Rehabilitation with Patterned Electrical Neuromuscular Stimulation for Individuals with Patellofemoral Pain

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APPROVAL OF THE DISSERTATION

This dissertation, "Rehabilitation with Patterned Electrical Neuromuscular Stimulation for Individuals with Patellofemoral Pain", 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

Patellofemoral pain (PFP) is one of the most common knee pathologies seen in clinical practice. It is challenging chronic condition due to its heterogeneous presentation of impairments, ranging from decreased flexibility, muscle weakness, altered muscle activation, and altered movement patterns during a variety of functional tasks. While traditional rehabilitation programs have produced improvement in strength and decrease pain, changes in muscle activity and movement patterns have not been found to improve. The long-term outcomes in those individuals are also sub-optimal, with pain and symptoms for years following initial diagnosis, suggesting that exercise alone may only be a small part at treating PFP. Exploring interventions to improve strength, muscle activation and correct altered movement patterns should be examined to improve these outcomes. Patterned electrical neuromuscular stimulation (PENS) has gained recent support when treating PFP, as single interventions have been found to decrease pain, improve muscle activation and improve altered kinematics during functional tasks. However, it is unknown the effect of PENS in conjunction with a rehabilitation program when treating individuals with PFP. Therefore, the purpose of this study is to determine the effect of a 4-week rehabilitation program with PENS on patient reported outcomes, range of motion, strength and activity level (Manuscript 1). Furthermore, we aimed to evaluated the effect of PENS with rehabilitation on muscle activity and movement patterns in both laboratory based tasks, such as a single leg squat and step down task (Manuscript 2) and in functional daily activities such as jogging (Manuscript 3).

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ABSTRACT

Context: Patellofemoral pain (PFP) is a chronic condition that presents with lower extremity muscle weakness, decreased flexibility, subjective functional limitations, and decreased physical activity. Patterned electrical neuromuscular stimulation (PENS) has been shown to affect muscle activation and pain following a single treatment for PFP, but its use has not been studied in a rehabilitation trial. **Objective:** To determine the effects of a 4-week impairment based rehabilitation program with PENS on strength, flexibility, subjective function, and physical activity in PFP patients. **Design:** Double-blinded randomized controlled trial. **Setting:** Laboratory setting. **Patients or Other Participants:** 21 patients with PFP (Sex= (M=5, F=16), Age: 23.4±7.6 years, Mass: 69.0±19.5kg, Height 168.0±7.5cm). **Intervention:** Participants completed a 4-week supervised rehabilitation program in conjunction with randomly assigned PENS or sham treatments. **Main Outcome Measures:** Subjective function, lower extremity strength, range of motion, pain and physical activity levels were assessed. Repeated measures ANOVA were conducted with appropriate post hoc testing with a significant level of $P \leq 0.05$ set *a priori*. Correlations were conducted between changes in strength, pain and subjective assessments. **Results:** Both groups had statistically and clinically significant improvements in subjective function, strength, range of motion, pain and activity level after 4-weeks of impairment based rehabilitation. The only group by time interaction difference was seen in hip internal rotation, which increased in the sham group compared to the PENS group. **Conclusion** Utilizing PENS into a rehabilitation program for treating PFP was not more effective during this 4-week treatment than rehabilitation alone. However, progressive rehabilitation that targets individual impairments was effective at improving subjective and objective function in PFP patients.

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Introduction

Patellofemoral pain (PFP) is one of the most commonly treated knee pathologies seen in the general population[1], active individuals,[2] and military personnel.[3] It accounts for 7% of all diagnoses for patients seeking medical care and up to 25% of all treatment for knee related injuries in sports medicine clinics.[1,2] While PFP is frequently seen in clinical practice, the etiology of this chronic condition is currently unknown. Those with PFP have retro or peri-patellar pain during common functional tasks, such as prolonged sitting, kneeling, jumping, and squatting. These tasks often produce pain due to an increase in stress placed on the patellofemoral joint.[4]

Individuals diagnosed with PFP often experience many debilitating consequences that negatively impact their daily activities. A decrease in physical activity due to pain is commonly seen within the short-term following diagnosis.[5] Muscle weakness and decreased range of motion are also commonplace when compared to healthy counterparts.[6-9] Weakness in the quadriceps and gluteus medius has been seen during strength assessment and has been theorized to contribute to influence movement in a variety of functional tasks.[6,10] These symptoms also have a negative influence on the subjective function, as a linear relationship has been found with decreased strength or increased pain on self-reported knee function.[11]

One of the challenges with treating PFP is the long-term consequence of this pathology. Up to 90% of all PFP patients present with long-term symptoms of pain and altered activity levels for up to 16 years following the initial diagnosis.[12,13] The chronicity of this condition may be a predisposing factor for the development of

patellofemoral osteoarthritis. [14] These alarming recurrence rates suggest the value of interventions to address the heterogeneous presentation of symptoms.

