumbar multifidus muscles are more classically studied muscles in the low back pain population due to their known dysfunction and should also be considered to determine a direct or indirect relationship between spinal stabilizers (transverse abdominis and lumbar multifidus) and the gluteal muscles in this population as they perform functional movements.

The gluteus medius is divided in many different parts, including a superficial, medial, anterior and posterior deep sections of the muscle. The gluteus maximus and tensor fasciae lata are commonly targeted as well with these exercises. [3] Ultrasound imaging of the gluteals, along with electromyography will provide a better outlook on the true activity of the gluteals in these commonly used exercises and positions in rehabilitation to determine if muscles are activating as expected for both healthy and pathologic populations, such as those low back pain and chronic ankle instability.

Hypothesis to be Tested

Objective: The objective of this study is to determine a healthy active individual and individual with low back pain's ability to activate their gluteus medius, gluteus maximus,

transverse abdominis, and lumbar multifidus in various hip abduction activities and functional positions.

The second objective is to determine a healthy active individual and chronic ankle sprain individual's ability to activate their gluteus medius and gluteus maximus during walking gait.

Hypothesis: We hypothesize that healthy, active individuals will be able to more effectively activate their gluteals, along with their spinal stabilizing muscles (transverse abdominis and lumbar multifidus) in these positions, as visualized via ultrasound imaging and electromyography, as compared to those with low back pain.

We hypothesize that healthy, active individuals will be able to more effectively activate their gluteals during gait as visualized via ultrasound imaging and electromyography as compared to those with chronic ankle instability.

Study Design: Biomedical

1. Will controls be used?

Healthy, recreationally active participants will be used as controls in this study.

4. What is the study design?

Case-controlled laboratory study

5. Does the study involve a placebo?

No placebo will be used in this study.

Human Participants

Ages: 18-45
Sex: Males & Females
Race: All races

Subjects- see below

1. Provide target # of subjects (at all sites) needed to complete protocol.

This study was powered to have 45 healthy subjects, 25 low back pain subjects, and 25 chronic ankle instability subjects, with 95 total.

2. Describe expected rate of screen failure/ dropouts/withdrawals from all sites.

We anticipate a 20% attrition for this study.

3. How many subjects will be enrolled at all sites? 115

4. How many subjects will sign a consent form under this UVa protocol? 115

6. Provide an estimated time line for the study.

We anticipate 100% subject enrollment, completion of data collection and data analysis in one year.

Inclusion/Exclusion Criteria

1. List the criteria for inclusion

A. Inclusion criteria for Healthy Participants

a. Ages 18-45
b. Male or female
c. Physically active individuals according to American College of Sports Medicine guidelines of 30 minutes of moderate activity for 5 days per week

B. Inclusion criteria for Low Back Pain Participants

a. Ages 18-45
b. Male or female
c. Physically active individuals according to American College of Sports Medicine guidelines of 30 minutes of moderate activity for 5 days per week
d. History of low back pain (5 episodes over lifetime OR 2 episodes within last 12 months)

C. Chronic Ankle Instability Participants

a. Ages 18-45
b. Male or female
c. History of at least 1 significant ankle sprain at least 12 months prior to study enrollment
d. At least 2 episodes of the injured ankle "giving way" and/or recurrent sprain and/or "feelings of instability" in the 6 months prior to study enrollment
e. No ankle sprain within past 3 months

2. List the criteria for exclusion

A. Exclusion criteria for Healthy Participants

a. History of lower extremity/hip joint injury within the last year
b. Current lower extremity/hip pain
c. History of lower extremity/hip joint surgery within the last year
d. Self-reported balance disorder
e. Subjects with known pregnancy
f. Subjects with known muscular abnormalities
g. History of cardiopulmonary disorder
h. Subjects with a previous history of stroke
i. History of neurological or psychiatric disorders including poorly controlled migraine headaches, seizure disorder, history or immediate family history or seizures and/or epilepsy
j. Subject with any type of neuropathy (numbness/tingling) in lower extremity
k. Subject with clinical diagnosis of Parkinson's disease
l. Subject with clinical diagnosis of Multiple Sclerosis (MS)

m. Subjects with implanted biomedical devices (active or inactive implants) including device leads, deep brain stimulators, cochlear implants and vagus nerve stimulators
n. Subjects with history of skull fracture

B. Exclusion criteria for Low Back Pain Participants

a. Current low back pain >8/10 on Visual Analogue Scale
b. No history of low back pain (5 episodes over lifetime OR 2 episodes within last 12 months)
c. Previous history of lumbar spine surgery
d. Previous history of spinal infection
e. Self-reported balance disorder
f. Subjects with known pregnancy
g. Subjects with known muscular abnormalities
h. History of cardiopulmonary disorder
i. Subjects with a previous history of stroke
j. History of neurological or psychiatric disorders including poorly controlled migraine headaches, seizure disorder, history or immediate family history or seizures and/or epilepsy
k. Subject with any type of neuropathy (numbness/tingling) in lower extremity
l. Subject with clinical diagnosis of Parkinson's disease
m. Subject with clinical diagnosis of Multiple Sclerosis (MS)
n. Subjects with implanted biomedical devices (active or inactive implants) including device leads, deep brain stimulators, cochlear implants and vagus nerve stimulators
o. Subjects with history of skull fracture

C. Participants considered to NOT be in chronic ankle instability group (as defined for this study):

a. Acute injury to musculoskeletal structures of the lower extremity within 3 months of study enrollment
b. History of previous surgeries to the musculoskeletal structures (i.e. bones, joints, nerves) in either limb of the lower extremity
c. History of a fracture in either limb of the lower extremity
d. . Self-reported balance disorder
f. Subjects with known pregnancy
g. Subjects with known muscular abnormalities
h. History of cardiopulmonary disorder
i. Subjects with a previous history of stroke
j. History of neurological or psychiatric disorders including poorly controlled migraine headaches, seizure disorder, history or immediate family history or seizures and/or epilepsy
k. Subject with any type of neuropathy (numbness/tingling) in lower extremity
l. Subject with clinical diagnosis of Parkinson's disease
m. Subject with clinical diagnosis of Multiple Sclerosis (MS)

n. Subjects with implanted biomedical devices (active or inactive implants) including device leads, deep brain stimulators, cochlear implants and vagus nerve stimulators
o. Subjects with history of skull fracture

3. List any restrictions on use of other drugs or treatments. None

Statistical Considerations

2. Is stratification/randomization involved? No

2. What are the statistical considerations for the protocol?
For this study, the end point is defined as collecting 45 total healthy subjects, 25 low back pain subjects, and 25 chronic ankle instability subjects which is based on the sample size estimate with a statistical power of 0.80 and an a-priori alpha level of 0.05.

3. Provide a justification for the sample size used in this protocol.
This sample size is based on a one sample t-test with a 20% attrition rate with a minimum difference estimate of 1.6 per group with a standard deviation of 1.6, which is consistent with prior literature assessing gluteus medius and maximus ultrasound and activation. [6] With the addition of another pathological group, chronic ankle instability, and with additional muscles being evaluated (transverse abdominis and lumbar multifidus), an additional 5 low back pain subjects are necessary, with 25 total chronic ankle instability subjects as well to meet the same power and alpha levels. We based these analyses and will use in all of our analyses a power of 0.80 and alpha level set a-priori at 0.05. Since all of these participants are active with minimal risk from participation, we do not expect a large amount of drop out.

4. What is your plan for primary variable analysis?
For primary variable analysis, we plan to compare the ultrasound and activation findings utilizing a multivariate ANOVA post hoc for each measure/position across groups.

5. What is your plan for secondary variable analysis?
For secondary variable analysis, we plan to use a Pearson's r correlation to determine relationship between ultrasound measures and activation for each of the functional positions.

6. Have you been working with a statistician in designing this protocol?
No statistician was consulted in the design process of this protocol.

7. Will data from multiple sites be combined during analysis?
There will not be multiple sites utilized during this study.

Biomedical Research

1. What will be done in this protocol?
Study Procedures:

1. Obtain informed consent for all subjects.
2. Screen all subjects according to inclusion/ exclusion criteria to ensure they are eligible to enroll.
3. Complete all patient-reported outcome subject questionnaires.
4. Hip range of motion, manual muscle testing, selected hip special tests performed.
5. Ultrasound imaging, activation collection while resting and during gluteal targeted tasks (weight shift, hip hitch, side-lying abduction (knee flexed and extended), active leg lengthening, wall squat, single leg squat, lateral band walk, lateral slide, and treadmill walking.) Treadmill walking will be on a flat dual-belt treadmill (no incline) at a set speed of 1.1m/second with a handrail present for stability if necessary.
    a. For treadmill walking, subjects will have reflective markers placed on thorax, low back, and lower extremity for movement tracking with infrared camera system.
6. Ultrasound imaging, activation collection of transverse abdominis at rest on a tabletop, standing (bipedal and unipedal), and during a single leg squat, and lumbar multifidus during a bird dog exercise, balancing seated on a physioball, an overhead squat, and during treadmill walking.

Consent & Screening:
Subjects will report to the Exercise and Sports Injury Lab (EASIL) in Memorial Gymnasium for all study procedures. Informed consent will be obtained for all subjects as outlined in the Consent Process Selection for this protocol. Following informed consent process, once obtained, subjects will be asked a series of questions about their general health and lower extremity, low back, hip, and foot/ankle health to determine eligibility for the study (administered by Study Coordinator). These questions include all previous and current medical history. The study coordinator will then determine, according to the answers, if the subject is eligible based on the inclusion and exclusion criteria. Demographic information will also be collected at this time by the Study Coordinator including, age, gender, height and weight. The study procedures will begin immediately after eligibility is determined or the subjects could choose to return at a later date to proceed with the study procedures.

Questions asked to determine eligibility:
1. Do you have a history of lower extremity or hip joint injury within the last year or any current lower extremity or hip joint pain?
2. Do you have a history of lower extremity or hip joint surgery?
3. Do you have any current low back pain or history of low back pain episodes?
4. Do you have any balance disorders?
5. Females: Are you currently pregnant?
6. Do you have a history of heart disease, stroke or lung disease?
7. Do you have a history of any neurological or psychiatric disorder?
8. Do you have numbness or tingling in the lower extremity?

9. Do you have any implanted biomedical devices, such as a pacemaker?
10. Do you have a history of skull fracture?

Patient Reported Outcomes (Subjective Questionnaires)

1. Visual Analogue Scale [10]
2. Tegner Activity Rating [11]
3. Godin Leisure-Time Questionnaire [12]
4. Oswestry Disability Index Questionnaire [13]
5. Cumberland Ankle Instability Tool (CAIT)[14]
6. Identification of Functional Ankle Instability (IdFAI)[15]
7. Foot and Ankle Ability Measure (FAAM)[16]
8. Foot and Ankle Ability Measure Sport (FAAM Sport)[17]
9. Patient Specific Functional Scale[18]
10. Tampa Scale of Kinesiophobia[19]
11. Fear-Avoidance Beliefs Questionnaire[20]

Ultrasound Imaging & Activation Assessment

Ultrasound imaging will be used to measure gluteal muscles, abdominal wall muscle tissue, lumbar muscle tissue beneath and skin via the Siemens Acuson Freestyle (Siemens, Mountain View, CA).

1. Sensors and reflective markers will be placed on the skin on the lateral aspect of the hip, abdomen, low back, and lower legs bilaterally.
2. Ultrasound gel will be put onto the skin.
3. The ultrasound transducer will be placed on the lateral aspect of the hip, followed by the abdomen, and finally low back.
4. Ultrasound images will be obtained while lying supine on a tabletop, and standing.
5. Upon completion of the standing image collection, the investigator will demonstrate each of the gluteal, and abdominal/low back targeted tasks.
6. Ultrasound images will then be collected during each of the tasks.
7. Images and activation level will be collected with the patient rested and while contracting their gluteals and abdominal/low back muscles.

Note: These collective protocols are not intended to provide any direct benefits to the enrolled subjects. They are designed to obtain valuable insight to underlying biomechanical function, in order to provide a generalized benefit to the patient population being studied. Video and still images of interest may be maintained for future research and/or academic purposes. Permission will be obtained to keep images and a research database protocol will be established as an image repository.

2. List the procedures, in bullet form, that will be done for <u>RESEARCH PURPOSES</u> as stipulated in this protocol.

- ALL procedures that will be done are for research purposes.

3. Will you be using data/specimens in this study that were collected previously, with the use of a research consent form, from another research study? No

4. Will any of the procedures listed in item # 2 have the potential to identify an incidental finding? This includes ALL procedures, assessments and evaluations that are being done for <u>RESEARCH PURPOSES</u> that may or may not be considered investigational. No

5. Do any of the procedures listed above, under question # 2, utilize any imaging procedures for <u>RESEARCH PURPOSES</u>? Yes

IF YES, list procedures:
Ultrasound imaging

►IF YES, *check one of the following two options:*

_✓_This imaging research examination utilizes the same imaging techniques, equipment, scanning sequences that would be used if the subject were to have the imaging performed for clinical care. There exists the potential for the discovery of clinically significant incidental findings.

Will the images be read by a licensed radiologist and the reading placed in the subject's medical record? No

►IF NO: The PI takes full responsibility for the identification of incidental findings:

- The PI will have all incidental findings reviewed by a radiologist who will advise the PI regarding clinical significance.
- The PI will inform the subjects verbally of all incidental findings that are of clinical significance or are of questionable significance**.**
- A follow-up letter describing the finding should be provided t**o** **t**he subject with instructions to either show the letter to their PC or if the subject has **no** PCP, the subject should be instructed to make an appointment at UVa or at the Free Clinic.

6. Will you be using viable embryos? No

11. **Will you be using embryonic stem cells?** No

12. **Are any aspects of the study kept secret from the participants?** No

13. **Is any deception used in the study?** No

14. **If this protocol involves study treatment, explain how a subject will be transitioned from study treatment when they have completed their participation in the study.** NA

Data and Safety Monitoring Plan

This study has been deemed minimal risk. Because this study poses minimal risk to the subject, **adverse events will only be collected or recorded if a causal relationship to the study intervention is suspected.** If any adverse event is considered serious and unexpected, the event must be reported to the IRB-HSR within 7 days from the time the study team receives knowledge of the event.

1. Definition:

1.1 How will you define <u>adverse events</u> (AE)?

An adverse event will be considered any undesirable sign, symptom or medical condition considered **related to the intervention**. Medical condition/diseases present before starting the intervention will be considered adverse events only if they worsen after starting the study and that worsening is considered to be related to the study intervention. An adverse event is also any undesirable and unintended effect of research occurring in human subjects as a result of the collection of identifiable private information under the research.

1.2 What is the definition of an unanticipated problem?

An unanticipated problem is any issue that involves increased risk(s) to participants or others. This means issues or problems that cause the subject or others to be placed at greater risk than previously identified, even if the subject or others do not incur actual harm. For example if a subject's confidentiality is compromised resulting in serious negative social, legal or economic ramifications, an unanticipated problem would need to be reported. (e.g serious loss of social status, loss of job, interpersonal conflict.)

1.3 What are the definitions of a protocol violation and/or noncompliance?

A **protocol violation** is defined as any change, deviation, or departure from the study design or procedures of research project that is NOT approved by the IRB-HSR prior to its initiation or implementation. Protocol violations may be major or minor violations.

Noncompliance can be a protocol violation OR deviation from standard operating procedures, Good Clinical Practices (GCPs), federal, state or local regulation**s**. Noncompliance may be serious or continuing.

1.4 What is the definition of a data breach?

A data breach is defined in the HITECH Act (43 USC 17932) as an unauthorized acquisition, access, or use of protected health information (PHI) that compromises the security or privacy of such information.

Additional Information may be found on the IRB-HSR Website: Data Breach

2. Identified risks and plans to minimize risk

Expected Risks related to study participation.	Frequency
Muscle soreness during or after testing	Occurs infrequently
Discomfort in joints of lower extremity or spine during or after testing	Occurs infrequently
Loss of balance during the exercise tasks	Occurs infrequently
Violation of subject's privacy and confidentiality	Minimized due to the requirements of the privacy plan in this protocol

The above expected risks will be minimized due to subject monitoring by investigators throughout the collection process. The subject will be informed to give any verbal feedback at any point in the collection period in order for the investigator to recognize the potential for any of the infrequent low level risks listed to avoid their occurrence.

3. When will recording/reporting of adverse events/unanticipated problems begin?

After subject signs consent

4. When will the recording/reporting of adverse events/unanticipated problems end?

End of study drug/device/intervention/participation

5. What is your plan for safety monitoring?

Safety monitoring and aggregate review of adverse events, unanticipated problems, protocol violations and any data breach will be performed by the PI and IRB-HSR through continuation review at least annually.

6. What is your plan for reporting a Unanticipated Problem, Protocol Violation or Data Breach?

Type of Event	To whom will it be reported:	Time Frame for Reporting	How reported?
Unanticipated Problems tha are not adverse events or protocol violations This would include a Data Breach.	IRB-HSR	Within 7 calendar days from the time the study team received knowledge of the event.	Unanticipated Problem report form. *http://www.virginia.edu/vprgs/irb/HSR_docs/Forms/Reporting_Requirements-Unanticipated_Problems.doc)*

Protocol Violations/Noncompliance (*The IRB-HSR only requires that MAJOR violation be reported, unless otherwise required by your sponsor, if applicable.)* **OR** **Enrollment Exceptions**	IRB-HSR	Within 7 calendar days from the time the study team received knowledge of the event.	Protocol Violation, Noncompliance and Enrollment Exception Reporting Form *http://www.virginia.edu/vprgs/irb/hsr_forms.html* *Go to 3rd bullet from the bottom.*
Data Breach of Protected Health Information	The UVa Corporate Compliance and Privacy Office ITC: if breach involves electronic data Police if breach includes items that are stolen: Stolen on UVA Grounds OR Stolen off UVa Grounds- contact police department of jurisdiction of last known location of PHI	As soon as possible and no later than 24 hours from the time the incident is identified. As soon as possible and no later than 24 hours from the time the incident is identified. IMMEDIATELY.	UVa Corporate Compliance and Privacy Office- Phone 924-9741 **ITC:** Information Security Incident Reporting procedure, http://www.itc.virginia.edu/security/reporting.html Police: phone- (434) 924-7166

Payment

What is the difference between compensation and reimbursement?

A reimbursement is used when the subject is paid back for travel expenses such as mileage, lodging, food while traveling. Receipts or mileage must be submitted for a reimbursement.

Compensation is "payment" for things such as time, discomfort, inconvenience. Total possible compensation should reflect the true value of the total possible dollar amount per participant for one year involvement in the study whether it be cash, check, gift card, goods, etc. or a combination of these items.

Retention "Gifts"- gifts may be given to a subject periodically during the study to remind them they are in the study. Sponsors may provide such items as water bottles, birthday cards etc. to the subject. NOTE: Cash or gift cards are NOT allowed as retention items.

1. **Are subjects being reimbursed for travel expenses** (receipts /mileage required)**?**
   Answer/Response: No

2. **Are subjects compensated for being in this study?**
   Answer/Response: YES, those in the low back pain group will be compensated through departmental funding (Curry School doctoral grant). Those in the control group and the chronic ankle instability group will not be compensated.

   ►IF YES, answer the following questions (2a-2d).

   2a. What is the maximum TOTAL compensation to be given over the duration of the protocol?
   Answer/Response: $30.00 will be given to the low back pain group ONLY, not the healthy control group or the chronic ankle instability group.

   2b. Explain compensation to be given.
   Answer/Response: $30.00 at the end of the study

   2c. Is payment pro-rated?
   e.g. some compensation is given even if subjects do not complete the entire study
   Answer/Response: No

   If No, explain why payment cannot be pro-rated.
   Answer/Response: There is only one study session so pro-rating the compensation is not necessary in this case.

   2d. Is money paid from UVa or State funds (including grant funds) or will items such as gift cards be distributed through UVa?
   Answer/Response: Yes

   ►IF YES, answer the following questions [2d(i)-2d(ii)].

   2d(i). How will the researcher compensate the subjects?
   _x____ Check issued to participant via UVA Oracle or State system

   2d(ii). Which category/ categories best describes the process of compensation?
   _x____ All compensation will be made via check issued to participant via UVA Oracle or State system
   The preferred method

Risk/ Benefit Analysis

1. What are the potential benefits for the participant as well as benefits which may accrue to society in general, as a result of this study?

There are no direct benefits for the participants in this study. This study can provide more information to better understand how the gluteus medius, gluteus maximus, transverse abdominis and lumbar multifidus activate in commonly utilized hip exercises and positions for treatment. This will provide clinical insight as to how rehabilitation exercises and treatments truly target their intended muscles with the focus on the gluteals and spinal stabilizers in individuals with low back pain and chronic ankle instability.