Interventions to address muscle weakness and soft tissue restriction are frequently used in clinical practice. [15-20] Strengthening exercises often focus on the quadriceps and gluteus medius muscle with a variety of knee extension, hip abduction, and hip external rotation tasks. [18-20] One of the challenges with strengthening these muscles is the presence of inhibition, which prevents the patient from reaching their full capacity of muscular contraction. [21] Neuromuscular electrical stimulation (NMES) is one treatment option for clinicians to overcome the muscular inhibition and allows for the neuromuscular reeducation of the atrophied or weakened muscles. While NMES has been used in conjunction with rehabilitation for PFP patients, those interventions typically only target the quadriceps. [22,23] In addition to this concern, the use of NMES often presents with patient discomfort, muscle fatigue and lack of functional applications. [24]

To overcome these concerns, novel forms of electrical stimulation have been developed to improve clinical outcomes. Patterned electrical neuromuscular stimulation (PENS) is one such novel treatment that delivers a rhythmical stimulus, targeting the vastus medialis oblique and gluteus medius; key muscles in PFP rehabilitation programs. [25] The precise stimulus to these muscles has been theorized to replicate normal firing patterns based off healthy normal muscle activation patterns. [25] A single intervention of PENS to PFP patients caused immediate improvements in lower extremity EMG activity, lower extremity kinematics, and decreased pain. [RW.ERROR - Unable to find reference:691] However, the utilization of PENS in conjunction with a prolonged rehabilitation program has not

been evaluated within this population. The purpose of this study is to evaluate changes in lower extremity strength, range of motion, subjective assessment and activity levels following a 4-week strengthening program with or without the use of PENS on PFP patients.

Methods:

Study Design:

This was a double-blinded, randomized, sham controlled laboratory study. Independent variables were electrical stimulation groups (PENS and sham) and time (pre- and post-rehabilitation). Dependent variables were patient reported outcomes, lower extremity isometric strength, range of motion, and activity levels. Anterior knee pain scale (AKPS), activities of daily living scale (ADLS), lower extremity functional scale (LEFS), visual analog scale for pain and global ratings of change (GROC) scores were collected to assess subjective function prior to the 4-week rehabilitation program and directly afterwards. Lower extremity strength was assessed at both the hip (extensors, abductors, internal rotators, external rotators) and knee (extension and flexion). Lower extremity range of motion was measured to assess the flexibility of the quadriceps, hamstrings, gastrocnemius, and IT band. Activity levels were also assessed weekly throughout the duration of the study via FitBit activity bands.

Participants:

Volunteers included 21 patients with PFP (Sex= (M=5, F=16), Age: 23.4±7.6 years, Mass: 69.0±19.5kg, Height 168.0±7.5cm) who were recruited from the local university, community, and orthopedic clinics for study participation. Diagnosis of PFP was determined with screening for inclusion and exclusion criteria, and included scoring

<85/100 on the anterior knee pain scale, and evaluation by a certified athletic trainer. [27] (Table 1) Participants were also screened for contraindications for electrical stimulation: biomedical device implants, history of neuropathy, electrical stimulation hypersensitivity, lower extremity muscular abnormalities, or active infection to lower limb. Approval was obtained from the University of Virginia's Institutional Review Board and registered with Clinicaltrials.gov (NCT02441712). All participants completed written consent prior to enrollment.

Instruments

Electrical stimulation

PENS treatments were administered with the Omnistim FX^2 (Accelerated Care Plus, Reno, NV, USA). PENS utilizes a 50-Hz pulse frequency, 70μs phase duration, and 200-millisecond stimulus train with an asymmetrical biphasic square waved stimulus. Alternating rhythmical contractions were created using two stimulation patterns to target the agonist muscles (vastus medalis oblique and gluteus medius) and antagonist muscles (hamstrings and adductors). Four 3" X 5" self-adherent electrodes were placed over these muscles as suggested by manufacturer recommendations. A 200-millisecond stimulus to the agonist muscles, a 200-millisecond stimulus to the antagonist muscles, and a 120-millisecond stimulus to the agonist, with a 40-millisecond stimulus overlap between agonist and antagonist. (Figure 1) Participants were randomized using concealed envelopes into a true PENS group, who received a strong motor response(40-80mA), or a sham group, which received a 1mA treatment. This subsensory, minimal stimulation allowed the machine to operate with all of its lights and timers and the participants were told that they would receive a subsensory stimulation treatment. All

participants had identical set-up of their intervention treatment, and was administered for 15-minutes prior to therapeutic exercise during each rehabilitation session.

Procedures

Participants within this current study were part of a larger randomized controlled study on neuromuscular and gait factors in PFP patients. Participants eligible for study enrollment attended an initial laboratory assessment for pre-interventions data collection.

Subjective Function:

Patient reported scales and pain assessments were collected prior to objective measurements in the initial session. (Figure 2) The Anterior Knee Pain Scale (AKPS), Activities of Daily living Scale (ADLS), Tegner Activity Scale, Fear Avoidance Belief Questionnaire-Knee, and Lower Extremity Functional Scale were collected to evaluate the function and impairments of the participants. These scales have been shown to be valid and reliable assessments for the PFP population. [28,29] Current pain level was also collected with the visual analog scale.

Strength:

Lower extremity strength of the hip and knees was assessed with three-5 second maximal voluntary isometric contractions using a handheld dynamometer (Accelerated Care Plus, Reno, NV) using standard methods. [30,31] Force measurements were collected for knee flexion, knee extension, hip abduction, hip internal and external rotation, hip extension with knee extension, and hip extension with knee flexion. The average force (N) of the three trials were averaged and normalized to the participant's body mass (kg).

Range of Motion:

Range of motion of the hip, knee and ankle was measured using both a 12" International Standards of Measurement goniometer and bubble inclinometer (Fabrications Enterprises INC, White Planes, NY). An average of two trials were collected for all assessments. Dorsiflexion was assessed in a seated straight-knee position with the goniometer. Hamstring flexibility was assessed in a supine straight leg raise test with a bubble inclinometer placed on the distal tibia.[28] Quadriceps flexibility was assessed prone with a knee flexion movement with bubble inclinometer on distal tibia. IT band was assessed in a side lying position with bubble inclinometer placed on the lateral knee joint.[28]

Activity Level

Participants were provided a FitBit Charge HR (FitBit INC, San Francisco, CA) at the conclusion of the initial assessment. Participants were instructed to wear the activity band on their non-dominate wrist at all times during the duration of the rehabilitation study, except while charging and showering and were instructed to not alter their normal activity levels. Each activity monitor was assigned an individual account user name that was only accessible by the research team. The FitBit was synced each week via Bluetooth with the FitBit Connect Application. Data was exported from the FitBit website each week with activity levels for each participant.

Rehabilitation Protocol

Rehabilitation was initiated within 96 hours after the initial assessment. Participants completed 12 rehabilitation sessions, which were administered as 3 sessions of supervised rehabilitation per week for 4 weeks. A single certified athletic trainer (A.N.S) with over 7 years of clinical experience supervised the rehabilitation sessions for

the duration of the study. All participants were instructed similar exercises to address range of motion restriction, strengthening exercises of the knee, hip and core, balance training, and motor training during functional tasks based on their ability and individual impairments. The duration of treatment was approximately one hour per rehabilitation session and consistent among treatment groups.

The lone difference in the rehabilitations sessions was the administration of the PENS or sham treatment, which was conducted prior to strengthening exercises. A random number generator was used prior to study enrollment to randomize the assignment of PENS or sham treatments for all participants. A 4-block randomization scheme was performed with allocation concealed in envelopes.

The rehabilitation program was a modification of exercises previously published treatment for PFP patients.[18] Strengthening exercises and balance were completed throughout the duration of the study, while functional retraining tasks were introduced on the 7th visit and conduced for the remainder of the study. (Table 2) All strengthening exercises were initiated at a percentage of the maximal strength measure collected during the initial testing session. This protocol was performed to challenge all participants from the start of the rehabilitation program depending on their presentation of lower extremity function. All exercises were progressed throughout the rehabilitation program based on the clinical judgment of the athletic trainer. Pain was assessed during each rehabilitation session to provide additional insight into daily modifications of the program to mimic clinical practice.

Follow-up Testing

Participants returned to the laboratory within 72-hours of the final rehabilitation session. Participants completed the same subjective assessment with the patient reported scales, lower extremity strength, and range of motion. Activity levels from the previous 4-5 weeks were collected from the FitBit. The global rating of change (GROC) questionnaire was also administered to all patients to evaluate the change in their knee function since initiating the rehabilitation study.

Statistical Analysis

Data was analyzed with SPSS software (V20.0, SPSS, Inc., Chicago, IL, USA). Dependent variables were evaluated for normality with skewness, kurtosis, and Levene's test for normal variance. A 2x2 repeated measures analysis of variance was conducted for self-reported function, pain, range of motion, strength, and activity level. The within-subject factor was time (pre-rehabilitation and post-rehabilitation) and the between-subject factor was group (PENS and sham). Pearson correlations were conducted comparing changes in lower extremity strength, pain and subjective function. Alpha was set *a priori* at .05 for all statistical analyses. Cohen's d effect sizes were calculated to examine the magnitude of change in dependent variables pre- and post-rehabilitation. Thresholds for effect sizes were set at <0.20 as trivial, 0.49-0.20 as small, 0.79-0.50 as moderate, and >.80 as large.

Results

Dependent variables, with the exception of hamstring flexibility and duration of symptoms, were normally distributed based off skewness, kurtosis, and normal variance as assessed by Levene's test >0.05. Baseline anthropometric, subjective and objective characteristics were compared for group differences. (Table 3)

Subjective Function

No significant group main effect or group by time interactions were identified in AKPS, ADLS, FABQ, LEFS, VAS-C. (Table 4) We did identify significant time-main effect in all self- subjective functional scores following rehabilitation AKPS (Pre: 76.3±7.5, Post:87.1±7.7, P<0.001), ADLS (Pre: 79.3±10.0, Post:88.0±5.5, P=0.001), FABQ (Pre: 13.3±4.4, Post:10.0±4.7, P=0.004), LEFS (Pre: 65.6±8.5, Post:73.1±4.6, P<0.001), and VAS-C (Pre: 1.3±1.5, Post:0.62±0.64, P=0.038) for combined groups. Large effect sizes were identified in the AKPS, ADLS, LEFS, moderate effect in FABQ and VAS-C. The average GROC score of the combined groups was 4.4±1.78, which equates to 'moderately better'.