2. Do the anticipated benefits justify asking subjects to undertake the risks?

The risks of this study for participants are low and include only minimal soreness and/or muscle fatigue from the usage of the gluteals and some balancing. These methods and other similar ones have been previously used in our lab (IRB-HSR # 16922, 17170, 17206) with no adverse events. Even without direct benefits for participants, the findings that could result from this study can be helpful in ensuring commonly used rehabilitation exercises and positions of function are working their intended muscle. The risk benefit ratio is acceptable.

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APPENDIX: Legal/Regulatory

Recruitment

The following procedures will be followed:

- Finders fees will not be paid to an individual as they are not allowed by UVa Policy.
- All recruitment materials will be approved by the IRB-HSR prior to use. They will be submitted to the IRB after the IRB-HSR has assigned an IRB-HSR # to the protocol.
- Only those individuals listed as personnel on this protocol will recruit and or conduct the consenting process with potential subjects.

Retention Incentives

Any item used by the sponsor/ study team to provide incentive to a subject to remain in the study, other than compensation identified in the Payment section, will be submitted to the IRB for review prior to use. The IRB-HSR will provide the study team with a Receipt Acknowledgement for their records. Retention incentive items are such things as water bottles, small tote bags, birthday cards etc. Cash and gift cards are not allowed as retention incentives.

Clinical Privileges

The following procedures will be followed:

- Investigators who are members of the clinical staff at the University of Virginia Medical Center must have the appropriate credentials and been granted clinical privileges to perform specific clinical procedures whether those procedures are experimental or standard.
- The IRB cannot grant clinical privileges.
- Performing procedures which are outside the scope of the clinical privileges that have been granted may result in denial of insurance coverage should claims of negligence or malpractice arise.
- Personnel on this protocol will have the appropriate credentials and clinical privileges in place before performing any procedures required by this protocol.
- Contact the Clinical Staff Office- 924-9055 or 924-8778 for further information.

Sharing of Data/Specimens

Data and specimens collected under an IRB approved protocol are the property of the University of Virginia. You must have "permission" to share data/ specimens outside of UVa other than for a grant application and or publication. This "permission" may come in the form of a contract with the sponsor or a material transfer agreement (MTA) with others. A contract/ MTA is needed to share the data outside of UVa even if the data includes no HIPAA identifiers and no code that could link the data back to a HIPAA identifier.

- No data will be shared outside of UVa, beyond using data for a grant application and or publication, without a signed contract/MTA approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.
- No specimens will be shared outside of UVa without a signed contract/MTA approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.

Prisoners

If the original protocol/ IRB application stated that no prisoners would be enrolled in this study and subsequently a subject becomes a prisoner, the study team must notify the IRB immediately. The study team and IRB will need to determine if the subject will remain in the study. If the subject will remain in the study, the protocol will have to be re-reviewed with the input of a prisoner advocate. The prisoner advocate will also have to be involved in the review of future continuations, modifications or any other reporting such as protocol violations or adverse events.

Prisoner- Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.
For additional information see the OHRP website at
http://www.hhs.gov/ohrp/policy/populations/index.html

Compensation in Case of Injury

If a subject requests compensation for an injury, the study team should notify the IRB-HSR (924-9634/2439847) the UVa Health System Patient Relations Department (924-8315). As a proactive courtesy, the study team may also notify UVa Health System Patient Safety and Risk Management (924-5595).

On request, the study team should provide the Risk Management Office with the following information/documents:

- Subject Name and Medical Record Number
- Research medical records
- Research consent form
- Adverse event report to IRB
- Any letter from IRB to OHRP

Subject Complaints

During a research study, the study team may receive complaints from a subject. If the study team is uncertain how to respond to a complaint, or is unable to resolve it with the subject, the study team may contact the IRB-HSR (924-9634/243-9847), the UVa Health System Patient Relations Department (924-8315).

Request for Research Records from Search Warrant or Subpoena

If the study team receives a request for research records from a search warrant or subpoena, they should notify UVa Health Information Services at 924-5136. It is important to notify them if information from the study is protected by a Certificate of Confidentiality.

APPENDIX: Unapproved Device Use (Unapproved Device being used but not evaluated)

1. **List name of device(s) being used in an unapproved manner in this protocol**.
    - Siemens Acuson Freestyle (Siemens Medical Solutions, Mountain View, GA) diagnostic ultrasound system

2. **Do you confirm the device is only being USED and NOT being evaluated in this study?**
   Yes

3. **Is the device a Research Use Only (RUO) device?**
   No, the Siemens Acuson Freestyle diagnostic ultrasound system is commonly used in research as well as in clinical settings. This particular device has been used in laboratory studies to assess musculoskeletal structures per its musculoskeletal setting preferences, as well as other structures. This current study will assess hip musculature thickness with the B and M-mode settings of the device according to manufacturer's guidelines. Further information can be found at www.siemens.com/healthcare or by calling 1-888-826-9702.

►If the device is NOT a RUO device, is the device currently approved for any indication?
No, this device will be used according to the instructions in the manufacturer's brochure that is included with submission.

4. **In how many humans has this device been used previously as it is being used in this study?**
   The use of musculoskeletal ultrasound imaging has become increasingly common to assess visually the makeup of muscle structures.

5. **Describe pertinent human data that is available regarding the safety of this device as you are using it in this protocol.**
   Diagnostic ultrasound imaging units have been used frequently in the assessment of muscle thickness with no reported adverse outcomes.

6. **If this protocol will be used in children, describe any previous use of this device with children of a similar age range as it is being used in this study.**
   This protocol outlined in this study will only recruit subjects aged 18-45 years.

7. **What steps will be taken to minimize risk?**
   Strict inclusion and exclusion criteria have been outlined and the manufacturer's instructions will be followed at all times with the usage of the Siemens Acuson Freestyle ultrasound unit.

8. **Would you consider the use of this device to be minimal risk? Why or why not?**
   The Siemens Acuson Freestyle ultrasound device emits ultrasound waves from its transducer that are safe for humans. Similar systems have been utilized frequently in research using human subjects.

APPENDIX: Recruitment

Recruitment includes identifying, review of records to determine eligibility or any contact to determine a potential subjects interest in the study.

*The UVa HIPAA covered entity is composed of the UVa VP Office of Research, the Health System, School of Medicine, School of Nursing, Nutrition Services (Morrisons), the Sheila C. Johnson Center, the Exercise and Sports Injury Laboratory and the Exercise Physiology Laboratory.

6. How do you plan to <u>identify</u> potential subjects?

e. __X__ Potential subjects will not be directly identified. They will respond to an advertisement such as a flyer, brochure etc.

If item # a, b or c is checked above and if this protocol involves the use of protected health information do you confirm the following to be true?

- The use or disclosure is sought solely to review protected health information as necessary to prepare the research protocol or other similar preparatory purposes.
- No PHI will be removed from the UVa covered entity.
- The PHI that the researcher seeks to use or access is necessary for the research purposes.

7.

8. How will potential subjects be <u>contacted?</u>

d.__X__ Indirect contact (flyer, brochure, TV, broadcast emails, patient provided info about the study from their health care provider and either the patient contacts study team or gives their healthcare provider permission for the study team to contact them.)

9. **Will any additional information be obtained from a potential subject during "prescreening"?** No

10. **Do you plan to ask the subjects to do anything, other than answering questions, for the study prior to signing a consent?** No

11. How will the consenting process take place with either the prospective subject, the subject's legally authorized representative or parent/legal guardian of a minor (if applicable)?

The consenting process will take place in the EASIL in Memorial Gymnasium in a quiet and private area. Subjects will be given a consent form and be asked to read through it in its entirety and be given as much time as necessary. If there is concern that the potential subject may not be able to read, the potential subject will be asked to read the first sentence of the consent form to determine if they are capable of reading. Depending on the response they will either be offered the opportunity to read the consent form or have the consent form read to them.

Subjects will be given the opportunity to ask questions and have all questions answered by a member of the research team prior to signing the consent form. A member of the research team will summarize the consent form and procedure verbally to ensure that the individual understands the protocol process. If the subject agrees to participate the person obtaining consent and the subject will sign the form and subjects will be given a copy of the signed consent form.

6. Will subjects sign a consent form for any part of the study? Yes

7. Will the study procedures be started the same day the subject is recruited for the study? Yes, however subjects have the option of returning at a later date to complete testing.

►IF YES, explain in detail why the subject cannot be given more time to make a decision to consent.
This study is a one day session that lasts approximately 1 hour and 30 minutes, but as noted in the previous answer the subject may return at a later date to complete testing.

►IF YES, explain in detail what will be done to assure the potential subject has enough time to make an informed decision.
The potential subject may sign the informed consent at this time or she may elect to take more time to consider participation without any obligation.

8. Is there the potential to recruit economically or educationally disadvantaged subjects, or other vulnerable subjects such as students or employees? Yes

IF YES, what protections are in place to protect the rights and welfare of these subjects so that any possible coercion or undue influence is eliminated?
Potential subjects may be recruited via in-direct contact (i.e. flyer, brochure, email). As applicable potential subjects will be informed that participation or lack thereof will not influence their grades, employment status or care and treatment.

9. Do you need to perform a "dry run" of any procedure outlined in this protocol? No

APPENDIX: Privacy Plan for Studies With Consent/HIPAA Authorization

2. Answer the questions below (1A-1G) to describe the plan to protect the data from improper use and disclosure.

1A. Will any HIPPA identifiers be collected by the UVa study team?

YES	NO	HIPAA Identifier
X		1. Name
	X	2. Postal address information, other than town or city, state, and zip code
	X	3. Age or Date of Birth if over the age of 89
	X	4. Telephone numbers
	X	5. Fax numbers
	X	6. Electronic mail addresses
	X	7. Social Security number
	X	8. Medical Record number
	X	9. Health plan beneficiary numbers
	X	10. Account numbers
	X	11. Certificate/license numbers
	X	12. Vehicle identifiers and serial numbers, including license plate numbers
	X	13. Device identifiers and serial numbers
	X	14. Web Universal Resource Locators (URLs)
	X	15. Internet Protocol (IP) address numbers
	X	16. Biometric identifiers, including finger and voice prints
	X	17. Full face photographic images and any comparable images
	X	18. Any other unique identifying number, characteristic, code that is derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security #, mother's maiden name, first 3 letters of last name.)
X		19. Any other information that could be used alone or in combination with other information to identify an individual. (*e.g. rare disease, study team or company has access to the health information and a HIPAA identifier or the key to the code*)

1A(1)►If you checked any item above, list the HIPAA identifiers that will be kept with the data in the same location (e.g. on the same electronic drive (e.g. F or O drive) or in the same paper file with the data).
Subject names will only be kept on the consent form and with a spreadsheet identifying the unique subject ID# assigned in a locked drawer in the office.

1B. How will data be collected?

1B(1)._____ Collection of data *ONTO** an individual-use device (e.g. desktop computer, smart

1B(2.)_____ Collection of data via web-based format (e.g. online consent, online surveys) via a non-UVa secure server (e.g. NOT HS/CS, ITS or SON SECUREnet)
See 1B(6) below for an exception.

1B(3)._____ Directly to a server managed by the principal investigator's department or school
If checked, please provide the name of the server: _____

1B(4)._____ Directly to an Information Technology Services (ITS) managed server.
If checked, please provide the name of the server: _____

1B(5).____ Directly to a Health Systems Computing Services (HS/CS), or School of Nursing SECUREnet with I Key managed server that is configured to store data regulated by HIPAA.

1B(6)._____ Directly to a server managed by the sponsor or CRO in which the data will be sent and stored in an encrypted fashion (e.g. must be shared and stored via Secure FX, Secure FTP, HTTPS, PGP) and the server is configured to store data regulated by HIPAA.

1.B(7).__X___ Paper

1C. How will data be stored by the UVa study team?

_____ Data, which may include health information or other highly sensitive data, will be stored with HIPAA identifiers.

__X___ Data, which may include health information or other highly sensitive data will NOT be stored with any HIPAA identifier except date(s). This means:

- Documents such as case report forms will have NO HIPAA identifiers except dates (e.g. no initials or medical record #)

- HIPAA identifiers, except dates will be stored in a different place than the health information. A code such as subject # 1 will be used to link the identity of the individual (HIPAA identifiers) with the persons health information.

1D. Will any of the data be stored electronically by the UVa study team? Yes

1D(1)►IF YES, will it include storage of any health information or other sensitive data?

Yes, responses to subject-reported outcome questionnaires regarding pain and activity level, along with height and weight will be stored.

1D(2)►IF YES, will you store/keep any of the HIPAA identifiers listed below in electronic format? Yes

ANSWER QUESTION IN TABLE BELOW

YES	NO	HIPAA Identifier
		1. Name
		2. Postal address information, other than town or city, state, and zip code
		3. Age or Date of Birth if over the age of 89
		4. Telephone numbers
		5. Fax numbers
		6. Electronic mail addresses
		7. Social Security number
		8. Medical Record number
		9. Health plan beneficiary numbers
		10. Account numbers
		11. Certificate/license numbers
		12. Vehicle identifiers and serial numbers, including license plate numbers
		13. Device identifiers and serial numbers
		14. Web Universal Resource Locators (URLs)
		15. Internet Protocol (IP) address numbers
		16. Biometric identifiers, including finger and voice prints
		17. Full face photographic images and any comparable images
		18. Any other unique identifying number, characteristic, code that is derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security #, mother's maiden name, first 3 letters of last name.)
		19. Any other information that could be used alone or in combination with other information to identify an individual. (*e.g. rare disease,key to code kept with study data/ health information*)

1D(4) Check all locations where the data with these HIPAA identifiers will be kept :

_____ with the specimens- *If checked list HIPAA identifiers:*_____

_____ in an electronic file- *If checked list HIPAA*

___X__ in paper file with the data- *If checked list HIPAA identifiers:_Name____*

1E. If you listed any HIPAA identifier under 1D(3), where will the data be stored?

___x__ NA- No HIPAA identifiers will be stored with the data

1E(1)_____ a server managed by the principal investigator's department or school that is configured to store data regulated by HIPAA or highly sensitive data.

- If checked, please provide the name of the server: _____

- Contact information for the person(s) who manages / supports this server.
  _____

1E(2)_____ a Information Technology Services (ITS) managed server that is configured to store data regulated by HIPAA

1E(3)_____ a Health Systems Computing Services (HS/CS) managed server that is configured to store data regulated by HIPAA.

1E(4)_____ a server managed by the sponsor or CRO in which the data will be sent and stored in an encrypted fashion (e.g. must be shared and stored via Secure FX, Secure FTP, HTTPS, PGP) onto a server that is configured to store data regulated by HIPAA.

1E(5)_____ Cloud (UVaBox, UVa-Collab)

►IMPORTANT: If you checked any of the items 1E(1) or 1E(2) submit ISPRO approval with new protocol submission.

You should consult with ISPRO during the development phase of this protocol if your protocol will involve highly technical issues such as the creation of a website to collect data, software application development, the use of a smart phone app, or if you plan to store identifiable data ONTO a tablet/laptop.

Otherwise submit the protocol to ISPRO for review when it is submitted to the IRB-HSR for pre-review.

ISPRO CONTACT INFORMATION:
UVa Office of Information Security, Policy & Records Office (ISPRO)
www.virginia.edu/ispro
Email: IT-Security@Virginia.edu

1F. Will any of the data be collected or stored in hard copy format by the UVa study team (*e.g. on paper*)? Yes

►IF YES, where will it be stored?

X_____ case report forms will be stored in a secure area with limited access.

_X__✓__ questionnaires/surveys will be stored in a secure area with limited access.

1G. The following procedures must also be followed.

- Only investigators for this study and clinicians caring for the patient will have access to the data. They will each use a unique login ID and password that will keep confidential. The password should meet or exceed the standards described on the Information Technology Services (ITS) webpage about *The Importance of Choosing Strong Passwords.*
- Each investigator will sign the University's Electronic Access Agreement forward the signed agreement to the appropriate department as instructed on the form.

If you currently have access to clinical data it is likely that you have already signed this form. You are not required to sign it again.

- UVa University Data Protection Standards will be followed http://www.virginia.edu/informationsecurity/dataprotection.
- If identifiable data is transferred to any other location such as a desktop, laptop, memory stick, CD etc. the researcher must follow the University's "Electronic Storage of Highly Sensitive Data Policy". Additional requirements may be found in the Universities Requirements for Securing Electronic Devices.
- If identifiable health information is taken away from the UVa Health System, Medical Center Policy # 0218 will be followed.
- The data will be securely removed from the server, additional computer(s), and electronic media according to the University's Electronic Data Removal Policy.
- The data will be encrypted or removed if the electronic device is sent outside of UVa for repair according to the University's Electronic Data Removal Policy.
- If PHI will be faxed, researchers will follow the Health System Policy # 0194.
- If PHI will be emailed, researchers will follow the Health System Policy # 0193 and University Data Protection Standards .
- The data may not be analyzed for any other study without additional IRB approval.
- If you are using patient information you must follow Health System Policy # 0021.
- Both data on paper and stored electronically will follow the University's Record Management policy and the Commonwealth statute regarding the Destruction of Public Records.

Summary of Requirements to Comply with UVa Health System, Medical Center and University Policies and Guidance as noted above:

Highly Sensitive Data is:
-personal information that can lead to identity theft if exposed or
-health information that reveals an individual's health condition and/or history of health services use.

Protected Health Information (PHI) a type of Highly Sensitive Data, is health information combined with a HIPAA identifier

Identifiable Health Information under HIPAA regulations is considered to be *Highly Sensitive Data at UVa.*

A **Limited Data Set** (LDS) under HIPAA regulations is considered to be *Moderately Sensitive Data at UVa. The only HIPAA identifiers associated with data: dates and or postal address information limited to town or city, state, and zip code.* See Table A below for details.

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
General Issues	*General Issues*
Discussions in private Do not share with those not on the study team or those who do not have a need to know.	Do not share with those not on the study team or those who do not have a need to know
Password protect	Password protect
Physically secure (lock) hard copies at all times if not directly supervised. If not supervised hard copies must have double protection (e.g. lock on room OR cabinet AND in building requiring swipe card for entrance).	Physically secure (lock) hard copies at all times if not directly supervised.
For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely.	For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely.
Encrypt See Encryption Solutions Guidance *Files on Health System Network drives are automatically encrypted. If not stored there it is study teams responsibility to make sure data are encrypted.*	
If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVa Purchase order.	If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVa Purchase order.
Store files on a network drive specifically designated for storing this type of data, e.g. high-level security servers managed by Information Technology Services or the "F" and "O" managed by Heath Systems Computing Services. You may access it via a shortcut icon on your desktop, but you are not allowed to take it off line to a local drive such as the desktop of your computer (e.g. C drive) or to an individual Use Device*. May access via VPN	
Do not share with sponsor or other outside group before consent is obtained or the IRB has granted appropriate approvals and contract/ MTA is in place	Do not share with sponsor or other outside group before consent is obtained or the IRB has granted appropriate approvals and contract/ MTA is in place
If collected without consent/ HIPAA authorization will NOT be allowed to leave UVa HIPAA covered entity unless disclosure is approved by the IRB and the disclosure is tracked in EPIC	If collected without consent/ HIPAA authorization will NOT be allowed to leave UVa HIPAA covered entity unless disclosure is approved by the IRB and an MTA is in place prior to sharing of data

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)**

Individual-Use Device	*Individual-Use Device*
Do not save to individual-use device* without written approval of your Department AND VP or Dean. If approval obtained, data must be password protected and encrypted.	
Do not save an email attachment containing HSD to an individual use device (e.g. smart phone)	
E Mail	*E Mail*
Do not share via email with Outlook Web/ or forward email using other email vendors like Gmail/ Yahoo	
Do not send via email on smart phone unless phone is set up by Health System	
Email may include name, medical record number or Social Security number only if sending email to or from a person with * HS in their email address. *NOTE: VPR & IRB staff do not meet this criteria!*	In addition to sharing LDS, may include initials if persons sending and receiving email work within the UVa HIPAA covered entity.**
FAX	*FAX*
Verify FAX number before faxing	Verify FAX number before faxing
Use Fax Cover Sheet with Confidentiality Statement	Use Fax Cover Sheet with Confidentiality Statement
Verify receiving fax machine is in a restricted access area	Verify receiving fax machine is in a restricted access area
Verify intended recipient is clearly indicated	Verify intended recipient is clearly indicated
Recipient is alerted to the pending transmission and is available to pick it up immediately	Recipient is alerted to the pending transmission and is available to pick it up immediately

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
Electronic Data Collection & Sharing	*Electronic Data Collection & Sharing*
(e.g. smart phone app, electronic consent using tablet etc.) MUST consult with ISPRO or Health System Web Development Office: 434-243-6702 University Side: IT-Security@virginia.edu Health System: Web Development Center: Contract must include required security measures.	
May NOT be stored in places like UVaBox, UVaCollab, QuestionPro. May also NOT be stored in non-UVa licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey, etc.	May be stored in places like UVaBox, UVaCollab, QuestionPro. May NOT be stored in non-UVa licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey, etc.
LOST OR STOLEN:	*LOST OR STOLEN:*
Must report in accordance with protocol/ in accordance with the Information Security Incident Reporting Policy	Must report in accordance with protocol/ in accordance with the Information Security Incident Reporting Policy

** Individual Use Device – examples include smart phone, CD, flash (thumb) drive, laptop, C drive of your computer.*

***The UVa HIPAA covered entity is composed of the UVa VP Office of Research, the Health System, School of Medicine, School of Nursing, Nutrition Services (Morrison's), the Sheila C. Johnson Center, the Exercise and Sports Injury Laboratory and the Exercise Physiology Laboratory.*

Table C4. University of Virginia Institutional Review Board Approved Consent Form (Manuscript 3) (IRB-HSR #18267)

Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

Principal Investigator:	Susan Saliba, Ph.D, M.P.T., ATC Department of Kinesiology PO Box 400407 Charlottesville, VA 22908 (P) 434-243-4033 (E) saf8u@virginia.edu
Sponsor:	Curry School of Education at The University of Virginia

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

The Curry School of Education is providing departmental funding for this study.

Why is this research being done?

The purpose of this study is to examine the muscle thickness with diagnostic ultrasound imaging and how the upper thigh and hip (gluteal) muscles activate (turn on) in healthy, active adults and in adults with low back pain, and adults with chronic ankle instability. All participants will be asked to get into certain positions and perform commonly used rehabilitation type movements that target the upper thigh and hip muscles. With this information we hope to see how people who are healthy and people with low back pain, and chronic ankle instability activate their core and hip muscles during these functional movements.

You are being asked to be in this study, because you are a healthy individual, you have low back pain, or chronic ankle instability.

Up to 115 individuals will be in this study at UVA.

How long will this study take?

Your participation in this study will require 1 study visit and the visit will last about 2 hours.

What will happen if you are in the study?

CONSENT and SCREENING (will take about 10-15 minutes):

If you agree to participate, you will sign this consent form before any study related procedures take place. Before you can start in the study, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible and it is safe for you to participate. These include the following:

- Review of your medical history
- Height and weight measurements

If these tests show you are eligible, you will return to the clinic at a later date to begin study treatment, or you may continue with the remainder of testing. The test and procedures in this study are being done for research purposes only.

STUDY PROCEDURES: (will last about 75-100 minutes)

If you eligible and agree to participate in this study, you will be asked to fill out some questionnaires. These questionnaires will ask about:

- General medical history
- Physical activity level
- Hip and lower extremity (leg) pain
- Low back pain (for **low back pain participants ONLY**)
- Ankle sprain history and symptoms (for **chronic ankle instability participants ONLY**)

It will take about 15-20 minutes to complete all questionnaires.

Hip Exam

Once you have completed the questionnaires, you will be asked to go through a basic clinical hip exam. This will include:

1. Measurement of hip motion while lying and sitting on a table.
2. Testing of muscle strength with investigator providing resistance while you lie or sit on a table.
3. Clinical tests for common hip injuries while lying on a table.

It will take about 15 minutes to complete all hip motion and strength testing.

Ultrasound Imaging & Muscle Activation

Upon completion of the questionnaires, you will complete the ultrasound imaging and muscle activation portion of the study lying on a tabletop, standing, and while completing different common hip rehabilitation exercises, and during treadmill walking.

1. Water-soluble ultrasound gel will be placed on your skin, on each side of your hips, abdomen, and low back.
2. The ultrasound transducer will be placed on the skin where the gel was placed, and that will display the muscle thickness images on the ultrasound computer screen.
3. Sensors will also be placed on the hip while the ultrasound transducer is on the screen and secured with double-sided adhesive tape. Small reflective markers will also be attached using Velcro belts for movement tracking during the positions.
4. Ultrasound images will be collected on both sides of your gluteal and hip muscles, and abdominal muscles, while lying on a tabletop, standing and during each of the exercise positions commonly performed during hip and low back rehabilitation.
5. You will be asked to perform 3 trials of each exercise.
6. You will be asked to perform approximately 5 minutes of treadmill walking*. *Chronic ankle instability and healthy participants will ONLY perform treadmill walking and standing exercises and will only have hip ultrasound performed, not abdomen or low back.

At the completion of the ultrasound and activation testing, your participation in the study will end.

If you want to know about the results before the study is done:

During the study your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you can ask for more information about the study results.

What are the risks of being in this study?

- muscle soreness during or after testing
- discomfort in at the joints of the lower extremity or spine during testing
- loss of balance during one of the tasks. If you experience a loss of balance and fall you may experience an injury that could injure a joint or muscle

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You will not benefit from being in this study. However the information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

The only choice is not to be in this study. If you are a patient at UVa your usual care will not be affected if you decide not to participate in this study. If you are an employee of UVa your job will not be affected if you decide not to participate in this study. If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

ONLY Participants with **low back pain** will be paid $30 for completion of this study. The other participants will not get any money for being in this study.

You should receive your payment as a check about 2-4 weeks after completion of the study. The income may be reported to the IRS as income.

You will not be paid at all if you decide not to finish the study. If the study leader says you cannot continue, you will be paid the full amount for the study.

If you owe any money to any Virginia state agency, the state can use the money you earn in this study to pay those debts. These state agencies include the UVa Medical Center, VCU Medical Center or a college or university. The money may be withheld to pay back debt for such things as unpaid medical bills, taxes, fines, child support. Even if this happens, the money you earn may be reported to the IRS as taxable income.

Will being in this study cost you any money?

The questionnaires, imaging, and exercise procedures, which are being collected for research purposes, will be provided at no cost to you or your health insurance. You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include

a) You become injured and can no longer participate in the study

b) The principal investigator closes the study for safety, administrative or other reasons

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

25. Personal information such as name, address and date of birth
26. Social Security number only if you are being paid to be in this study
27. Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Susan Saliba, Ph.D, M.P.T., ATC
Human Services, Curry School of Education
Department of Kinesiology
PO Box 400407
Charlottesville, VA 22908
(P) 434-243-4033
(E) saf8u@virginia.edu

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908
Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
___ PERSON OBTAINING CONSENT (SIGNATURE)	___ PERSON OBTAINING CONSENT (PRINT)	_ DATE

Table C5. Pre-Screening Form

IRB-HSR# 17909
PFP PENS Prescreening Form

Subject Number _____

Inclusion	Yes	No
1) Between 15-65 years old	☐	☐
2) Knee pain due to non traumatic event	☐	☐
3) Pain for more than 3 months	☐	☐
4) Pain with the following activities		
a. Stair ascent or descent	☐	☐
b. Running	☐	☐
c. Kneeling	☐	☐
d. Squatting	☐	☐
e. Prolonged sitting	☐	☐
f. Jumping	☐	☐
g. Contracting thigh muscle	☐	☐
h. Putting pressure on your patellar	☐	☐
Exclusion		
1) Previous knee surgery	☐	☐
2) Injury to your knee ligaments or meniscus	☐	☐
3) History of other anterior knee pain (ie: tendonitis)	☐	☐
4) History of neuropathy	☐	☐
5) Biomedical devices (ie: pacemaker or defibrillators)	☐	☐
6) Muscular abnormalities	☐	☐
7) Currently pregnant	☐	☐
8) Hypersensitivity to electrical stimulation	☐	☐
9) Active infection over thigh or hip muscles	☐	☐
10) Currently involved in a physician-prescribed rehabilitation program	☐	☐

To be completed by the Researcher:

Does the subject have an 85 or less on the AKPS questionnaire	☐	☐
Does the subject have greater than 3 on the Visual Analog Scale	☐	☐
Does this subject meet inclusion to this study?	☐	☐

Version Date: 12/2/13

Table C6. PFP Training Study Schedule

PENS PFP Training Study Schedule

Pre-Intervention
- Screening Form
- AKPS
- Consent
- ADLS,FABQ, Tegner, GL, SF-12, LEFS
- LE ROM
- LE Strength
- US Measurements
- Planking endurance
- MVIC with EMG
- Quad hardness
- 15 SLS (VAS)
- 15 Lunges (VAS)
- 15 Steps each leg (VAS)
- 5 min walking
- 5 min jogging (VAS)

Visit 1:
- VAS Pre Rehab
- VAS Post Rehab

Visit 2:
- VAS Pre Rehab
- VAS Post Rehab

Visit 3:
- VAS Pre Rehab
- VAS Post Rehab
- Godin Leisure
- AKPS
- FABQ
- MMT: Knee Ext, Hip Abd & ER

Visit 4:
- VAS Pre Rehab
- VAS Post Rehab

Visit 5:
- VAS Pre Rehab
- VAS Post Rehab

Visit 6:
- VAS Pre Rehab
- VAS Post Rehab
- Godin Leisure
- AKPS
- FABQ
- MMT: Knee Ext, Hip Abd & ER

Visit 7:
- VAS Pre Rehab
- VAS Post Rehab

Visit 8:
- VAS Pre Rehab
- VAS Post Rehab

Visit 9:
- VAS Pre Rehab
- VAS Post Rehab
- Godin Leisure
- AKPS
- FABQ
- MMT: Knee Ext, Hip Abd & ER

Visit 10:
- VAS Pre Rehab
- VAS Post Rehab

Visit 11:
- VAS Pre Rehab
- VAS Post Rehab

Visit 12:
- VAS Pre Rehab
- VAS Post Rehab
- Godin Leisure
- AKPS
- FABQ
- MMT: Knee Ext, Hip Abd & ER

Post Intervention
- Screening Form
- AKPS
- ADLS,FABQ, Tegner, GL, SF-12, LEFS
- GROC
- LE ROM
- LE Strength
- US Measurements
- Planking endurance
- MVIC with EMG
- Quad hardness
- 15 SLS (VAS)
- 15 Lunges (VAS)
- 15 Steps each leg (VAS)
- 5 min walking
- 5 min jogging (VAS)

Table C7. Weeks 1-2 Rehabilitation Form

Impairment Based Rehabilitation

Range of Motion 2minutes

Patella Joint Mobilization	Sets	Duration (minutes)	Grade Mob.

Stretching exercises: 3x30 seconds each selected

Stretch Position	Sets	Duration (seconds)
Quadriceps		
Hamstring		
IT Band		
Gastrocnemius		

Intrinsic Foot Exercises Progression if needed

Short Foot Exercises	Sets	Duration (minutes)

REHAB FOR ALL

Quad/Hip Strength

Exercise (circle appropriate)	Sets	Repetitions	Weight
4-way SLR			
NK knee flex/ext			
Wall Squats			
Hip abd/lat rotation			
Clam Shells			

Core Strengthening

Exercise (circle appropriate)	Sets	Repetitions	Weight
• TrA/Multifidus Prone • TrA/Multifidus on Swiss ball			

Balance

Static Balance (circle appropriate phase) Goal 3x30 seconds	Sets	Duration (seconds)
1. Eyes Open Single leg balance		
2. Eyes Open Single leg balance on a foam		
3. Eyes Open Single leg balance on Dynadisc™		
Eyes Closed Progression		
1. Eyes Closed Single leg balance		
2. Eyes Closed Single leg balance on a foam		
3. Eyes Closed Single leg balance on Dynadisc™		

NOTES:

Table C8. Weeks 3-4 Rehabilitation Form

Impairment Based Rehabilitation

Range of Motion 2minutes

Patella Joint Mobilization	Sets	Duration (minutes)	Grade Mobilization

Stretching exercises: 3x30 seconds each selected

Stretch Position	Sets	Duration (seconds)
Quadriceps		
Hamstring		
IT Band		
Gastrocnemius		

Intrinsic Foot Exercises Progression if needed

Short Foot Exercises	Sets	Duration (minutes)

REHAB FOR ALL

Quad/Hip Strength

Exercise (circle appropriate)	Sets	Repetitions	Weight
4-way SLR			
NK knee flex/ext			
Wall Squats			
Step Ups/Down			
Lat Rot in CKC			
Pelvic Drop			
Clam Shells			

Core Strengthening

Exercise	Sets	Repetitions	Weight
Anterior Plank			
Lateral Plank			
Trunk Extension on Swiss Ball			

Balance

Static Balance (circle appropriate phase) Goal 3x30 seconds	Sets	Duration (seconds)
1. Eyes Open Single leg balance		
2. Eyes Open Single leg balance on a foam		
3. Eyes Open Single leg balance on Dynadisc™		
Eyes Closed Progression		
1. Eyes Closed Single leg balance		
2. Eyes Closed Single leg balance on a foam		
3. Eyes Closed Single leg balance on Dynadisc™		

Functional Exercises:

Goal is 3x12 each leg	Sets	Repetitions	TheraBand(color)
Single Leg Squat			
Lunge			
Single Leg Deadlift			

NOTES:

Table C9. Anterior Knee Pain Scale

Anterior Knee Pain Scale

Subject Number: _____
Date: _____
Knee: L/R

For each question, circle the latest choice (letter), which corresponds to your knee symptoms.

1. Limp
(a) None
(b) Slight or periodical
(c) Constant

2. Support
(a) Full support without pain
(b) Painful
(c) Weight bearing impossible

3. Walking
(a) Unlimited
(b) More than 1 mile
(c) Less than 1 mile
(d) Unable

4. Stairs
(a) No difficulty
(b) Slight pain when descending
(c) Pain both when descending and ascending
(d) Unable

5. Squatting
(a) No difficulty
(b) Repeated squatting painful
(c) Painful each time
(d) Possible with partial weight bearing
(e) Unable

6. Running
(a) No difficulty
(b) Pain after more than 1 mile
(c) Slight pain from start
(d) Severe pain
(e) Unable

7. Jumping
(a) No difficulty
(b) Slight difficulty
(c) Constant pain
(d) Unable

8. Prolonged sitting with the knees flexed
(a) No difficulty
(b) Pain after exercise
(c) Constant pain
(d) Pain forces to extend knees temporarily
(e) Unable

9. Pain
(a) None
(b) Slight and occasional
(c) Interferes with sleep
(d) Occasionally severe
(e) Constant and severe

10. Swelling
(a) None
(b) After severe exertion
(c) After daily activities
(d) Every evening
(e) Constant

11. Abnormal painful kneecap (patellar) movements (subluxations)
(a) None
(b) Occasionally in sports activities
(c) Occasionally in daily activities
(d) At least one documented dislocation
(e) More than two dislocations

12. Atrophy of thigh
(a) None
(b) Slight
(c) Severe

13. Flexion deficiency
(a) None
(b) Slight
(c) Severe

Total Score: _____/100

Table C10. Activities of Daily Living Scale

ACTIVITIES OF DAILY LIVING SCALE

Subject Number: _____ Date _____

1- **Instructions:** The following questionnaire is designed to determine the symptoms and limitations that you experience because of your knee while you perform your usual daily activities. Please answer each question by checking the one statement that best describes you over the last 1 to 2 days.

2- **Symptoms:** To what degree does each of the following symptoms affect your level of daily activity? (circle 1 number on each line)

	I do not have the symptoms	I have the symptom but it does not affect my activity	The symptoms affect my activity slightly	The symptom affects my activity moderately	The symptom affects my activity severely	The symptoms prevent me from all daily activities
Pain	5	4	3	2	1	0
Stiffness	5	4	3	2	1	0
Swelling	5	4	3	2	1	0
Giving way or buckling	5	4	3	2	1	0
Weakness	5	4	3	2	1	0
Limping	5	4	3	2	1	0

3- **Functional Limitation with Activities of Daily Living**
How does your knee affect your ability to. . . . (circle 1 number on each line)

	Activity is not difficult	Activity is minimally difficult	Activity is somewhat difficult	Activity is fairly difficult	Activity is very difficult	I am unable to do the activity
Walk	5	4	3	2	1	0
Go up stairs	5	4	3	2	1	0
Go down stairs	5	4	3	2	1	0
Stand	5	4	3	2	1	0
Kneel on front of knee	5	4	3	2	1	0
Squat	5	4	3	2	1	0
Sit with your knee bent	5	4	3	2	1	0
Rise from a chair	5	4	3	2	1	0

4- How would you rate your level of functioning during your usual daily activities on a scale from 0 to 100 with 100 being your level of function prior to your knee problem and 0 being the inability to perform any of your usually daily activities? ___.0%

5- How would you rate the overall function of your knee during your usually daily activities? (please check the best one)
- ☐ Normal
- ☐ Nearly Normal
- ☐ Abnormal
- ☐ Severely Abnormal

6- As a result of your knee problem, how would you rate your current level of daily activity? (please check the best one)
- ☐ Normal
- ☐ Nearly Normal
- ☐ Abnormal
- ☐ Severely Abnormal

7- Over the past 24 hours, how bad has your pain been?

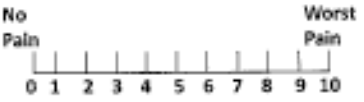

Table C11. Godin Leisure-Time Exercise Questionnaire

Godin Leisure-Time Exercise Questionnaire

1. During a typical **7-Day period** (a week), how many times on the average do you do the following kinds of exercise for **more than 15 minutes** during your free time (write on each line the appropriate number).

	Times Per Week
a) **STRENUOUS EXERCISE** **(HEART BEATS RAPIDLY)** (e.g., running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)	_____
b) **MODERATE EXERCISE** **(NOT EXHAUSTING)** (e.g., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)	_____
c) **MILD EXERCISE** **(MINIMAL EFFORT)** (e.g., yoga, archery, fishing from river bank, bowling, horseshoes, golf, snow-mobiling, easy walking)	_____

2. During a typical **7-Day period** (a week), in your leisure time, how often do you engage in any regular activity **long enough to work up a sweat** (heart beats rapidly)?

OFTEN	SOMETIMES	NEVER/RARELY
1. ☐	2. ☐	3. ☐

Table C12. Tegner Activity Level Scale

TEGNER ACTIVITY LEVEL SCALE

Please indicate in the spaces below the HIGHEST level of activity that you participated in BEFORE YOUR INJURY and the highest level you are able to participate in CURRENTLY.

BEFORE INJURY: Level_____ CURRENT: Level_____

Level 10	**Competitive sports- soccer, football, rugby (national elite)**
Level 9	**Competitive sports- soccer, football, rugby (lower divisions), ice hockey, wrestling, gymnastics, basketball**
Level 8	**Competitive sports- racquetball or bandy, squash or badminton, track and field athletics (jumping, etc.), down-hill skiing**
Level 7	**Competitive sports- tennis, running, motorcars speedway, handball** **Recreational sports- soccer, football, rugby, bandy, ice hockey, basketball, squash, racquetball, running**
Level 6	**Recreational sports- tennis and badminton, handball, racquetball, down-hill skiing, jogging at least 5 times per week**
Level 5	**Work- heavy labor (construction, etc.)** **Competitive sports- cycling, cross-country skiing,** **Recreational sports- jogging on uneven ground at least twice weekly**
Level 4	**Work- moderately heavy labor (e.g. truck driving, etc.)**
Level 3	**Work- light labor (nursing, etc.)**
Level 2	**Work- light labor** **Walking on uneven ground possible, but impossible to back pack or hike**
Level 1	**Work- sedentary (secretarial, etc.)**
Level 0	**Sick leave or disability pension because of knee problems**

Y Tegner and J Lysolm. *Rating Systems in the Evaluation of Knee Ligament Injuries.* Clinical Orthopedics and Related Research. Vol. 198: 43-49, 1985.

Table C13. Fear-Avoidance Beliefs Questionnaire Knee

Fear-Avoidance Beliefs Questionnaire Knee

Subject Number:_____ **Pre/Post** **Date:**_____/_____/_____

Here are some of the things other patients have told us about their pain. For each statement please circle the number from 0 to 6 to indicate how much physical activities such as walking, running, kneeling, or driving affect or would affect your knee pain.

	Completely Disagree			Unsure			Completely Agree
1. My pain was caused by physical activity.	0	1	2	3	4	5	6
2. Physical activity makes my pain worse.	0	1	2	3	4	5	6
3. Physical activity might harm my knee.	0	1	2	3	4	5	6
4. I should not do physical activities which (might) make my pain worse.	0	1	2	3	4	5	6
5. I cannot do physical activities which (might) make my pain worse.	0	1	2	3	4	5	6

The following statements are about how your normal work affects or would affect your knee pain.

	Completely Disagree			Unsure			Completely Agree
6. My pain was caused by my work or by an accident at work.	0	1	2	3	4	5	6
7. My work aggravated my pain.	0	1	2	3	4	5	6
8. I have a claim for compensation for my pain.	0	1	2	3	4	5	6
9. My work is too heavy for me.	0	1	2	3	4	5	6
10. My work makes or would make my pain worse.	0	1	2	3	4	5	6
11. My work might harm by knee.	0	1	2	3	4	5	6
12. I should not do my regular work with my present pain.	0	1	2	3	4	5	6
13. I cannot do my normal work with my present pain.	0	1	2	3	4	5	6
14. I cannot do my normal work until my pain is treated.	0	1	2	3	4	5	6
15. I do not think that I will be back to my normal work within 3 months.	0	1	2	3	4	5	6
16. I do not think that I will ever be able to go back to that work.	0	1	2	3	4	5	6

FABQPA (2,3,4,5): ____/24 FABQW (6,7,9,10,11,12,15): ____/42

Table C14. Lower Extremity Functional Scale

The Lower Extremity Functional Scale

We are interested in knowing whether you are having any difficulty at all with the activities listed below **because of your lower limb problem** for which you are currently seeking attention. Please provide an answer for **each** activity.