Strength

Significant time-main effects demonstrated improvements in knee flexion, hip abduction, hip external rotation, hip internal rotation and hip extension strength. (Table 5) No group-main effects were found for any strength measures. Significant group by time interactions was found with an increase in hip internal rotation and a trend towards significance increase in knee flexion strength in the sham group. Combined strength differences between pre- and post-rehabilitation was present in hip abduction (Pre: 2.9±0.8 N/kg, Post: 4.5±2.5 N/kg, P=0.006), hip external rotation (Pre: 1.5±0.4 N/kg, Post: 3.2±3.5 N/kg, P=0.033), hip internal rotation (Pre: 1.4±0.5 N/kg, Post: 1.7±0.4 N/kg, P=0.007) and hip extension (Pre: 3.5±1.3 N/kg, Post: 4.5±1.3 N/kg, P=0.001). There was a trend towards significance for both knee strength measures, flexion (Pre:2.2±0.6 N/kg, Post: 2.4±0.7 N/kg, P=0.061) and extension 3.9±1.5 N/kg, Post: 4.9±2.9 N/kg, P=0.062). A large effect size was identified for hip abduction, moderate

effect sizes for hip external rotation, hip internal rotation and hip extension, and trivial effect sizes for knee extension and flexion.

Range of Motion

Range of motion of the quadriceps, hamstrings, IT band, and gastrocnemius had significant time-main effects. (Table 6). No group-main effects or group by time interactions were found in any range of motion measures. Significant improvements in lower extremity range of motion were found in combined groups pre-post-rehabilitation: quadriceps (Pre:134.8±7.8°, Post:138.8±7.0°, P=0.033), hamstrings (Pre:78.8±28.7°, Post:94.8±12.4°, P=0.010), IT band (Pre:28.0±13.5°, Post:34.2±7.5°, P=0.044), gastrocnemius (Pre:14.4±6.8°, Post:17.7±4.9°, P=0.037). Moderate effect sizes were seen for all four muscles following the rehabilitation program, with hamstring range of motion being the only variable that did not cross zero.

Activity level

A significant time-main effect (p=0.040) was identified in steps per week [(PENS: Pre: 8,660.2±1,932.4, Post: 9,593.6±2,350.5), (Sham: Pre: 8,970.7±1,968.7, Post: 10,128.6±2,987.7)]. No significance was found in either group-main effect (P=0.690) or with a group by time interaction (P=0.56). A trivial effect size was identified for activity level 0.41with confidence intervals that crossed zero (1.04, -0.20).

Correlations

Significant correlations between changes were identified with the AKPS and improvements in knee flexion strength (r=.621, P=0.004), and hip internal rotation strength (r=.479, P=0.033). Significant correlations between strength gains were also identified, improvements in knee extension strength was found to have a relationship

with improvements in hip external rotation (r=0.863, P<0.001) and hip abduction (r=.741, P<0.001). A significant relationship was also found between hip abduction strength improvement and hip external rotation (r=.818, p<0.001).

We did see some small relationships on the subjective scales. The change score in the LEFS had a moderate negative relationship with current pain levels (r=-0.493, P=0.027). There were also small relationships between changes in the LEFS score with other subjective functional scales, such as the AKPS (r=0.443, P=0.05) and the ADLS (r=0.50, P=0.025).

Discussion:

The purpose of this study was to evaluate the effect of a 4-week impairment based rehabilitation program with or without PENS on subjective and objective measures in PFP patients. We did not see any significant differences in subjective function, strength, range of motion, or activity levels between the PENS or Sham groups. However, regardless of the use of PENS, impairment based rehabilitation on the combined groups identified improvements in subjective function, knee and hip strength, lower extremity range of motion and activity level in PFP patients.

Subjective

Following rehabilitation, we found similar improvements in the AKPS[17,32], ADLS[33], and LEFS [3234] as other rehabilitation programs. Subjective function was not different between the two groups over the 4-week rehabilitation program. However, the combined subjective function improved in all three scales AKPS (10 points), ADLS (8.7 points), and LEFS (7.5 points). These values significantly improved and were above the minimal clinically important change threshold of 8 points in the AKPS, 7 points in the

ADLS, while the change in LEFS was not above the required 9 points. [29,32] The clinically significant improvement and large effect sizes that did not cross zero suggest the effectiveness of rehabilitation for PFP on improving subjective function. While we expected PENS to improve the ability to gain strength and improve function, perhaps the magnitude of change from the exercise made it difficult to detect the effect of any additional treatment.

Current rehabilitation programs have focused on evaluating the effectiveness of knee-focused exercises to hip-focused programs. [16,17,32,34] There are also varying duration of treatment and amount of exercises between studies, which provides some insight into treating PFP, it does not mimic clinical practice and makes it difficult to compare changes in subjective function between studies. When comparing other 4-week programs we had similar improvement in the LEFS when compared to Dolak et al. [34] who found that improvements of 8 and 5 points in hip and knee based programs.