Today, do you or would you have any difficulty at all with:

	Activities	Extreme Difficulty or Unable to Perform Activity	Quite a Bit of Difficulty	Moderate Difficulty	A Little Bit of Difficulty	No Difficulty
1	Any of your usual work, housework, or school activities.	0	1	2	3	4
2	Your usual hobbies, recreational or sporting activities.	0	1	2	3	4
3	Getting into or out of the bath.	0	1	2	3	4
4	Walking between rooms.	0	1	2	3	4
5	Putting on your shoes or socks.	0	1	2	3	4
6	Squatting.	0	1	2	3	4
7	Lifting an object, like a bag of groceries from the floor.	0	1	2	3	4
8	Performing light activities around your home.	0	1	2	3	4
9	Performing heavy activities around your home.	0	1	2	3	4
10	Getting into or out of a car.	0	1	2	3	4
11	Walking 2 blocks.	0	1	2	3	4
12	Walking a mile.	0	1	2	3	4
13	Going up or down 10 stairs (about 1 flight of stairs).	0	1	2	3	4
14	Standing for 1 hour.	0	1	2	3	4
15	Sitting for 1 hour.	0	1	2	3	4
16	Running on even ground.	0	1	2	3	4
17	Running on uneven ground.	0	1	2	3	4
18	Making sharp turns while running fast.	0	1	2	3	4
19	Hopping.	0	1	2	3	4
20	Rolling over in bed.	0	1	2	3	4
	Column Totals:					

Minimum Level of Detectable Change (90% Confidence): 9 points **SCORE: _____/ 80 (fill in the blank with the sum of your responses)**

Source: Binkley et al (1999): The Lower Extremity Functional Scale (LEFS): Scale development, measurement properties, and clinical application. Physical Therapy. 79:371-383.

Table C15. Global Rating of Change Score

Subject #:_____

PATIENT GLOBAL RATING

Date:_____/_____/_____
mm dd yy

Please rate the overall condition of your knee ***from the time that you began treatment until now*** (check only one):

☐ A very great deal worse	☐ About the same	☐ A very great deal better
☐ A great deal worse		☐ A great deal better
☐ Quiet a bit worse		☐ Quiet a bit better
☐ Moderately worse		☐ Moderately better
☐ Somewhat worse		☐ Somewhat better
☐ A little bit worse		☐ A little bit better
☐ A tiny bit worse (almost the same)		☐ A tiny bit better (almost the same)

Table C16. Overall Study Procedures

1. Attend baseline collection at Exercise and Sport Injury Laboratory in Memorial Gymnasium
    a. Obtain informed consent
    b. Assess inclusion and exclusion criteria
    c. Completed patient-reported outcome measures (C15)
        i. Anterior Knee Pain Scale
        ii. Activities of Daily Living Scale
        iii. Fear Avoidance Beliefs Questionnaire-Knee
        iv. Lower Extremity Functional Scale
        v. Tegner Activity Scale
        vi. Godin Leisure-Time Exercise Questionnaire
        vii. SF-12
        viii. Visual Analog Scale
    d. Complete physical examination to complete demographic information
        i. Obtain participant's height
        ii. Obtain participant's weight
        iii. Obtain symptom history, pain characteristics
    e. Perform comprehensive evaluation dictating impairment-based rehabilitation starting point (C18)
    f. Perform ultrasound imaging measures (C16)
2. Dismiss participant from baseline collection session
3. Participants attend 12 rehabilitation sessions over a 4-week period (C19)
4. Repeat steps 1c-1f within 48 hours of final rehabilitation session
5. Dismiss participant from study.

Table C17. Patient-Reported Outcome Measures Collection

1. Participants will complete patient-reported outcome measures following consent and screening in a quiet desk area in the laboratory with a member of the study team supervising the completion of the questionnaires.
2. All participants will complete all of the following questionnaires at both the initial and final data collection session. Some questionnaires will be filled out at intermittent time points throughout the rehabilitation program.
    a. General Health History Form (EaSIL)
    b. Anterior Knee Pain Scale
    c. Activities of Daily Living Scale
    d. Fear Avoidance Beliefs Questionnaire-Knee
    e. Lower Extremity Functional Scale
    f. Tegner Activity Scale
    g. Godin Leisure-Time Exercise Questionnaire
    h. SF-12
    i. Visual Analog Scale (performed after each functional task, at the beginning and end of each rehabilitation session)

Table C18. Ultrasound Imaging Collection Procedures

1. Ultrasound System Setup
    a. On Siemens Acuson Freestyle ultrasound unit monitor, press the power button on the left side of the lower panel. (Figure C1)
    b. Once blank scanning screen appears (after startup of system), remove the 8-MHz linear transducer from the holding area on the back of the monitor.
    c. Insert a battery pack into the back of the linear transducer and power on with two fingers pressed simultaneously on the + and – buttons on the transducer. An auditory chiming sound will ring as the transducer powers on.
    d. Check that Bluetooth is operating with a battery indicator on the lower right of the screen with a P for probe.

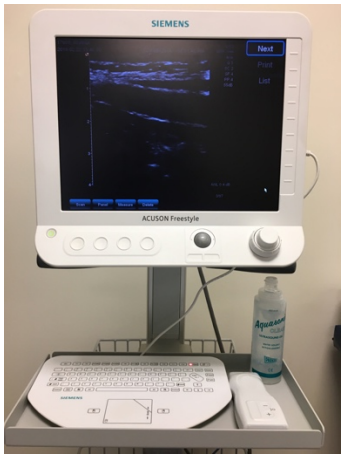

Figure C1. Siemens Acuson Freestyle Ultrasound with linear transducer displayed in bottom right corner next to keyboard

2. New Participant File Setup
    a. Press Setup tab on bottom of screen or use mouse on keyboard for all selections and scrolling (Figure C2)

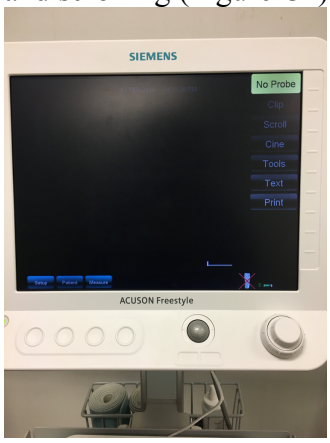

Figure C2. Startup screen of Acuson Freestyle

    b. Press “New Patient Study” on the setup menu (Figure C3)

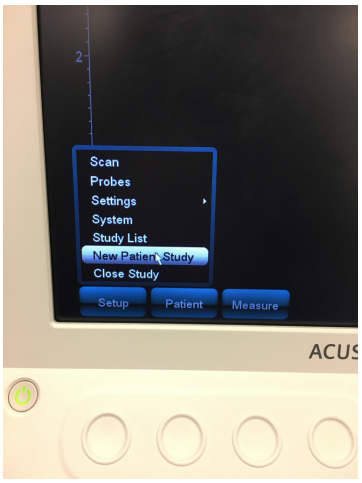

Figure C3. New Patient Study Setup Menu

c. Under the last name, type “IRB#_Subject#” and press save (Figure C4)

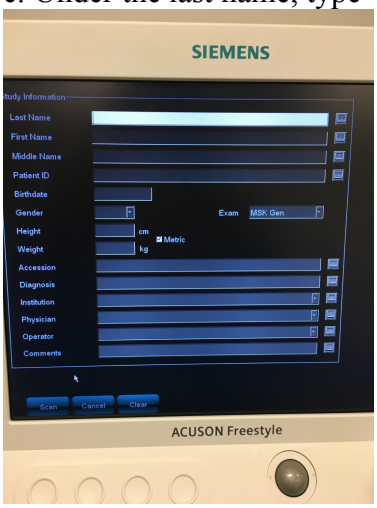

Figure C4. Input screen for Patient ID with IRB and Subject #

d. Select the “Scan” button and the unit is ready for ultrasound image collection.
e. Ensure that the correctly named file appears in the top left hand corner of the screen prior to saving the first image.

Part 1: Transverse Abdominis (Manuscript 1 & 3)

3. **Tabletop measures:** participants were placed in a supine, hook-lying position with a bolster under their knees.

a. Ultrasound gel was placed on the lateral abdominal wall with a towel tucked into the waistband of their shorts.
b. The linear transducer was placed 10cm lateral to the umbilicus and depth on the screen was adjusted to show the apex of the musculotendinous junction of the transverse abdominis and fascial borders from obliques.

c. To save an image, the “Freeze” button was pressed in the top right corner (Figure C5), followed by pressing the “Save” button just below the previously clicked “Freeze” button, which will read as “Unfreeze” once clicked initially

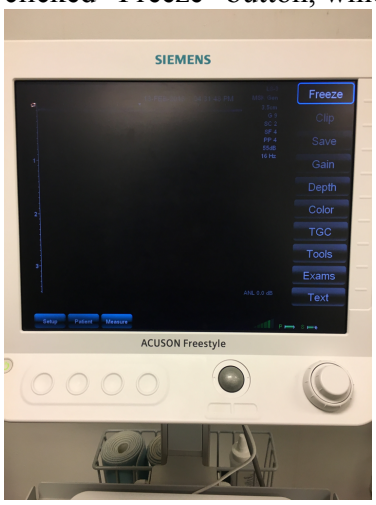

Figure C5. Freeze button in top right corner

d. Once saved, click “Unfreeze” and continue with subsequent image capture (Figure C6)

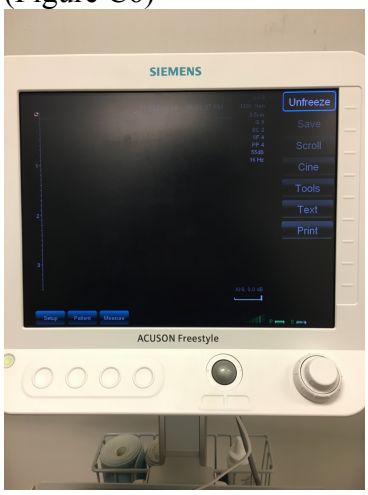

Figure C6. Unfreeze button in top right when image is frozen to be saved

e. For contracted images, participants were asked to perform an abdominal draw-in maneuver by bringing their umbilicus toward their spine after exhalation. Image capture and saving occurred while participants held this contraction.

4. **Bipedal stance measures:** participants were asked to stand and the transducer was placed inside a medium density foam block with an elastic Velcro belt to hold the transducer and block onto their lateral abdominal wall.

a. Steps 3a-3d were repeated in the bipedal stance with both feet shoulder width apart and the participant looking straight ahead.

Figure C7. Bipedal stance with abdominal ultrasound

5. **Unipedal stance measures:** participants were asked to place their arms across their chest with hands on the opposite shoulder while balancing on a single limb (the same side as the transducer) for 3 rested and 3 contracted images following steps 3a-3d the same as before.
6. **Single leg squat measures:** participants were asked to perform 6 single leg squats (3 "rested" as they normally would perform and 3 "contracted" while holding an abdominal draw-in maneuver throughout the squat).
    a. Steps 3a-3d were repeated with the belt in the same position as the bipedal and unipedal stances.

Part 2: Gluteus maximus and gluteus medius (Manuscript 2)

7. **Tabletop measures:** participants were placed in a side-lying position with ultrasound gel placed on the posterolateral aspect of their hip. A towel was tucked into their waistband to avoid gel getting onto their clothing throughout collection.
    a. The transducer was placed on the lateral aspect of their hip until the Gmax and Gmed were visualized on the screen with the Gmax superior to the Gmed.
    b. 3 rested images were captured using the same procedure as 3c-3d.
    c. Contracted images were captured during a side-lying hip abduction approximately 12in off of the table. Images were saved using the same procedure as 3c-3d.
8. **Bipedal stance measures:** participants were asked to stand with feet shoulder width apart looking straight ahead and arms relaxed by their sides. The transducer was placed into the medium density foam block with the elastic belt holding the transducer onto their posterolateral hip in the same position as the tabletop measures (7a).
    a. 3 rested images were captured same as 3a-3d.
    b. Contracted images were frozen and saved while participants performed a bilateral gluteal squeeze.
9. **Unipedal stance measures:** participants moved into the same positioning as step 5 above with transducer on their lateral hip. Steps 8a-b were repeated.
10. **Single leg squat measures:** participants performed the same squats as in step 6, with steps 8a-b repeated.
11. All measures were completed bilaterally starting with the right hip and repeated on the left.

Table C19. Electromyography Collection Procedures

1. Trigno Control Utility was opened and electrodes were turned on by pressing small black button on each bar electrode
    a. A green light will appear on each electrode and lights on control utility window turned green by each numbered electrode as they were powered on
2. Skin was prepared for electrode adhesion
    a. Shaved with a disposable razor
    b. Lightly debrided with a small brillo pad
    c. Cleaned with an isopropyl alcohol pad
3. Electrodes were placed on the gluteus maximus and gluteus medius
    a. Gluteus maximus: Participant was prone and electrode was placed at 50% distance between sacral vertebrae and greater trochanter
    b. Gluteus medius: Participant was side-lying and electrode was placed at 50% between greater trochanter and super aspect of the iliac crest
4. EMG was collected in quiet bipedal stance for at least 10 seconds
5. EMG was collected bilaterally during single leg squats

Table C20. Additional comprehensive evaluation

1. Range of Motion Assessment
    a. Ankle range of motion
        i. Dorsiflexion, plantarflexion: axis aligned with lateral malleolus, moving arm aligned with 5th metatarsal, stationary arm aligned with fibular head
        ii. Inversion, eversion: axis in center of anterior ankle between malleoli; moving arm aligned with 2nd phalanx; stationary arm aligned with tibial tuberosity
    b. Knee range of motion
        i. Knee flexion; axis aligned with lateral epicondyle, moving arm aligned with lateral malleolus, stationary arm aligned with greater trochanter
    c. Hip range of motion
        i. Internal and external rotation; axis aligned with mid-line of patella, moving arm aligned with tibial crest, stationary arm aligned perpendicular to the ground
        ii. IT band: bubble inclinometer used and zeroed parallel to floor on top of treatment table and placed proximal to lateral knee joint line
        iii. Hamstring: bubble inclinometer used and zeroed parallel to floor on top of treatment table and placed on anterior portion of distal tibia
2. Manual Muscle Testing
    a. Three trials were completed in each position bilaterally
    b. Participant was instructed to push as hard as possible into the hand-held dynamometer for a total of 5 seconds counted by the measuring investigator
    c. Participant did not push through entire range of motion, as blocked by the measuring investigator

i. Ankle motion: dorsiflexion, inversion, eversion performed in neutral position; plantarflexion performed in prone position with knee flexed to 90 degrees

ii. Knee motion: flexion performed in prone position; extension performed in short-sitting position

iii. Hip motion: flexion performed in short-sitting position; extension performed with knee extended and flexed to 90 degrees; abduction performed side-lying; adduction performed short-sitting; internal and external rotation performed prone

3. Functional Task Assessments

a. Single leg squat: participants instructed to cross arms across chest, hands to opposite shoulders, single leg stance on PFP-affected limb, 2 second descend and 2 second ascend with 3 possible practice trials

i. 5 squats were collected with a max of 3 practice trials

ii. 1-minute of rest was provided between trials

b. Stair ambulation: participants were instructed to stand in front of stairs, step up with left leg and alter foot strike up and down stairs and returned back to starting position

i. Participants completed 5 trials with a max of 3 practice trials

ii. 1-minute of rest was provided between trials

c. Step-down task: participants were asked to cross arms across their chest and stand on PFP limb and lower body off step until contralateral foot touched the ground and returned to starting position

i. Completed 5 trials with a max of 3 practice trials

ii. 1-minute of rest was provided between trials

d. Lunges: participants were instructed to step forward with arms on hips until foot comes in contact with the floor, lower their body by flexing knee, and returning to starting position

i. Completed 5 trials on each limb with a max of 3 practice trials

ii. 1-minute of rest was provided between trials

e. Walking: participants walked on a treadmill at a speed of 1.1km/hr for 30 seconds

f. Jogging: participants jogged on a treadmill at a speed of 3.55km/hr for 30 seconds

Table C21. Rehabilitation Program

Weeks	Exercise	Set	Repetitions or Seconds, s
1-2	4-Way SLR	3	10
	Seated Knee Flexion and Extension	3	10
	Wall Squats	3	10
	Isometric Hip Abd/ER	3	10
	Clam Shells	3	10
	Pelvic Tilt Prone	3	20s
	Pelvic Tilt on Swiss Ball	3	20s
	Single Leg Balance, eyes open	3	30s
	Single Leg Balance, eyes closed	3	30s
3-4	4-Way SLR	3	10
	Seated Knee Flexion and Extension	3	10
	Wall Squats	3	10
	Step Ups/Downs	3	10
	Lateral Rotation in CKC	3	10
	Pelvic Drops	3	10
	Clam Shells	3	10
	Planks (Anterior and Lateral)	3	30s
	Trunk Extension on Swiss Ball	3	10
	Single Leg Balance, eyes open	3	30s
	Single Leg Balance, eyes closed	3	30s
	Single Leg Squat w/ mirror training	3	10
	Lunge w/ mirror training	3	10
	Single Leg Deadlift w/ mirror training	3	10

Table C22. Ultrasound Imaging Processing

1. Open ImageJ software
2. Open image to measure by clicking, “File”, then “Open”
3. Choose measurement scale based on depth of image collection, as visible by scale on the left side of the image.
4. To determine pixel conversion for measurement scale:
    a. Select Distance tool from tool menu
    b. Draw a vertical line from 1cm to 2cm on the left-hand side scale on the image and click Ctrl+M to measure the line
    c. This distance will serve as the 1cm conversion for images at that depth of capture
    d. Click on “Analyze” on the top toolbar, then “Set scale” and enter the pixel distance measured into “Distance in pixels” and 1.00 into “Known distance”, cm into “Unit of length”, click global and press “ok” to set the scale.
5. Measure muscle thickness using the distance tool with appropriate scale applied and pressing Ctrl+M to measure distance
6. Copy and paste all measured distances into a separate Microsoft Excel file for further exportation into analysis spreadsheet.