While AKPS and LEFS are more commonplace in the PFP literature, the ADLS produces some of the strongest psychometric properties for both evaluating the presence of PFP and assessing responsiveness to interventions. Esculier et al. [33] completed an 8-week rehabilitation on runners with PFP and found larger improvements in ADLS (17.8 points) than our study (9.7 points). While both studies used a multimodal rehabilitation program to address the individuals needs of the patients, our program was only half the duration of rehabilitation, which may suggest why our improvement was approximately half as large. Esculier et al. [33] also had a lower baseline ADLS score and used <85 on the ADLS for study inclusion, while we used <85 on the AKPS, which allows for the potential for greater improvements during rehabilitation.

Strength

We had similar baseline strength values compared to other RCT rehabilitation trials treating PFP patients. [16] However, we found greater improvements in post rehabilitation strength of the knee and hip muscles. There may be a few reasons for the greater improvements in strength compared to Ferber et al[16], who completed a 6-week program comparing knee to hip strengthening programs. While we had two weeks less of rehabilitation we administered a greater number of exercises during each rehabilitation sessions, compared to Ferber et al. who administered as few as 3 exercises per session. Our protocol was developed to individualize treatment based off impairments and use baseline strength values to challenge the participants from the initial visit. This study design was completed to improve the external validity by mimicking the treatment to clinical practice.

Correlations in subjective function and lower extremity strength have been previously identified in both the AKPS and ADLS questionnaires. [11,35] We hypothesized that improvements in knee extensor or hip abduction strength would correlate with improvements in subjective function, however this was not found in the current study. A longer training program that induces hypertrophy gains in these individuals may be required, as a larger magnitude in strength changes might be required. We did see positive correlations for changes in strength of the knee extensors to the hip abductors and external rotators, suggesting that the rehabilitation program was successful at strengthening multiple lower extremity muscles.

Range of motion

Improvements in range of motion were seen in the combined groups between the four measurements. Lower extremity range of motion is commonly prescribed in rehabilitation programs[20,36,37], but is rarely evaluated as an outcome measure. We did identify largest soft tissues restriction in the hamstrings, which was improved by over 10° following rehabilitation. The hamstrings play an important role, as decreased flexibility has been theorized to increase quadriceps force production to complete functional tasks, which may increase stress on the patellofemoral joint.[28]

Avraham et al.[36] was one of the few studies that compared the effectiveness of variations of stretching and strengthening combinations for treatment of PFP. They found that while stretching only did have improvement in pain and functional assessment, greater improvement was seen in conjunction with strengthening programs. Combining multiple treatment options depending on the individual's patient appears to be beneficial to improve the impairments.

Activity levels

PFP patients have been found to have a decrease in physical activity, which also relates to their subjective function.[5,38] We found that 4-weeks of rehabilitation improves weekly physical activity in PFP patients by over 1,000 steps per day. While this improvement appears positive, there is still a large discrepancy in the activity level post-rehabilitation compared to healthy individual activity level values.[38] Physical activity has many health related benefits and there is evidence of its ability to delay the development of osteoarthritis.[39] Since PFP may be a risk factor in the development PFOA, interventions to improve activity level in PFP patients should be evaluated its effect on

both short-term and long-term outcomes. However, it is unclear if the improvements in activity were a result of the rehabilitation or utilizing the activity bands.[40]

Limitations

This study is not without its limitations. First, we had a relatively small number of participants enrolled in this study, which may decrease generalizability of the findings. A study with a larger sample size should be conducted to further examine the effect of PENS on lower extremity clinical measures in a PFP population. This would also allow for more advanced statistical analyses to determine which improved values may be more valuable for clinicians who commonly treat this condition. Secondly, we only conducted 4-weeks of rehabilitation which would be responsible for more neuromuscular adaptations. Longer rehabilitation programs may be required to produce more hypertrophy based gains. Third, while we used a true interventions group and sham group, we did not use a true control group in this study. However, due to the chronicity of PFP impairments, it is a safe assumption that changes in clinical measures will not change in individuals who do not receive any treatment.

Conclusion

A 4-week impairment based rehabilitation program with PENS did not improve clinical measures more than a rehabilitation program with a sham electrical stimulation treatment. While there were no differences between the two groups, improvements in subjective function, strength, range of motion, and activity level all improved following an impairment based rehabilitation program.

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Table 1.1. Inclusion/Exclusion Criteria

Inclusion Criteria:

- Non-traumatic peri- or retro patella pain greater than 3 months
- Pain greater than 3/10 assessed by Visual Analog Scale
- Pain with 2 or more of the following activities
  - Stair ambulation
  - Running
  - Jumping
  - Prolonged sitting
  - Quadriceps contraction
  - Kneeling
  - Pressure over the patella

Exclusion Criteria

- Previous knee surgery
- Ligamentous instability
- Additional source of anterior knee pain (tendonitis, bursitis, patellar subluxation, etc.)
- Lower extremity, back, or concussion in last year

Table 1.2. 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 1.3. Baseline anthropometric, subjective, and objective characteristics

Demographics	PENS (n = 11)	Sham (n = 10)	p-value
Age, yrs	23.8±5.6	23.0±3.7	.70
Height, cm	169.1±7.3	166.7±7.8	.48
Mass. kg	68.2±11.4	69.8±19.0	.81
Sex	8F, 3M	8F, 2M	
Duration, months	26.3±26.3	23.0±27.8	.77
Quadriceps ROM, deg	134.7±8.2	135.9±7.8	.94
Hamstring ROM, deg	74.2±37.4	83.9±14.8	.45
Gastrocnemius ROM, deg	14.6±5.9	14.1±7.9	.87
IT Band ROM, deg	32.5±10.4	23.0±15.2	.10
Activity level (Average Steps/Day)	7963.7±2949.0	8970.7±1968.7	.37

Yrs= Years, cm=centimeters, kg=kilograms, deg=degrees

Table 1.4. Pre-post rehabilitation self-reported subjective function and Cohen's d effect sizes with 95% confidence intervals

	Group (Mean±SD)		Group (Mean±SD)					
	PENS		Sham		Time Main Effect	Group Main Effect	Group x Time Interaction	Pooled Pre-Post Effect Size
Muscle	Pre	Post	Pre	Post	P-value	P-value	P-value	Cohen's d (UL, LL)
VAS-C	0.8±0.8	0.5±0.6	1.8±2.0	0.7±0.6	.03	.164	.143	-0.58 (-1.21,0.04)
AKPS	80.4±5.0	87.2±9.7	73.1±7.9	87.0±5.6	<.001	.196	.054	1.4 (2.11,0.74)
ADLS	79.1±8.5	88.6±5.9	79.6±12.0	87.3±5.2	.002	.802	.814	1.07 (1.73, 0.42)
FABQ	12.4±5.3	8.6±5.2	14.4±3.6	11.4±3.8	.005	.186	.713	-0.73 (-0.09, -1.36)
LEFS	67.0±5.9	72.7±4.9	64.2±10.7	73.5±4.6	<.001	.714	.283	1.09 (1.75, 0.43)
Global Rating of Change		4.6±1.8		4.2±1.8		.630		

VAS-C = Visual Analog Scale-Current, AKPS=Anterior Knee Pain Scale, ADLS= Activities of Daily Living Scale, FABQ=Fear Avoidance Questionnaire, LEFS= Lower Extremity Functional Scale

Table 1.5. Pre-post rehabilitation strength (N/kg) for the PENS and Sham groups and Cohen's d effect sizes with 95% confidence interval

Muscle	Group (Mean±SD) PENS Pre	Group (Mean±SD) PENS Post	Group (Mean±SD) Sham Pre	Group (Mean±SD) Sham Post	Time Main Effect P-value	Group Main Effect P-value	Group X Time Interaction P-value	Pooled Pre-Post Effect Size Cohen's d (UL, LL)
Knee Extension	4.3±1.3	5.5±3.6	3.7±1.7	4.3±1.9	.065	.359	.480	0.41 (1.03, -0.21)
Knee Flexion	2.5±0.6	2.5±0.7	1.7±0.4	2.4±0.6	.045	.263	.051	0.31 (0.93, -0.30)
Hip Abduction	3.0±0.8	4.6±2.9	2.9±0.8	4.3±2.3	.007	.741	.835	0.85 (1.49, 0.21)
Hip ER	1.7±0.4	3.7±4.4	1.4±0.5	2.8±2.5	.038	.504	.667	0.66 (1.29, 0.03)
Hip IR	1.7±0.5	1.7±0.4	1.2±0.4	1.7±0.4	.002	.228	.006	0.67 (1.30, 0.04)
Hip Extension	3.5±1.1	4.2±1.1	3.7±1.5	4.8±1.4	<.001	.453	.467	0.70 (1.34, 0.08)

SD= Standard Deviation UL= Upper Limit, LL= Lower Limit
Effect sizes were calculated comparing pooled group's pre and post scores where a positive size denotes an increase in strength after rehabilitation

Table 1.6. Pre-post rehabilitation range of motion measurements and Cohen's d effect sizes with 95% confidence intervals

Muscle	Group (Mean±SD) PENS Pre	Group (Mean±SD) PENS Post	Group (Mean±SD) Sham Pre	Group (Mean±SD) Sham Post	Time Main Effect P-value	Group Main Effect P-value	Group X Time Interaction P-value	Pooled Pre-Post Effect Size Cohen's d (UL, LL)
Quadriceps	134.9±8.6	141.2±3.6	135.0±7.8	136.5±8.9	.029	.447	.171	0.54 (1.16,-0.08)
Hamstring	81.6±29.7	97.7±13.6	83.9±14.8	91.8±13.3	.010	.810	.344	0.71 (1.35,0.09)
IT Band	31.4±10.2	32.4±9.6	23.0±15.2	35.9±4.4	.033	.511	.065	0.56 (1.19, -0.06)
Gastrocnemius	14.0±5.8	15.4±4.6	14.1±7.9	20.0±4.3	.034	.275	.175	0.55 (1.18, -0.07)