APPENDIX D: Additional Results

Manuscript I

Table D1. Traditional activation ratio for all positions for TrA

Descriptive Statistics

	Mean	Std. Deviation	N
Mass	69.5936842	15.0762072	19
PRE_Table_tra_AR	1.53868559	.335072518	19
PRE_BIP_tra_AR	1.53588718	.366565667	19
PRE_UNI_tra_AR	1.06391519	.113625853	19
PRE_SLS_tra_AR	1.25989792	.293008507	19

Descriptive Statistics

	Mean	Std. Deviation	N
Mass	69.5936842	15.0762072	19
POST_Table_tra_AR	1.54105764	.288132867	19
POST_BIP_tra_AR	1.38578604	.329939488	19
POST_UNI_tra_AR	1.03109351	.128371048	19
POST_SLS_tra_AR	1.17713408	.193274351	19

Table D2. Correlation matrix: mass (kg) and TrA activation (pre-rehab)

Correlations

		Mass	PRE_Table_tra_AR	PRE_BIP_tra_AR	PRE_UNI_tra_AR	PRE_SLS_tra_AR
Mass	Pearson Correlation	1	-.320	.082	.371	.082
	Sig. (2-tailed)		.182	.740	.118	.739
	N	19	19	19	19	19
PRE_Table_tra_AR	Pearson Correlation	-.320	1	.533*	.034	.029
	Sig. (2-tailed)	.182		.019	.890	.905
	N	19	19	19	19	19
PRE_BIP_tra_AR	Pearson Correlation	.082	.533*	1	.442	.092
	Sig. (2-tailed)	.740	.019		.058	.707
	N	19	19	19	19	19
PRE_UNI_tra_AR	Pearson Correlation	.371	.034	.442	1	.689**
	Sig. (2-tailed)	.118	.890	.058		.001
	N	19	19	19	19	19
PRE_SLS_tra_AR	Pearson Correlation	.082	.029	.092	.689**	1
	Sig. (2-tailed)	.739	.905	.707	.001	
	N	19	19	19	19	19

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

Table D3. Correlation matrix: mass (kg) and TrA activation (post-rehab)

Correlations

		Mass	POST_Table_tra_AR	POST_BIP_tra_AR	POST_UNI_tra_AR	POST_SLS_tra_AR
Mass	Pearson Correlation	1	.099	-.154	-.054	-.141
	Sig. (2-tailed)		.687	.528	.826	.566
	N	19	19	19	19	19
POST_Table_tra_AR	Pearson Correlation	.099	1	.195	.199	.047
	Sig. (2-tailed)	.687		.423	.413	.847
	N	19	19	19	19	19
POST_BIP_tra_AR	Pearson Correlation	-.154	.195	1	.283	.048
	Sig. (2-tailed)	.528	.423		.241	.845
	N	19	19	19	19	19
POST_UNI_tra_AR	Pearson Correlation	-.054	.199	.283	1	.664**
	Sig. (2-tailed)	.826	.413	.241		.002
	N	19	19	19	19	19
POST_SLS_tra_AR	Pearson Correlation	-.141	.047	.048	.664**	1
	Sig. (2-tailed)	.566	.847	.845	.002	
	N	19	19	19	19	19

**. Correlation is significant at the 0.01 level (2-tailed).

Table D4. Mass correlation matrix to TABLETOP rested thickness measures

Correlations

		Mass	Table_TrA_path_rest_AVG	Table_TrA_path_cont_AVG	Table_TrA_path_AR_AVG
Mass	Pearson Correlation	1	.525*	.216	-.232
	Sig. (2-tailed)		.021	.375	.339
	N	19	19	19	19
Table_TrA_path_rest_AVG	Pearson Correlation	.525*	1	.440	-.425
	Sig. (2-tailed)	.021		.059	.069
	N	19	19	19	19
Table_TrA_path_cont_AVG	Pearson Correlation	.216	.440	1	.604**
	Sig. (2-tailed)	.375	.059		.006
	N	19	19	19	19
Table_TrA_path_AR_AVG	Pearson Correlation	-.232	-.425	.604**	1
	Sig. (2-tailed)	.339	.069	.006	
	N	19	19	19	19

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

Table D5. Mass correlation matrix to BIPEDAL rested thickness measures

Correlations

		Mass	BIP_TrA_path_rest_AVG	BIP_TrA_path_cont_AVG	BIP_TrA_path_AR_AVG
Mass	Pearson Correlation	1	.034	.161	.157
	Sig. (2-tailed)		.889	.511	.521
	N	19	19	19	19
BIP_TrA_path_rest_AVG	Pearson Correlation	.034	1	.536*	-.157
	Sig. (2-tailed)	.889		.018	.521
	N	19	19	19	19
BIP_TrA_path_cont_AVG	Pearson Correlation	.161	.536*	1	.725**
	Sig. (2-tailed)	.511	.018		.000
	N	19	19	19	19
BIP_TrA_path_AR_AVG	Pearson Correlation	.157	-.157	.725**	1
	Sig. (2-tailed)	.521	.521	.000	
	N	19	19	19	19

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

Table D6. Mass correlation matrix to UNIPEDAL rested thickness measures

Correlations

		Mass	UNI_TrA_path_rest_AVG	UNI_TrA_path_cont_AVG	UNI_TrA_path_AR_AVG
Mass	Pearson Correlation	1	.430	.204	-.087
	Sig. (2-tailed)		.066	.402	.723
	N	19	19	19	19
UNI_TrA_path_rest_AVG	Pearson Correlation	.430	1	.612**	-.021
	Sig. (2-tailed)	.066		.005	.932
	N	19	19	19	19
UNI_TrA_path_cont_AVG	Pearson Correlation	.204	.612**	1	.760**
	Sig. (2-tailed)	.402	.005		.000
	N	19	19	19	19
UNI_TrA_path_AR_AVG	Pearson Correlation	-.087	-.021	.760**	1
	Sig. (2-tailed)	.723	.932	.000	
	N	19	19	19	19

**. Correlation is significant at the 0.01 level (2-tailed).

Table D7. Mass correlation matrix to SLS rested thickness measures

Correlations

		Mass	SLS_TrA_path_rest_AVG	SLS_TrA_path_cont_AVG	SLS_TrA_path_AR_AVG
Mass	Pearson Correlation	1	-.210	-.033	-.008
	Sig. (2-tailed)		.388	.894	.973
	N	19	19	19	19
SLS_TrA_path_rest_AVG	Pearson Correlation	-.210	1	.823**	.098
	Sig. (2-tailed)	.388		.000	.690
	N	19	19	19	19
SLS_TrA_path_cont_AVG	Pearson Correlation	-.033	.823**	1	.463*
	Sig. (2-tailed)	.894	.000		.046
	N	19	19	19	19
SLS_TrA_path_AR_AVG	Pearson Correlation	-.008	.098	.463*	1
	Sig. (2-tailed)	.973	.690	.046	
	N	19	19	19	19

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Table D8. Multivariate analysis of TrA contracted thickness in all positions

Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.
time	Pillai's Trace	.000	.000[b]	1.000	18.000	.993
	Wilks' Lambda	1.000	.000[b]	1.000	18.000	.993
	Hotelling's Trace	.000	.000[b]	1.000	18.000	.993
	Roy's Largest Root	.000	.000[b]	1.000	18.000	.993
position	Pillai's Trace	.401	3.577[b]	3.000	16.000	.038
	Wilks' Lambda	.599	3.577[b]	3.000	16.000	.038
	Hotelling's Trace	.671	3.577[b]	3.000	16.000	.038
	Roy's Largest Root	.671	3.577[b]	3.000	16.000	.038
time * position	Pillai's Trace	.469	4.707[b]	3.000	16.000	.015
	Wilks' Lambda	.531	4.707[b]	3.000	16.000	.015
	Hotelling's Trace	.883	4.707[b]	3.000	16.000	.015
	Roy's Largest Root	.883	4.707[b]	3.000	16.000	.015

a. Design: Intercept
Within Subjects Design: time + position + time * position

b. Exact statistic

Table D9. Within-subjects contrasts contracted TrA in all positions

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	time	position	Type III Sum of Squares	df	Mean Square	F	Sig.
time	Level 1 vs. Level 2		2.546E-8	1	2.546E-8	.000	.993
Error(time)	Level 1 vs. Level 2		.005	18	.000		
position		Level 1 vs. Level 4	.009	1	.009	11.301	.003
		Level 2 vs. Level 4	.002	1	.002	2.572	.126
		Level 3 vs. Level 4	.001	1	.001	1.500	.236
Error(position)		Level 1 vs. Level 4	.014	18	.001		
		Level 2 vs. Level 4	.011	18	.001		
		Level 3 vs. Level 4	.010	18	.001		
time * position	Level 1 vs. Level 2	Level 1 vs. Level 4	.007	1	.007	4.719	.043
		Level 2 vs. Level 4	.005	1	.005	8.989	.008
		Level 3 vs. Level 4	7.377E-5	1	7.377E-5	.105	.749
Error(time*position)	Level 1 vs. Level 2	Level 1 vs. Level 4	.027	18	.002		
		Level 2 vs. Level 4	.010	18	.001		
		Level 3 vs. Level 4	.013	18	.001		

Table D10. Multivariate analysis of TrA FAR in unipedal vs. SLS

Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.
time	Pillai's Trace	.017	.315[b]	1.000	18.000	.582
	Wilks' Lambda	.983	.315[b]	1.000	18.000	.582
	Hotelling's Trace	.018	.315[b]	1.000	18.000	.582
	Roy's Largest Root	.018	.315[b]	1.000	18.000	.582
position	Pillai's Trace	.397	11.862[b]	1.000	18.000	.003
	Wilks' Lambda	.603	11.862[b]	1.000	18.000	.003
	Hotelling's Trace	.659	11.862[b]	1.000	18.000	.003
	Roy's Largest Root	.659	11.862[b]	1.000	18.000	.003
time * position	Pillai's Trace	.041	.761[b]	1.000	18.000	.395
	Wilks' Lambda	.959	.761[b]	1.000	18.000	.395
	Hotelling's Trace	.042	.761[b]	1.000	18.000	.395
	Roy's Largest Root	.042	.761[b]	1.000	18.000	.395

a. Design: Intercept
Within Subjects Design: time + position + time * position

b. Exact statistic

Table D11. Within-Subjects Contrasts TrA FAR in unipedal vs. SLS

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	time	position	Type III Sum of Squares	df	Mean Square	F	Sig.
time	Level 1 vs. Level 2		.028	1	.028	.315	.582
Error(time)	Level 1 vs. Level 2		1.579	18	.088		
position		Level 1 vs. Level 2	.629	1	.629	11.862	.003
Error(position)		Level 1 vs. Level 2	.954	18	.053		
time * position	Level 1 vs. Level 2	Level 1 vs. Level 2	.058	1	.058	.761	.395
Error(time*position)	Level 1 vs. Level 2	Level 1 vs. Level 2	1.381	18	.077		

Table D12. Multivariate analysis of TrA rested thickness in all positions

Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.
time	Pillai's Trace	.052	.983[b]	1.000	18.000	.335
	Wilks' Lambda	.948	.983[b]	1.000	18.000	.335
	Hotelling's Trace	.055	.983[b]	1.000	18.000	.335
	Roy's Largest Root	.055	.983[b]	1.000	18.000	.335
position	Pillai's Trace	.782	19.095[b]	3.000	16.000	.000
	Wilks' Lambda	.218	19.095[b]	3.000	16.000	.000
	Hotelling's Trace	3.580	19.095[b]	3.000	16.000	.000
	Roy's Largest Root	3.580	19.095[b]	3.000	16.000	.000
time * position	Pillai's Trace	.156	.988[b]	3.000	16.000	.423
	Wilks' Lambda	.844	.988[b]	3.000	16.000	.423
	Hotelling's Trace	.185	.988[b]	3.000	16.000	.423
	Roy's Largest Root	.185	.988[b]	3.000	16.000	.423

a. Design: Intercept
Within Subjects Design: time + position + time * position

b. Exact statistic

Table D13. Within-Subjects Contrasts of TrA rested thickness in all positions

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	time	position	Type III Sum of Squares	df	Mean Square	F	Sig.
time	Level 1 vs. Level 2		.000	1	.000	.983	.335
Error(time)	Level 1 vs. Level 2		.003	18	.000		
position		Level 1 vs. Level 4	.012	1	.012	43.477	.000
		Level 2 vs. Level 4	.004	1	.004	9.570	.006
		Level 3 vs. Level 4	.003	1	.003	12.770	.002
Error(position)		Level 1 vs. Level 4	.005	18	.000		
		Level 2 vs. Level 4	.007	18	.000		
		Level 3 vs. Level 4	.005	18	.000		
time * position	Level 1 vs. Level 2	Level 1 vs. Level 4	.002	1	.002	1.384	.255
		Level 2 vs. Level 4	1.747E-5	1	1.747E-5	.028	.870
		Level 3 vs. Level 4	.000	1	.000	.325	.576
Error(time*position)	Level 1 vs. Level 2	Level 1 vs. Level 4	.022	18	.001		
		Level 2 vs. Level 4	.011	18	.001		
		Level 3 vs. Level 4	.006	18	.000		

Table D14. Paired t-test analysis of all TrA thickness and activation measures

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	Table_TrA_rest - Table_TrA_rest	.004924051	.018073194	.004146275	-.00378695	.013635052	1.188	18	.250
Pair 2	BIP_TrA_rest - BIP_TrA_rest	-.00552657	.023379249	.005363568	-.01679501	.005741864	-1.030	18	.316
Pair 3	UNI_TrA_rest - UNI_TrA_rest	-.00703116	.019222377	.004409916	-.01629605	.002233725	-1.594	18	.128
Pair 4	SLS_TrA_rest - SLS_TrA_rest	-.00456767	.025099173	.005758145	-.01666508	.007529749	-.793	18	.438
Pair 5	Table_TrA_cont_AVG - Table_TrA_cont_AVG	.009926144	.032947240	.007558615	-.00595392	.025806205	1.313	18	.206
Pair 6	BIP_TrA_cont_AVG - BIP_TrA_cont_AVG	.007156458	.026391238	.006054565	-.00556371	.019876627	1.182	18	.253
Pair 7	UNI_TrA_cont_AVG - UNI_TrA_cont_AVG	-.00748286	.031844967	.007305736	-.02283165	.007865920	-1.024	18	.319
Pair 8	SLS_TrA_cont_AVG - SLS_TrA_cont_AVG	-.00945331	.022889772	.005251274	-.02048583	.001579207	-1.800	18	.089
Pair 9	Table_TrA_AR - Table_TrA_AR	.083015631	.734774307	.168568787	-.27113425	.437165511	.492	18	.628
Pair 10	BIP_TrA_AR - BIP_TrA_AR	.199046067	.387831704	.088974695	.012117169	.385974965	2.237	18	.038
Pair 11	UNI_TrA_AR - UNI_TrA_AR	.022595589	.336768098	.077259900	-.13972144	.184912617	.292	18	.773
Pair 12	SLS_TrA_AR - SLS_TrA_AR	-.01969825	.304521634	.069862054	-.16647298	.127076481	-.282	18	.781
Pair 13	UNI - UNI	.010432492	.294001998	.067448684	-.13127193	.152136920	.155	18	.879
Pair 14	SLS - SLS	.065854512	.356935937	.081886720	-.10618310	.237892126	.804	18	.432

Table D15. Correlation Matrix of Global Rating of Change and Anterior Knee Pain Scale Change Scores

Correlations

		GROC	AKPS
GROC	Pearson Correlation	1	.493*
	Sig. (2-tailed)		.032
	N	19	19
AKPS	Pearson Correlation	.493*	1
	Sig. (2-tailed)	.032	
	N	19	19

*. Correlation is significant at the 0.05 level (2-tailed).

Table D16-17. Frequency of Global Rating of Change and Anterior Knee Pain Scale Change Scores

GROC

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	1	5.3	5.3	5.3
	1	1	5.3	5.3	10.5
	3	3	15.8	15.8	26.3
	4	2	10.5	10.5	36.8
	5	6	31.6	31.6	68.4
	6	5	26.3	26.3	94.7
	7	1	5.3	5.3	100.0
	Total	19	100.0	100.0	

AKPS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	3	1	5.3	5.3	5.3
	4	2	10.5	10.5	15.8
	6	3	15.8	15.8	31.6
	8	2	10.5	10.5	42.1
	11	2	10.5	10.5	52.6
	12	1	5.3	5.3	57.9
	13	2	10.5	10.5	68.4
	15	3	15.8	15.8	84.2
	16	2	10.5	10.5	94.7
	34	1	5.3	5.3	100.0
	Total	19	100.0	100.0	

Table D18. High/Low performer test of within-subjects contrasts – TrA rested

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	time	position	Type III Sum of Squares	df	Mean Square	F	Sig.
time	Level 1 vs. Level 2		1.204E-6	1	1.204E-6	.625	.440
time * High_Low_coded	Level 1 vs. Level 2		1.442E-7	1	1.442E-7	.075	.788
Error(time)	Level 1 vs. Level 2		3.274E-5	17	1.926E-6		
position		Level 1 vs. Level 4	.000	1	.000	39.867	.000
		Level 2 vs. Level 4	4.048E-5	1	4.048E-5	10.379	.005
		Level 3 vs. Level 4	3.410E-5	1	3.410E-5	11.845	.003
position * High_Low_coded		Level 1 vs. Level 4	7.492E-7	1	7.492E-7	.260	.617
		Level 2 vs. Level 4	3.705E-6	1	3.705E-6	.950	.343
		Level 3 vs. Level 4	5.462E-7	1	5.462E-7	.190	.669
Error(position)		Level 1 vs. Level 4	4.904E-5	17	2.885E-6		
		Level 2 vs. Level 4	6.630E-5	17	3.900E-6		
		Level 3 vs. Level 4	4.893E-5	17	2.878E-6		
time * position	Level 1 vs. Level 2	Level 1 vs. Level 4	1.221E-5	1	1.221E-5	.972	.338
		Level 2 vs. Level 4	1.787E-7	1	1.787E-7	.027	.871
		Level 3 vs. Level 4	1.879E-6	1	1.879E-6	.590	.453
time * position * High_Low_coded	Level 1 vs. Level 2	Level 1 vs. Level 4	5.882E-6	1	5.882E-6	.468	.503
		Level 2 vs. Level 4	2.917E-7	1	2.917E-7	.044	.836
		Level 3 vs. Level 4	5.540E-6	1	5.540E-6	1.740	.205
Error(time*position)	Level 1 vs. Level 2	Level 1 vs. Level 4	.000	17	1.256E-5		
		Level 2 vs. Level 4	.000	17	6.567E-6		
		Level 3 vs. Level 4	5.412E-5	17	3.184E-6		

Table D19. High/Low Performer ANOVA table for TrA rested measures pre-post

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
Table_TrA_path_rest_AVG	Between Groups	.000	1	.000	.001	.974
	Within Groups	.000	17	.000		
	Total	.000	18			
POST_Table_TrA_R_rest_AVG	Between Groups	.000	1	.000	.182	.675
	Within Groups	.000	17	.000		
	Total	.000	18			
BIP_TrA_path_rest_AVG	Between Groups	.000	1	.000	.007	.935
	Within Groups	.000	17	.000		
	Total	.000	18			
POST_BIP_TrA_R_rest_AVG	Between Groups	.000	1	.000	.527	.478
	Within Groups	.000	17	.000		
	Total	.000	18			
UNI_TrA_path_rest_AVG	Between Groups	.000	1	.000	.003	.954
	Within Groups	.000	17	.000		
	Total	.000	18			
POST_UNI_TrA_R_rest_AVG	Between Groups	.000	1	.000	.135	.717
	Within Groups	.000	17	.000		
	Total	.000	18			
SLS_TrA_path_rest_AVG	Between Groups	.000	1	.000	.535	.475
	Within Groups	.000	17	.000		
	Total	.000	18			
POST_SLS_TrA_R_rest_AVG	Between Groups	.000	1	.000	.015	.904
	Within Groups	.000	17	.000		
	Total	.000	18			

Table D20. High/Low Performer ANOVA table for TrA contracted measures pre-post

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
Table_TrA_path_rest_AVG	Between Groups	.000	1	.000	.098	.757
	Within Groups	.000	17	.000		
	Total	.000	18			
POST_Table_TrA_R_rest_AVG	Between Groups	.000	1	.000	.483	.496
	Within Groups	.000	17	.000		
	Total	.000	18			
BIP_TrA_path_rest_AVG	Between Groups	.000	1	.000	.496	.491
	Within Groups	.000	17	.000		
	Total	.000	18			
POST_BIP_TrA_R_rest_AVG	Between Groups	.000	1	.000	.012	.915
	Within Groups	.000	17	.000		
	Total	.000	18			
UNI_TrA_path_rest_AVG	Between Groups	.000	1	.000	.320	.579
	Within Groups	.000	17	.000		
	Total	.000	18			
POST_UNI_TrA_R_rest_AVG	Between Groups	.000	1	.000	.112	.742
	Within Groups	.000	17	.000		
	Total	.000	18			
SLS_TrA_path_rest_AVG	Between Groups	.000	1	.000	.533	.475
	Within Groups	.000	17	.000		
	Total	.000	18			
POST_SLS_TrA_R_rest_AVG	Between Groups	.000	1	.000	.277	.605
	Within Groups	.000	17	.000		
	Total	.000	18			

Table D21. High/Low Performer ANOVA table for plank time comparison

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
Pre_MeanFPlank	Between Groups	1536.492	1	1536.492	.280	.603
	Within Groups	93137.192	17	5478.658		
	Total	94673.684	18			
Post_MeanFPlank	Between Groups	6105.306	1	6105.306	1.042	.322
	Within Groups	99653.641	17	5861.979		
	Total	105758.947	18			
Pre_PathPlank	Between Groups	341.107	1	341.107	.666	.426
	Within Groups	8700.577	17	511.799		
	Total	9041.684	18			
Post_PathPlank	Between Groups	259.379	1	259.379	.382	.545
	Within Groups	11554.410	17	679.671		
	Total	11813.789	18			
Pre_NonpathPlank	Between Groups	.422	1	.422	.000	.990
	Within Groups	44930.526	17	2642.972		
	Total	44930.947	18			
Post_NonpathPlank	Between Groups	386.673	1	386.673	.586	.454
	Within Groups	11208.064	17	659.298		
	Total	11594.737	18			

Table D22. TrA rested measures tests of within-subjects contrasts

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	time	position	Type III Sum of Squares	df	Mean Square	F	Sig.
time	Level 1 vs. Level 2		1.540E-6	1	1.540E-6	.843	.371
Error(time)	Level 1 vs. Level 2		3.289E-5	18	1.827E-6		
position		Level 1 vs. Level 4	.000	1	.000	42.793	.000
		Level 2 vs. Level 4	3.684E-5	1	3.684E-5	9.472	.006
		Level 3 vs. Level 4	3.423E-5	1	3.423E-5	12.453	.002
Error(position)		Level 1 vs. Level 4	4.979E-5	18	2.766E-6		
		Level 2 vs. Level 4	7.000E-5	18	3.889E-6		
		Level 3 vs. Level 4	4.948E-5	18	2.749E-6		
time * position	Level 1 vs. Level 2	Level 1 vs. Level 4	1.834E-5	1	1.834E-5	1.505	.236
		Level 2 vs. Level 4	8.463E-8	1	8.463E-8	.014	.908
		Level 3 vs. Level 4	6.068E-7	1	6.068E-7	.183	.674
Error(time*position)	Level 1 vs. Level 2	Level 1 vs. Level 4	.000	18	1.219E-5		
		Level 2 vs. Level 4	.000	18	6.218E-6		
		Level 3 vs. Level 4	5.966E-5	18	3.315E-6		