Figure 1.1: Patterned Electrical Neuromuscular Stimulation Pattern

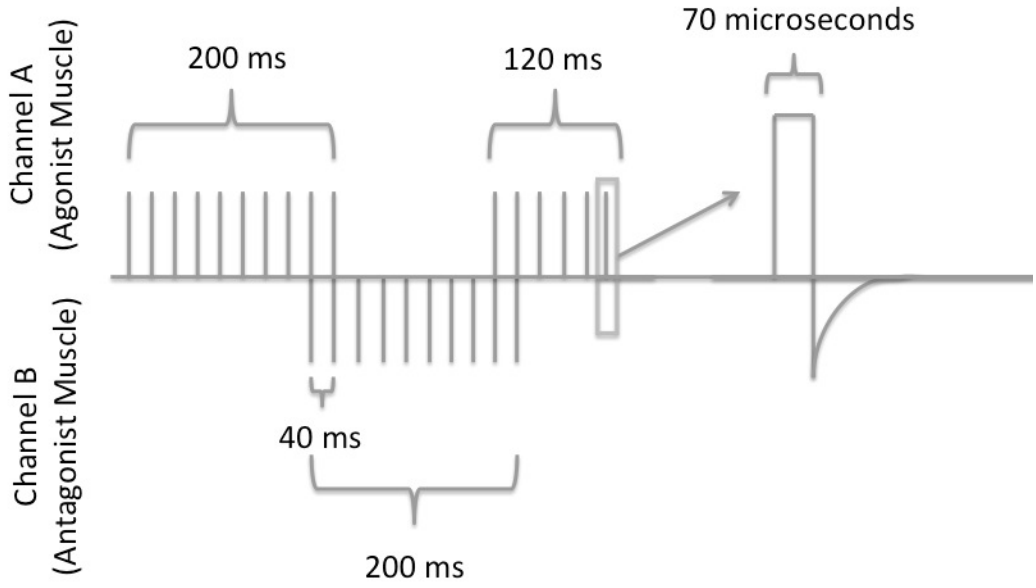
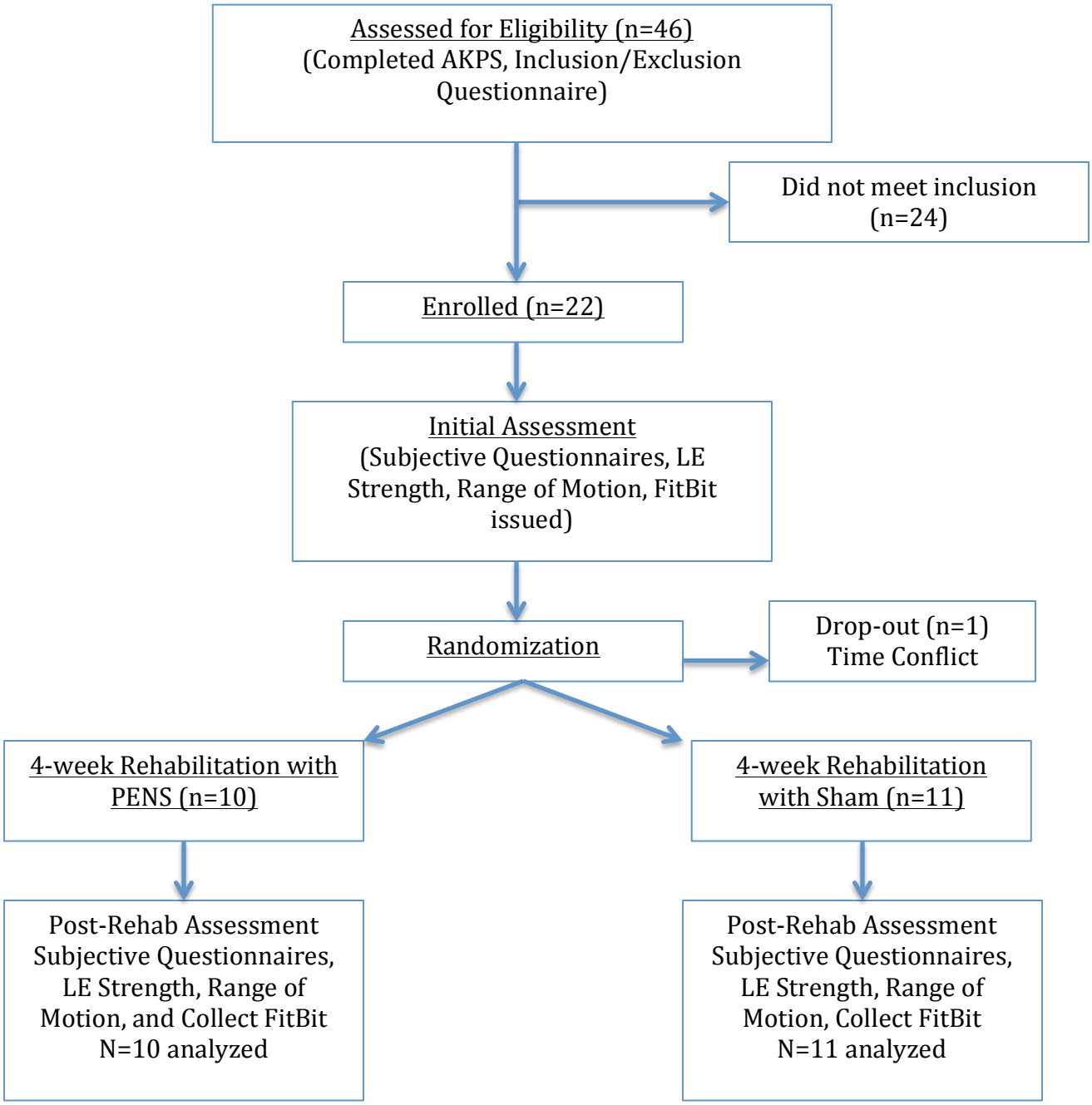