Table D23. Plank times tests of within-subjects contrasts

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	time	position	Type III Sum of Squares	df	Mean Square	F	Sig.
time	Level 1 vs. Level 2		26731.251	1	26731.251	14.018	.001
Error(time)	Level 1 vs. Level 2		34324.082	18	1906.893		
position		Level 1 vs. Level 3	26085.053	1	26085.053	31.625	.000
		Level 2 vs. Level 3	26196.329	1	26196.329	16.322	.001
Error(position)		Level 1 vs. Level 3	14846.947	18	824.830		
		Level 2 vs. Level 3	28889.421	18	1604.968		
time * position	Level 1 vs. Level 2	Level 1 vs. Level 3	112189.474	1	112189.474	27.717	.000
		Level 2 vs. Level 3	125632.895	1	125632.895	26.134	.000
Error(time*position)	Level 1 vs. Level 2	Level 1 vs. Level 3	72858.526	18	4047.696		
		Level 2 vs. Level 3	86530.105	18	4807.228		

Table D24. Single leg squat depth paired t-test comparison

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	Pre_PeakKneeFlex - Post_PeakKneeFlex	4.96949946	12.6819387	2.90943628	-1.1429993	11.0819983	1.708	18	.105

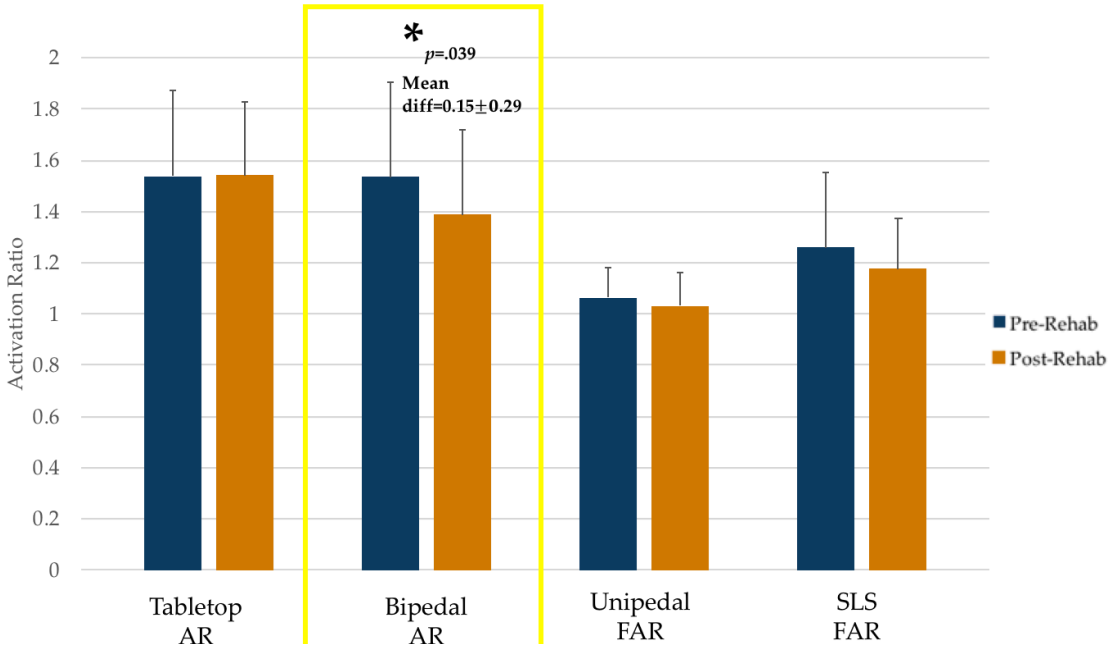

Figure D1. TrA activation ratio (ADIM/rested) in all positions

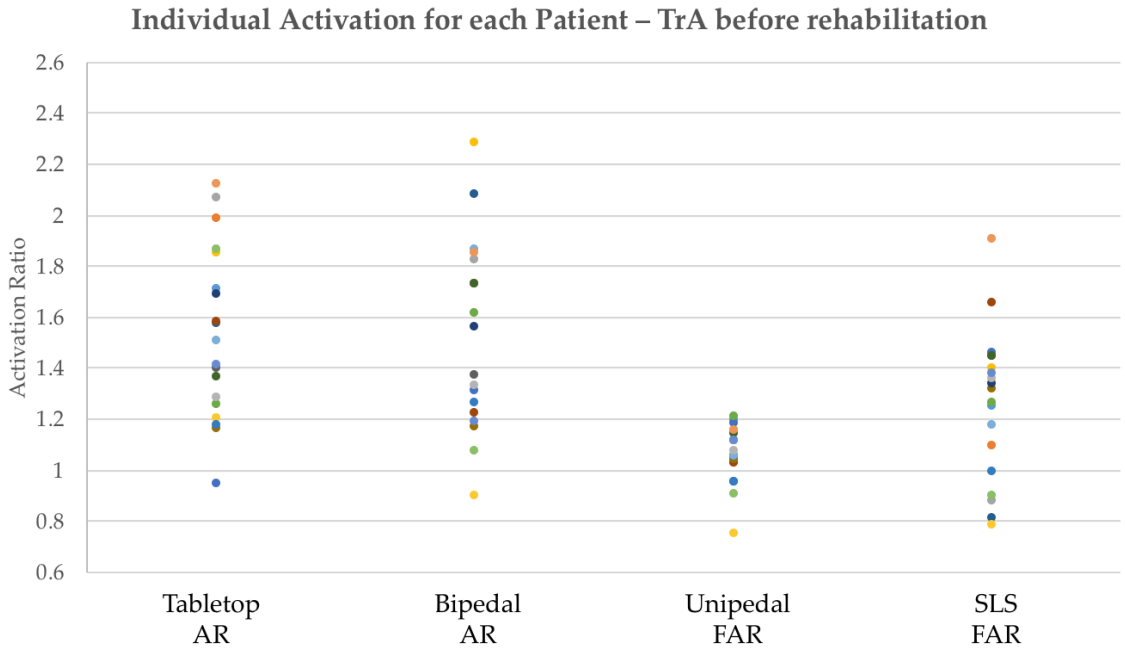

Figure D2. TrA activation ratio (ADIM/rested) in all positions – individual values before rehabilitation

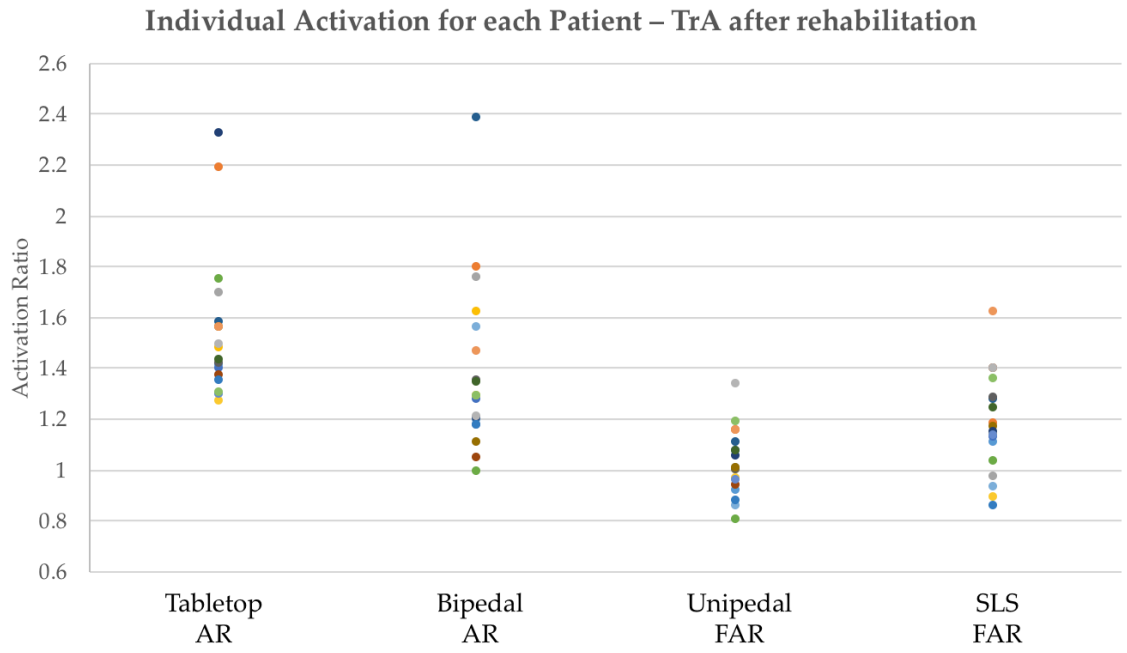

Figure D3. TrA activation ratio (ADIM/rested) in all positions – individual values after rehabilitation

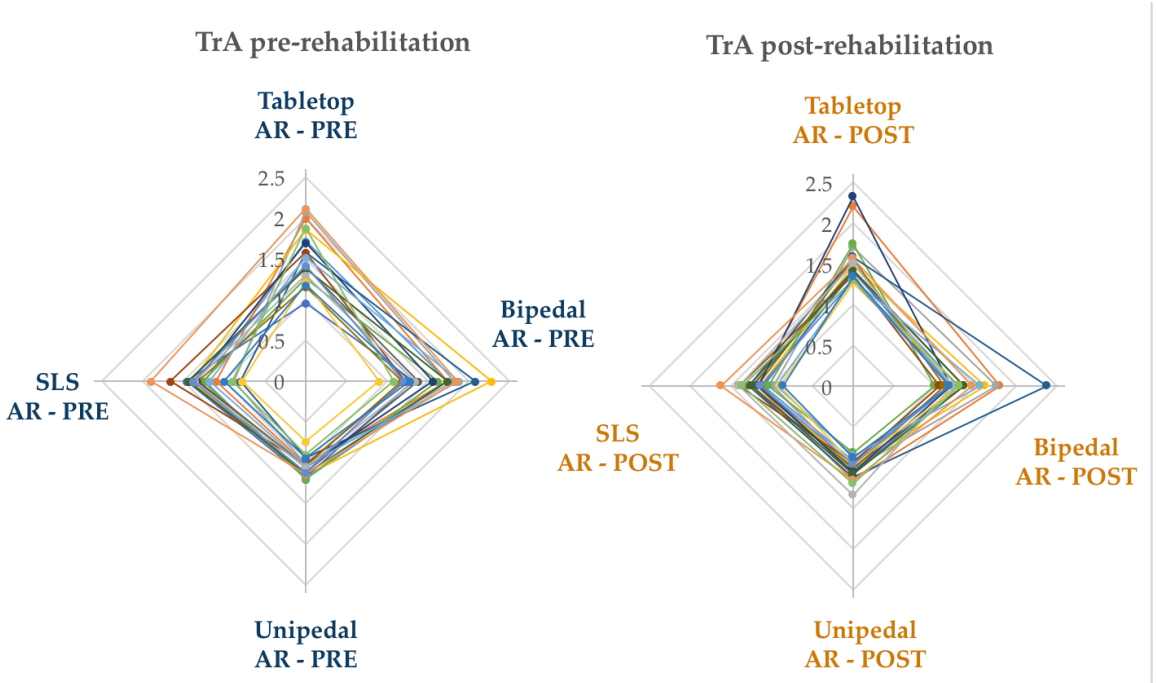

Figure D4. Radar plot of TrA activation pre-post rehabilitation in all positions

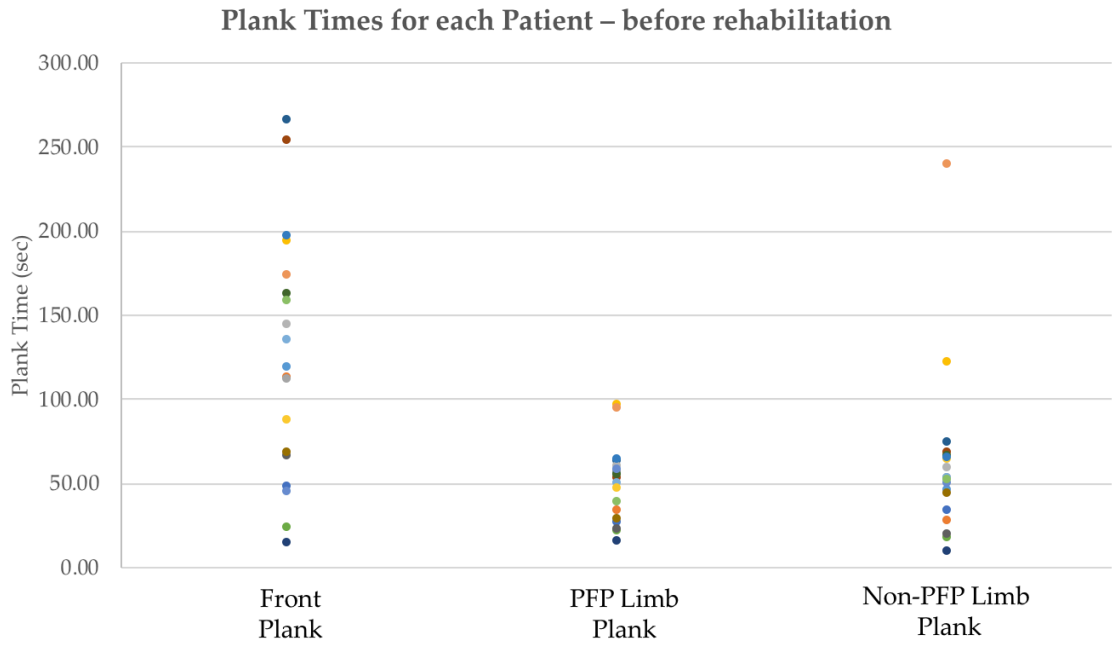

Figure D5. Plank times for individual patients before rehabilitation

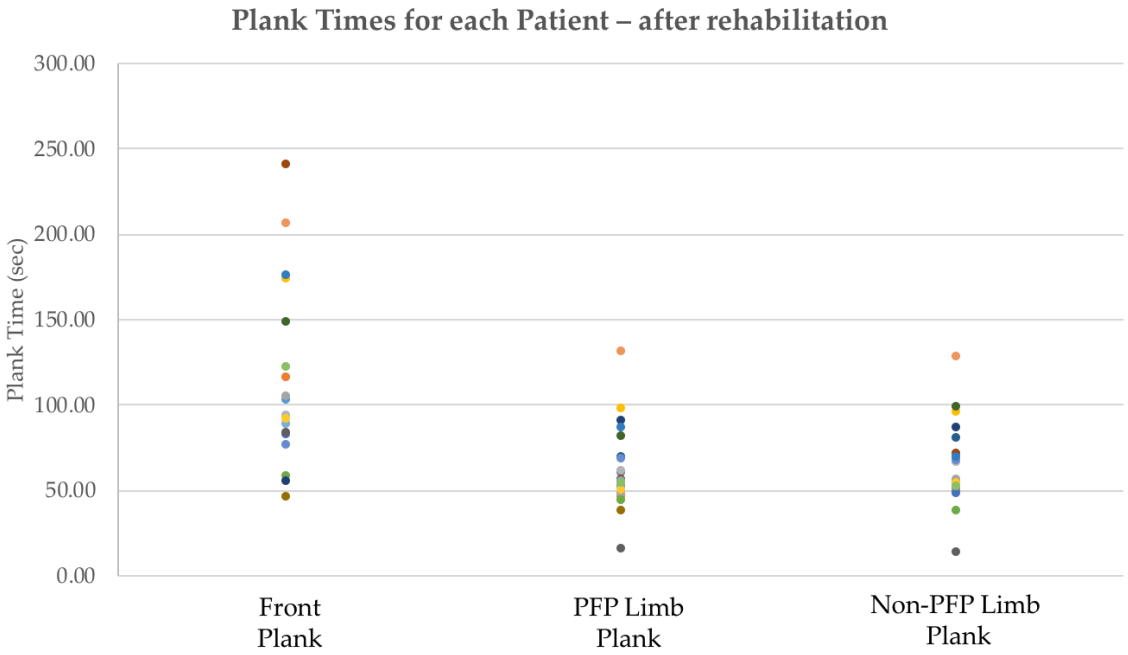

Figure D6. Plank times for individual patients after rehabilitation

Table D25. Mass Correlation Matrix to Gmax and Gmed US measures for TABLETOP

Correlations

		Mass	Table_Gmax_R_rest_avg	Table_Gmed_R_rest_avg	Table_Gmax_R_cont_avg	Table_Gmed_R_cont_avg	Table_Gmax_R_AR	Table_Gmed_R_AR
Mass	Pearson Correlation	1	.623**	.251	.574*	.226	-.135	.015
	Sig. (2-tailed)		.004	.299	.010	.351	.583	.951
	N	19	19	19	19	19	19	19
Table_Gmax_R_rest_avg	Pearson Correlation	.623**	1	.454	.860**	.258	-.374	-.208
	Sig. (2-tailed)	.004		.051	.000	.286	.115	.392
	N	19	19	19	19	19	19	19
Table_Gmed_R_rest_avg	Pearson Correlation	.251	.454	1	.441	.839**	-.033	-.190
	Sig. (2-tailed)	.299	.051		.059	.000	.895	.435
	N	19	19	19	19	19	19	19
Table_Gmax_R_cont_avg	Pearson Correlation	.574*	.860**	.441	1	.286	.142	-.191
	Sig. (2-tailed)	.010	.000	.059		.235	.561	.433
	N	19	19	19	19	19	19	19
Table_Gmed_R_cont_avg	Pearson Correlation	.226	.258	.839**	.286	1	.047	.363
	Sig. (2-tailed)	.351	.286	.000	.235		.849	.127
	N	19	19	19	19	19	19	19
Table_Gmax_R_AR	Pearson Correlation	-.135	-.374	-.033	.142	.047	1	.035
	Sig. (2-tailed)	.583	.115	.895	.561	.849		.886
	N	19	19	19	19	19	19	19
Table_Gmed_R_AR	Pearson Correlation	.015	-.208	-.190	-.191	.363	.035	1
	Sig. (2-tailed)	.951	.392	.435	.433	.127	.886	
	N	19	19	19	19	19	19	19

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Table D26. High/Low performer tests of within-subjects contrasts – Gmax rested

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	time	position	Type III Sum of Squares	df	Mean Square	F	Sig.
time	Level 1 vs. Level 2		.001	1	.001	6.501	.021
time * High_Low_coded	Level 1 vs. Level 2		.000	1	.000	1.725	.207
Error(time)	Level 1 vs. Level 2		.002	17	.000		
position		Level 1 vs. Level 4	9.805E-5	1	9.805E-5	1.734	.205
		Level 2 vs. Level 4	6.512E-7	1	6.512E-7	.020	.890
		Level 3 vs. Level 4	4.380E-5	1	4.380E-5	1.780	.200
position * High_Low_coded		Level 1 vs. Level 4	7.961E-5	1	7.961E-5	1.408	.252
		Level 2 vs. Level 4	2.131E-6	1	2.131E-6	.065	.802
		Level 3 vs. Level 4	5.044E-9	1	5.044E-9	.000	.989
Error(position)		Level 1 vs. Level 4	.001	17	5.656E-5		
		Level 2 vs. Level 4	.001	17	3.297E-5		
		Level 3 vs. Level 4	.000	17	2.460E-5		
time * position	Level 1 vs. Level 2	Level 1 vs. Level 4	.000	1	.000	1.304	.269
		Level 2 vs. Level 4	2.853E-6	1	2.853E-6	.031	.863
		Level 3 vs. Level 4	2.152E-5	1	2.152E-5	.366	.553
time * position * High_Low_coded	Level 1 vs. Level 2	Level 1 vs. Level 4	.000	1	.000	2.378	.141
		Level 2 vs. Level 4	7.480E-6	1	7.480E-6	.080	.781
		Level 3 vs. Level 4	3.307E-5	1	3.307E-5	.563	.463
Error(time*position)	Level 1 vs. Level 2	Level 1 vs. Level 4	.002	17	.000		
		Level 2 vs. Level 4	.002	17	9.335E-5		
		Level 3 vs. Level 4	.001	17	5.873E-5		

Table D27. High/Low performer test of within-subjects contrasts – Gmed rested

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	time	position	Type III Sum of Squares	df	Mean Square	F	Sig.
time	Level 1 vs. Level 2		.001	1	.001	15.163	.001
time * High_Low_coded	Level 1 vs. Level 2		9.209E-5	1	9.209E-5	1.338	.263
Error(time)	Level 1 vs. Level 2		.001	17	6.881E-5		
position		Level 1 vs. Level 4	3.277E-5	1	3.277E-5	.936	.347
		Level 2 vs. Level 4	2.576E-5	1	2.576E-5	1.590	.224
		Level 3 vs. Level 4	9.794E-7	1	9.794E-7	.084	.775
position * High_Low_coded		Level 1 vs. Level 4	2.055E-6	1	2.055E-6	.059	.811
		Level 2 vs. Level 4	3.925E-5	1	3.925E-5	2.423	.138
		Level 3 vs. Level 4	1.163E-5	1	1.163E-5	1.002	.331
Error(position)		Level 1 vs. Level 4	.001	17	3.501E-5		
		Level 2 vs. Level 4	.000	17	1.620E-5		
		Level 3 vs. Level 4	.000	17	1.160E-5		
time * position	Level 1 vs. Level 2	Level 1 vs. Level 4	3.533E-8	1	3.533E-8	.000	.988
		Level 2 vs. Level 4	.000	1	.000	2.664	.121
		Level 3 vs. Level 4	9.816E-7	1	9.816E-7	.019	.893
time * position * High_Low_coded	Level 1 vs. Level 2	Level 1 vs. Level 4	1.036E-7	1	1.036E-7	.001	.979
		Level 2 vs. Level 4	.000	1	.000	4.347	.052
		Level 3 vs. Level 4	.000	1	.000	3.504	.079
Error(time*position)	Level 1 vs. Level 2	Level 1 vs. Level 4	.003	17	.000		
		Level 2 vs. Level 4	.001	17	7.285E-5		
		Level 3 vs. Level 4	.001	17	5.276E-5		

Table D28. Gmax and Gmed EMG quiet stance paired t-tests

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	Pre_Gmax_Quiet - Post_Gmax_Quiet	.00000000	.00000077	.00000018	-.00000037	.00000037	-.015	18	.988
Pair 2	Pre_Gmed_Quiet - Post_Gmed_Quiet	-.00000145	.00000375	.00000086	-.00000326	.00000036	-1.688	18	.109

Table D29. Gmax rested tests of within-subjects contrasts

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	time	position	Type III Sum of Squares	df	Mean Square	F	Sig.
time	Level 1 vs. Level 2		.090	1	.090	5.609	.029
Error(time)	Level 1 vs. Level 2		.289	18	.016		
position		Level 1 vs. Level 4	.016	1	.016	2.630	.122
		Level 2 vs. Level 4	.000	1	.000	.052	.822
		Level 3 vs. Level 4	.005	1	.005	1.667	.213
Error(position)		Level 1 vs. Level 4	.110	18	.006		
		Level 2 vs. Level 4	.052	18	.003		
		Level 3 vs. Level 4	.051	18	.003		
time * position	Level 1 vs. Level 2	Level 1 vs. Level 4	.032	1	.032	2.664	.120
		Level 2 vs. Level 4	.001	1	.001	.064	.803
		Level 3 vs. Level 4	.004	1	.004	1.071	.314
Error(time*position)	Level 1 vs. Level 2	Level 1 vs. Level 4	.219	18	.012		
		Level 2 vs. Level 4	.175	18	.010		
		Level 3 vs. Level 4	.068	18	.004		

Table D30. Gmed rested tests of within-subjects contrasts

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	time	position	Type III Sum of Squares	df	Mean Square	F	Sig.
time	Level 1 vs. Level 2		.130	1	.130	15.714	.001
Error(time)	Level 1 vs. Level 2		.149	18	.008		
position		Level 1 vs. Level 4	.003	1	.003	.974	.337
		Level 2 vs. Level 4	.001	1	.001	.711	.410
		Level 3 vs. Level 4	.000	1	.000	.261	.616
Error(position)		Level 1 vs. Level 4	.057	18	.003		
		Level 2 vs. Level 4	.032	18	.002		
		Level 3 vs. Level 4	.026	18	.001		
time * position	Level 1 vs. Level 2	Level 1 vs. Level 4	1.145E-6	1	1.145E-6	.000	.993
		Level 2 vs. Level 4	.009	1	.009	1.077	.313
		Level 3 vs. Level 4	.001	1	.001	.150	.703
Error(time*position)	Level 1 vs. Level 2	Level 1 vs. Level 4	.264	18	.015		
		Level 2 vs. Level 4	.154	18	.009		
		Level 3 vs. Level 4	.086	18	.005		

Table D31. Gmax contracted tests of within-subjects contrasts

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	time	position	Type III Sum of Squares	df	Mean Square	F	Sig.
time	Level 1 vs. Level 2		.098	1	.098	5.653	.029
Error(time)	Level 1 vs. Level 2		.312	18	.017		
position		Level 1 vs. Level 4	.005	1	.005	.831	.374
		Level 2 vs. Level 4	.004	1	.004	.689	.417
		Level 3 vs. Level 4	.015	1	.015	5.394	.032
Error(position)		Level 1 vs. Level 4	.111	18	.006		
		Level 2 vs. Level 4	.094	18	.005		
		Level 3 vs. Level 4	.050	18	.003		
time * position	Level 1 vs. Level 2	Level 1 vs. Level 4	.007	1	.007	.445	.513
		Level 2 vs. Level 4	.001	1	.001	.082	.778
		Level 3 vs. Level 4	.001	1	.001	.112	.741
Error(time*position)	Level 1 vs. Level 2	Level 1 vs. Level 4	.270	18	.015		
		Level 2 vs. Level 4	.272	18	.015		
		Level 3 vs. Level 4	.105	18	.006		

Table D32. Gmed contracted tests of within-subjects contrasts

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	time	position	Type III Sum of Squares	df	Mean Square	F	Sig.
time	Level 1 vs. Level 2		.130	1	.130	12.157	.003
Error(time)	Level 1 vs. Level 2		.192	18	.011		
position		Level 1 vs. Level 4	.001	1	.001	.574	.458
		Level 2 vs. Level 4	.002	1	.002	1.208	.286
		Level 3 vs. Level 4	.004	1	.004	2.307	.146
Error(position)		Level 1 vs. Level 4	.042	18	.002		
		Level 2 vs. Level 4	.033	18	.002		
		Level 3 vs. Level 4	.028	18	.002		
time * position	Level 1 vs. Level 2	Level 1 vs. Level 4	.001	1	.001	.025	.875
		Level 2 vs. Level 4	.010	1	.010	1.140	.300
		Level 3 vs. Level 4	.000	1	.000	.037	.850
Error(time*position)	Level 1 vs. Level 2	Level 1 vs. Level 4	.391	18	.022		
		Level 2 vs. Level 4	.159	18	.009		
		Level 3 vs. Level 4	.148	18	.008		

Table D33. Unipedal and SLS FAR tests of within-subjects contrasts

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	time	position	Type III Sum of Squares	df	Mean Square	F	Sig.
time	Level 1 vs. Level 2		.036	1	.036	.690	.417
Error(time)	Level 1 vs. Level 2		.932	18	.052		
position		Level 1 vs. Level 2	.016	1	.016	.439	.516
Error(position)		Level 1 vs. Level 2	.645	18	.036		
time * position	Level 1 vs. Level 2	Level 1 vs. Level 2	.007	1	.007	.161	.693
Error(time*position)	Level 1 vs. Level 2	Level 1 vs. Level 2	.781	18	.043		

Table D34. Paired t-tests for Gmax activity pre-post rehabilitation

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	TABLE_GMAX_REST - TABLE_GMAX_REST	.035718361	.129943444	.029811071	-.02691237	.098349096	1.198	18	.246
Pair 2	BIP_GMAX_REST - BIP_GMAX_REST	.071261957	.134248446	.030798706	.006556277	.135967637	2.314	18	.033
Pair 3	UNI_GMAX_REST - UNI_GMAX_REST	.091619126	.149368651	.034267519	.019625741	.163612511	2.674	18	.015
Pair 4	SLS_GMAX_REST - SLS_GMAX_REST	.076989749	.154453414	.035434043	.002545587	.151433912	2.173	18	.043
Pair 5	TABLE_GMAX_REST - TABLE_GMAX_REST	.057215423	.164001735	.037624578	-.02183088	.136261728	1.521	18	.146
Pair 6	BIP_GMAX_REST - BIP_GMAX_REST	.084058919	.141437653	.032448023	.015888153	.152229686	2.591	18	.018
Pair 7	UNI_GMAX_REST - UNI_GMAX_REST	.070094958	.142312648	.032648761	.001502457	.138687459	2.147	18	.046
Pair 8	SLS_GMAX_REST - SLS_GMAX_REST	.075974497	.154474236	.035438820	.001520299	.150428696	2.144	18	.046
Pair 9	TABLE AR - TABLE AR	.061081130	.174249596	.039975599	-.02290449	.145066748	1.528	18	.144
Pair 10	UNI FAR - UNI FAR	.052964202	.192251827	.044105594	-.03969821	.145626616	1.201	18	.245
Pair 11	SLS FAR - SLS FAR	.033765610	.297108577	.068161382	-.10943614	.176967360	.495	18	.626

Table D35. Paired t-tests for Gmed activity pre-post rehabilitation

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	TABLE_GMED_REST - TABLE_GMED_REST	-.08659054	.108670928	.024930821	-.13896825	-.03421283	-3.473	18	.003
Pair 2	BIP_GMED_REST - BIP_GMED_REST	-.06484357	.107326010	.024622275	-.11657305	-.01311409	-2.634	18	.017
Pair 3	UNI_GMED_REST - UNI_GMED_REST	-.09298901	.090645827	.020795579	-.13667890	-.04929912	-4.472	18	.000
Pair 4	SLS_GMED_REST - SLS_GMED_REST	-.08683607	.118978832	.027295616	-.14418203	-.02949011	-3.181	18	.005
Pair 5	TABLE_GMED_REST - TABLE_GMED_REST	-.09337276	.133641091	.030659369	-.15778571	-.02895982	-3.045	18	.007
Pair 6	BIP_GMED_REST - BIP_GMED_REST	-.06494506	.104194966	.023903965	-.11516542	-.01472469	-2.717	18	.014
Pair 7	UNI_GMED_REST - UNI_GMED_REST	-.08399263	.101516677	.023289523	-.13292210	-.03506315	-3.606	18	.002
Pair 8	SLS_GMED_REST - SLS_GMED_REST	-.08799125	.143300903	.032875482	-.15706008	-.01892243	-2.677	18	.015

Table D36. High/Low Performer ANOVA table for Gmax and Gmed rested measures pre-post

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
Tabletop_Gmax_rest	Between Groups	.000	1	.000	.184	.674
	Within Groups	.003	17	.000		
	Total	.003	18			
Tabletop_Gmed_rest	Between Groups	.000	1	.000	.158	.696
	Within Groups	.001	17	.000		
	Total	.001	18			
Bipedal_Gmax_rest	Between Groups	.000	1	.000	3.072	.098
	Within Groups	.002	17	.000		
	Total	.003	18			
Bipedal_Gmed_rest	Between Groups	.000	1	.000	1.611	.221
	Within Groups	.002	17	.000		
	Total	.002	18			
Unipedal_Gmax_rest	Between Groups	.001	1	.001	3.700	.071
	Within Groups	.003	17	.000		
	Total	.004	18			
Unipedal_Gmed_rest	Between Groups	.000	1	.000	.955	.342
	Within Groups	.001	17	.000		
	Total	.001	18			
SLS_Gmax_rest	Between Groups	.001	1	.001	3.557	.076
	Within Groups	.002	17	.000		
	Total	.003	18			
SLS_Gmed_rest	Between Groups	.000	1	.000	.034	.856
	Within Groups	.002	17	.000		
	Total	.002	18			
Tabletop_Gmax_rest	Between Groups	.000	1	.000	1.415	.251
	Within Groups	.000	17	.000		
	Total	.000	18			
Tabletop_Gmed_rest	Between Groups	.000	1	.000	.532	.476
	Within Groups	.001	17	.000		
	Total	.001	18			
Bipedal_Gmax_rest	Between Groups	.000	1	.000	1.868	.190
	Within Groups	.000	17	.000		
	Total	.000	18			
Bipedal_Gmed_rest	Between Groups	.000	1	.000	2.323	.146
	Within Groups	.000	17	.000		
	Total	.000	18			
Unipedal_Gmax_rest	Between Groups	.000	1	.000	.263	.615
	Within Groups	.001	17	.000		
	Total	.001	18			
Unipedal_Gmed_rest	Between Groups	.000	1	.000	3.975	.062
	Within Groups	.000	17	.000		
	Total	.000	18			
SLS_Gmax_rest	Between Groups	.000	1	.000	.783	.389
	Within Groups	.001	17	.000		
	Total	.001	18			
SLS_Gmed_rest	Between Groups	.000	1	.000	.391	.540
	Within Groups	.001	17	.000		
	Total	.001	18			

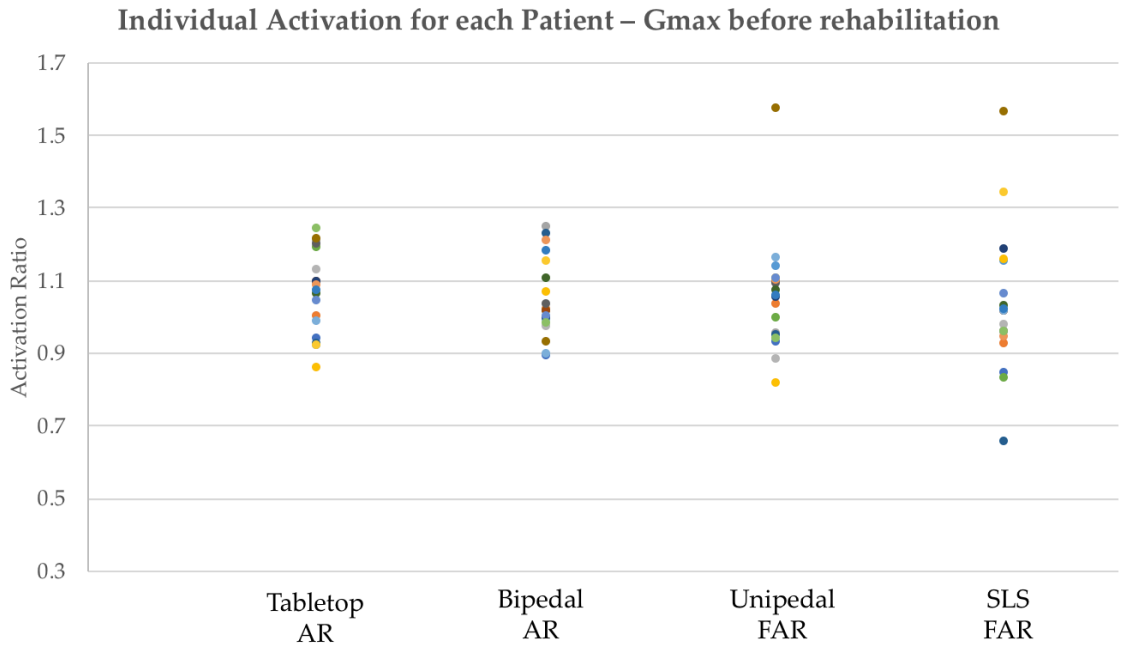

Figure D7. Gmax activation ratio (ADIM/rested) in all positions – individual values before rehabilitation

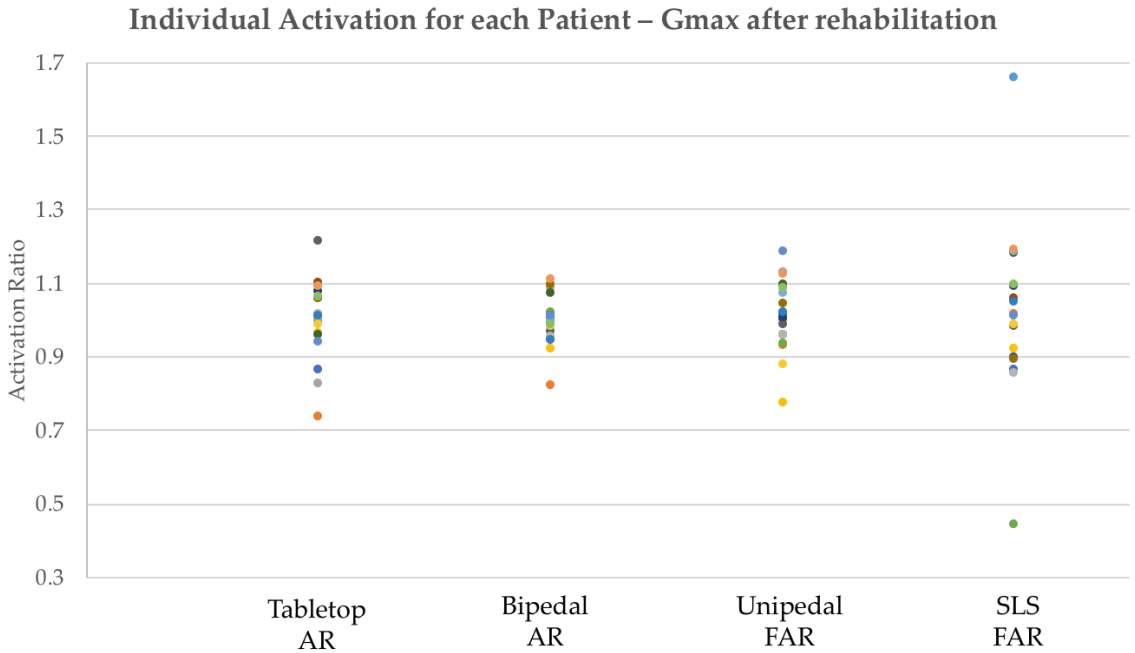

Figure D8. Gmax activation ratio (ADIM/rested) in all positions – individual values after rehabilitation

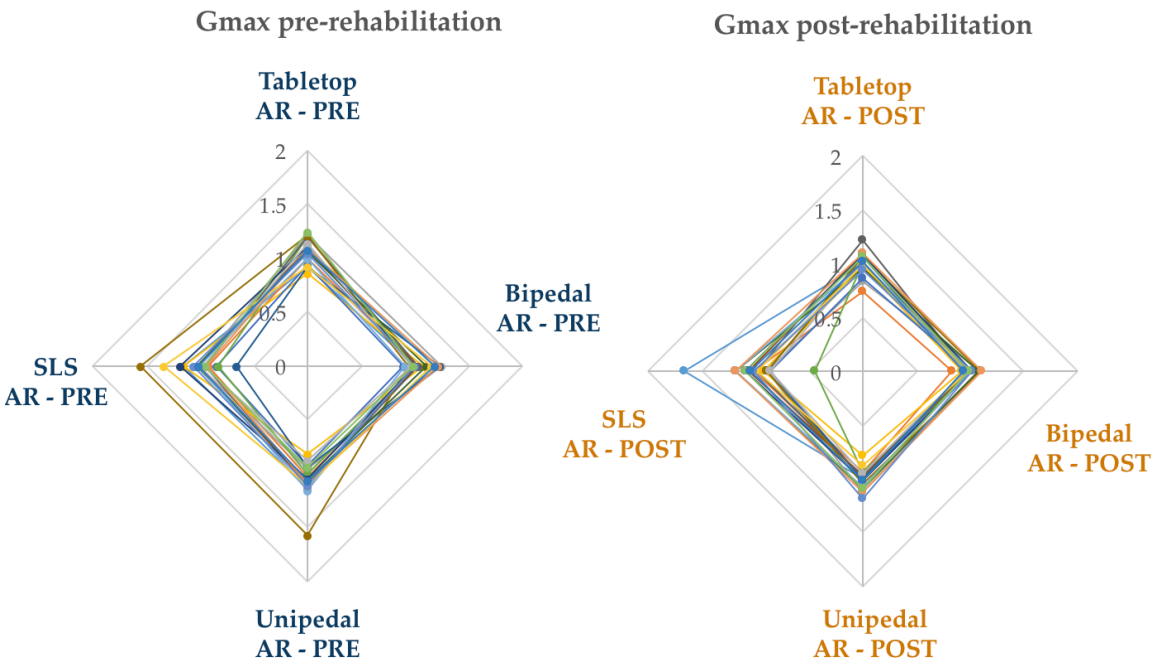

Figure D9. Radar plots of Gmax activation ratios in all positions pre-post rehabilitation

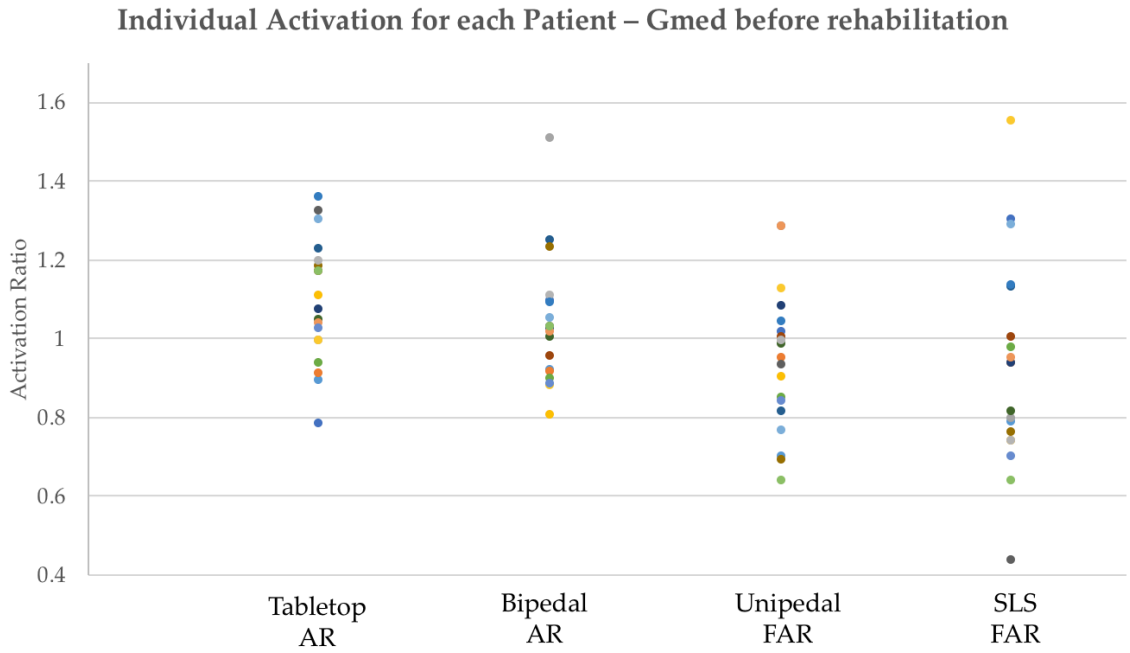

Figure D10. Gmed activation ratio (ADIM/rested) in all positions – individual values before rehabilitation

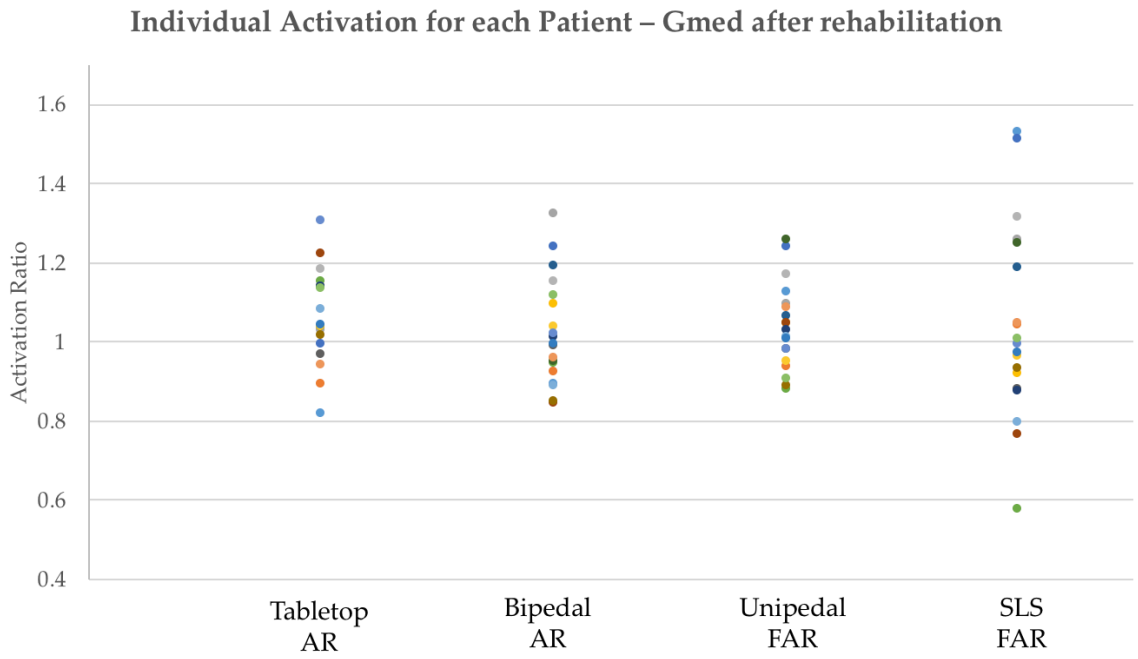

Figure D11. Gmed activation ratio (ADIM/rested) in all positions – individual values after rehabilitation

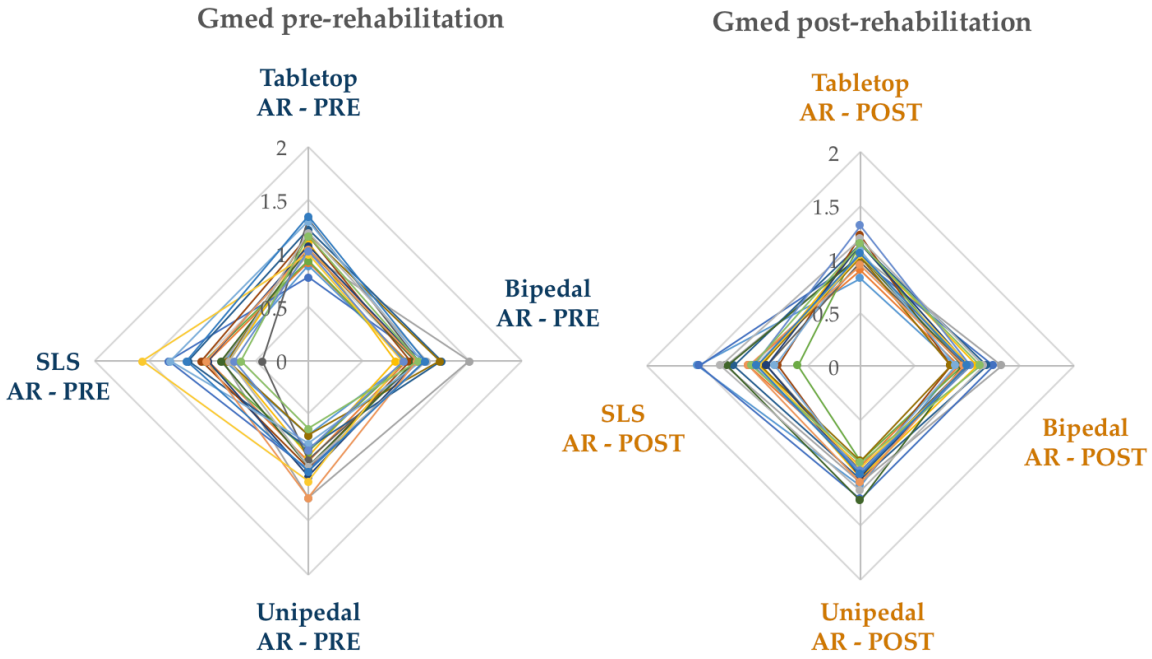

Figure D12. Radar plots of Gmed activation ratios in all positions pre-post rehabilitation

Table D37. ANOVA of all groups position differences

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
Tabletop	Between Groups	.000	2	.000	.324	.724
	Within Groups	.035	96	.000		
	Total	.035	98			
Bipedal	Between Groups	.002	2	.001	1.314	.274
	Within Groups	.069	96	.001		
	Total	.071	98			
Unipedal	Between Groups	.002	2	.001	1.916	.153
	Within Groups	.055	96	.001		
	Total	.057	98			
SLS	Between Groups	.004	2	.002	2.107	.127
	Within Groups	.083	96	.001		
	Total	.087	98			

Table D38. ANOVA for injured vs. healthy in all positions

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
Tabletop	Between Groups	.000	1	.000	.164	.687
	Within Groups	.035	97	.000		
	Total	.035	98			
Bipedal	Between Groups	.002	1	.002	2.646	.107
	Within Groups	.069	97	.001		
	Total	.071	98			
Unipedal	Between Groups	.002	1	.002	3.838	.053
	Within Groups	.055	97	.001		
	Total	.057	98			
SLS	Between Groups	.003	1	.003	3.759	.055
	Within Groups	.083	97	.001		
	Total	.087	98			

Table D39. ANOVA for demographic comparisons between 3 groups

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
Age	Between Groups	91.111	2	45.555	3.488	.034
	Within Groups	1253.798	96	13.060		
	Total	1344.909	98			
Height	Between Groups	420.685	2	210.342	.554	.576
	Within Groups	36417.344	96	379.347		
	Total	36838.029	98			
Mass_kg	Between Groups	144.430	2	72.215	.349	.707
	Within Groups	19889.384	96	207.181		
	Total	20033.814	98			
Tegner_current	Between Groups	7.156	2	3.578	1.116	.332
	Within Groups	307.753	96	3.206		
	Total	314.909	98			

Table D40. 3 group – tests of between-subjects effects of all positions

Tests of Between-Subjects Effects

Source	Dependent Variable	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	Table_TrA_rest_AVG	1.916E-6[a]	2	9.581E-7	.260	.772
	BIP_TrA_rest_AVG	2.587E-5[b]	2	1.294E-5	1.989	.143
	UNI_TrA_rest_AVG	2.259E-5[c]	2	1.130E-5	1.995	.142
	SLS_TrA_rest_AVG	4.180E-5[d]	2	2.090E-5	2.467	.090
Intercept	Table_TrA_rest_AVG	.003	1	.003	913.916	.000
	BIP_TrA_rest_AVG	.005	1	.005	722.925	.000
	UNI_TrA_rest_AVG	.005	1	.005	908.817	.000
	SLS_TrA_rest_AVG	.007	1	.007	793.786	.000
Injury_coded	Table_TrA_rest_AVG	1.916E-6	2	9.581E-7	.260	.772
	BIP_TrA_rest_AVG	2.587E-5	2	1.294E-5	1.989	.143
	UNI_TrA_rest_AVG	2.259E-5	2	1.130E-5	1.995	.142
	SLS_TrA_rest_AVG	4.180E-5	2	2.090E-5	2.467	.090
Error	Table_TrA_rest_AVG	.000	94	3.686E-6		
	BIP_TrA_rest_AVG	.001	94	6.504E-6		
	UNI_TrA_rest_AVG	.001	94	5.663E-6		
	SLS_TrA_rest_AVG	.001	94	8.474E-6		
Total	Table_TrA_rest_AVG	.004	97			
	BIP_TrA_rest_AVG	.006	97			
	UNI_TrA_rest_AVG	.007	97			
	SLS_TrA_rest_AVG	.009	97			
Corrected Total	Table_TrA_rest_AVG	.000	96			
	BIP_TrA_rest_AVG	.001	96			
	UNI_TrA_rest_AVG	.001	96			
	SLS_TrA_rest_AVG	.001	96			

a. R Squared = .005 (Adjusted R Squared = -.016)

b. R Squared = .041 (Adjusted R Squared = .020)

c. R Squared = .041 (Adjusted R Squared = .020)

d. R Squared = .050 (Adjusted R Squared = .030)

Table D41. 2 group – tests of between-subjects effects of all positions

Tests of Between-Subjects Effects

Source	Dependent Variable	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	Table_TrA_rest_AVG	6.020E-7[a]	1	6.020E-7	.164	.686
	BIP_TrA_rest_AVG	2.568E-5[b]	1	2.568E-5	3.989	.049
	UNI_TrA_rest_AVG	2.251E-5[c]	1	2.251E-5	4.017	.048
	SLS_TrA_rest_AVG	3.777E-5[d]	1	3.777E-5	4.482	.037
Intercept	Table_TrA_rest_AVG	.004	1	.004	1049.693	.000
	BIP_TrA_rest_AVG	.006	1	.006	865.425	.000
	UNI_TrA_rest_AVG	.006	1	.006	1083.069	.000
	SLS_TrA_rest_AVG	.008	1	.008	945.718	.000
Group_coded	Table_TrA_rest_AVG	6.020E-7	1	6.020E-7	.164	.686
	BIP_TrA_rest_AVG	2.568E-5	1	2.568E-5	3.989	.049
	UNI_TrA_rest_AVG	2.251E-5	1	2.251E-5	4.017	.048
	SLS_TrA_rest_AVG	3.777E-5	1	3.777E-5	4.482	.037
Error	Table_TrA_rest_AVG	.000	95	3.661E-6		
	BIP_TrA_rest_AVG	.001	95	6.438E-6		
	UNI_TrA_rest_AVG	.001	95	5.604E-6		
	SLS_TrA_rest_AVG	.001	95	8.427E-6		
Total	Table_TrA_rest_AVG	.004	97			
	BIP_TrA_rest_AVG	.006	97			
	UNI_TrA_rest_AVG	.007	97			
	SLS_TrA_rest_AVG	.009	97			
Corrected Total	Table_TrA_rest_AVG	.000	96			
	BIP_TrA_rest_AVG	.001	96			
	UNI_TrA_rest_AVG	.001	96			
	SLS_TrA_rest_AVG	.001	96			

a. R Squared = .002 (Adjusted R Squared = -.009)

b. R Squared = .040 (Adjusted R Squared = .030)

c. R Squared = .041 (Adjusted R Squared = .030)

d. R Squared = .045 (Adjusted R Squared = .035)

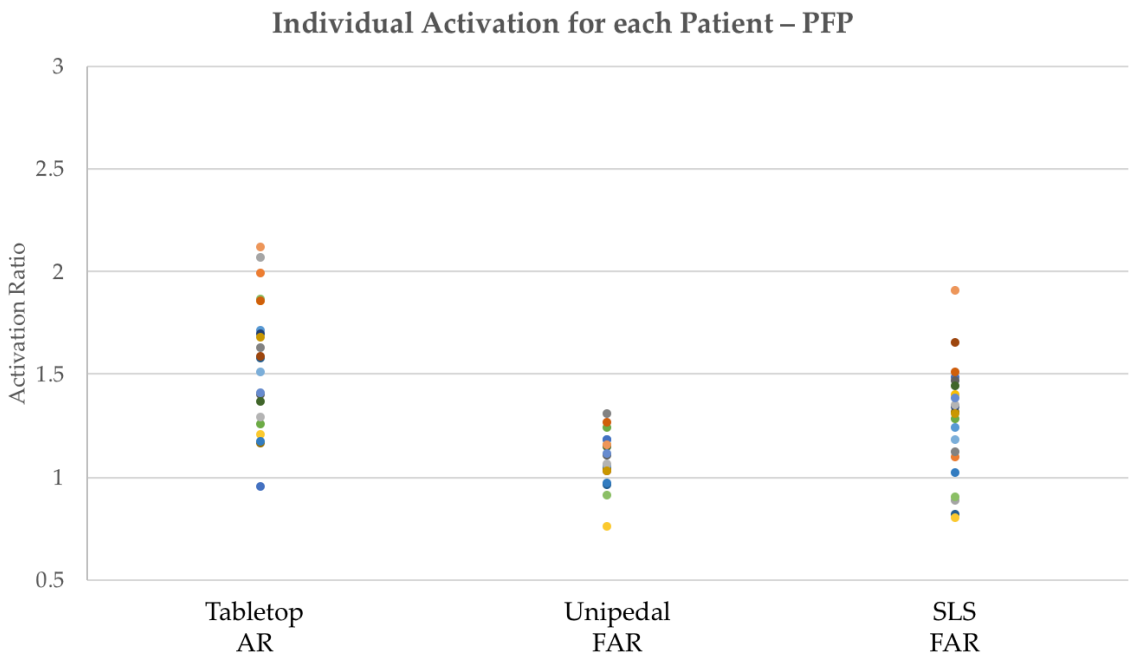

Figure D13. Individual activation for each patient in PFP group

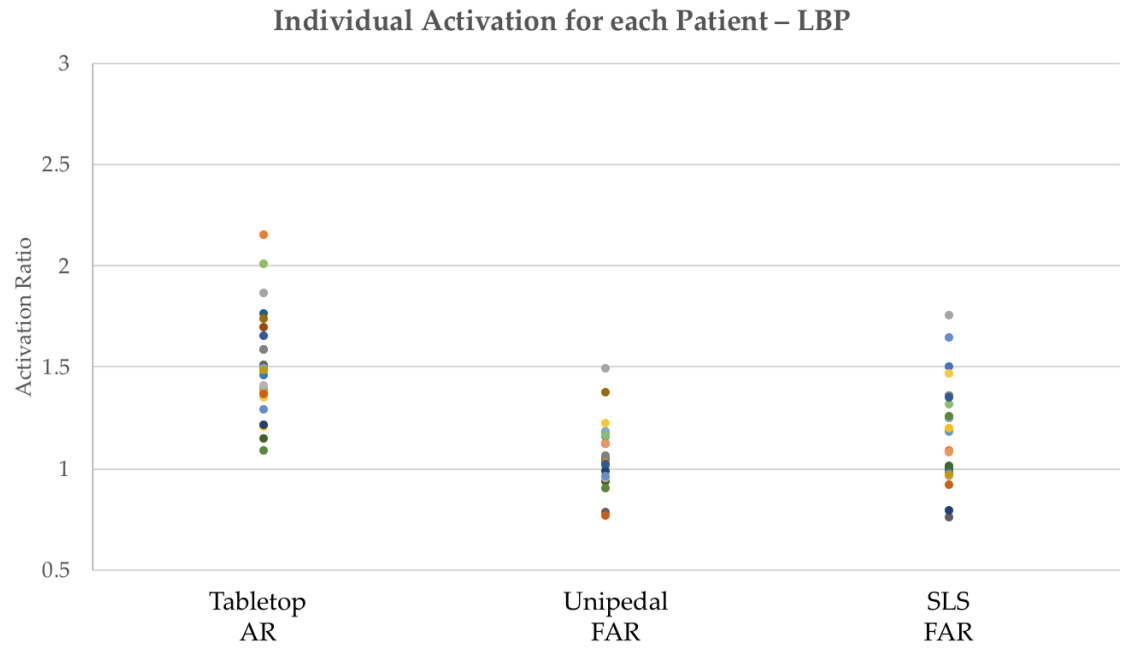

Figure D14. Individual activation for each patient in NSLBP group

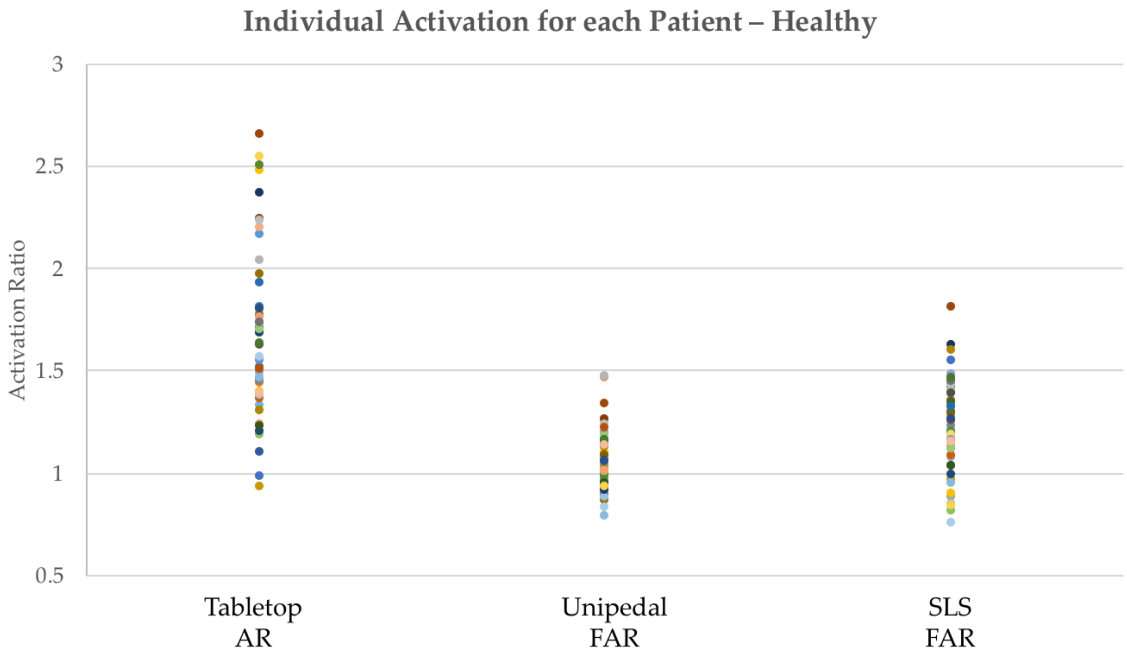

Figure D15. Individual activation for each patient in healthy group

APPENDIX E: Back Matter

Recommendations for Future Research

- Use of ultrasound imaging to create more robust clinical screening of muscle activity to identify potential impairments and follow prospectively for injury occurrence
- Extension of impairment-based rehabilitation approach using ultrasound imaging not only at baseline and final collection, but throughout rehab to guide progression of exercises
- Biofeedback program with impairment-based model structure for training of transverse abdominis, gluteus maximus and medius
- Further examination of clinical subgroups of patellofemoral pain based on current findings with core-focused segment of rehabilitation and potential singular impairment
- Continued use of wireless ultrasound to bring these techniques to clinicians directly in a mobile manner to quantify muscle activity
- Creation of clinical prediction based on core muscle function in those with patellofemoral pain and non-specific low back pain in athletes and younger, lower level disability, higher activity patients

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