Figure 1.2: CONSORT Flowchart



SECTION II: MANUSCRIPT II

EFFECT OF REHABILITATION WITH PATTERNED ELECTRICAL STIMULATION ON LOWER EXTREMITY KINEMATICS AND MUSCLE ACTIVITY DURING FUNCTIONAL TASKS

Abstract

Context: Individuals with patellofemoral pain (PFP) often have altered lower extremity mechanics and altered electromyography (EMG) activity compared to a healthy cohort. While rehabilitation improves strength, therapeutic exercise rarely affects kinematic and EMG changes for PFP patients. A single application of patterned electrical nerve stimulation (PENS) has been shown to improve EMG activity in this patient population, but its effect with rehabilitation has not been studied. **Objective:** To determine the effects of a 4-week rehabilitation program with PENS on lower extremity biomechanics and EMG activity during a single leg squat (SLS) and a step-down task (SDT) in PFP patients. **Design:** Double-blinded randomized controlled trial **Setting:** Laboratory setting **Patients or Other Participants:** 16 females with PFP (Age: 23.3±4.9 years, Mass: 66.3±13.5kg, height 166.1±5.9cm) volunteered. **Intervention:** Participants completed a 4-week supervised rehabilitation program with PENS or a sham treatment. **Main Outcome Measures:** Curve analyses for lower extremity kinematics and EMG activity were constructed by plotting group means across 100% of each task before and after the rehabilitation program. Discrete variables of kinematic excursions, peak EMG and area under the curve were compared between groups and pre to post-rehabilitation. Correlations were completed to evaluate the relationship between changes in muscle activity and kinematic excursions. **Results:** At baseline, there were no differences, nor were there EMG or kinematic differences in the sham group post rehabilitation. However, in the PENS group, there were several significant findings following rehabilitation. Frontal plane hip movement was reduced between 29-47% (Pre: 14.97±1.63° Post: 10.35±1.20°) of the SLS and between 43-69% (Pre: 24.10±0.74° Post: 17.54±0.81°) of the SDT. Throughout the entire SDT, there was a decrease in trunk flexion (Pre: 14.58±2.58° Post: 3.67±0.91°). EMG identified decreases in muscle activity in the vastus lateralis (6.5 less activity), biceps femoris(1.3-3.4 less activity), and gluteus medius(3.5 less activity) during the SLS. Muscle activity of the gluteus maximus (1.3 less activity) was reduced throughout the entire SDT. **Conclusion:** Rehabilitation with PENS improved kinematics in both the SLS and SDT, tasks that often a problematic for PFP patients. The decrease in EMG activity suggests that rehabilitation with PENS may improve muscle function during those activities. Rehabilitation of PFP without the augmentation of PENS did not alter lower extremity biomechanics.
Word Count: 364

Keywords: Anterior Knee Pain, Functional Tasks, Movement Patterns, Muscle Activity

Introduction:

Patellofemoral pain (PFP) is one of the most common knee pathologies seen in clinical practice. [1,2] Females are at greater risk of having both a history of PFP and are twice as likely to develop PFP than their male counterparts. [3] PFP presents with retro- or peri-patellar pain during a variety of functional tasks, such as squatting and stair ambulation. This pain has been linked to a decrease in activity level, [4] decreased quality of life, [5] and long-term consequences following the initial diagnosis. [6,7]

While the etiology is currently unknown, a multitude of neuromuscular impairments have been identified in PFP patients. Lower extremity muscle weakness, faulty lower extremity activation patterns, and altered movement patterns are three common impairments that have also been identified in females with PFP. [8-13] These factors are considered to be modifiable, yet researchers have not identified whether these impairments result in PFP or are a consequence of PFP. Finding therapeutic interventions that specifically target these impairments may improve overall outcomes in rehabilitation.

Females often present with muscle weakness in many of their lower extremity muscles, specifically their quadriceps and gluteus medius muscles. [10,14] Quadriceps atrophy is often seen in these pathological individuals, resulting in knee extension weakness. [15,16] Weakness of the gluteus medius is also often reported, as females with PFP have been found to have 26% less hip abduction strength and 24-36% weakness in hip external rotation strength when compared to healthy controls. [8,10] The gluteus medius muscle is responsible for hip abduction and external rotation. Individuals with weakness of the gluteus medius may be unable to eccentrically control these excursions during functional tasks. [9]

In addition to muscle weakness, these pathological individuals also have altered muscle activity during a variety of functional tasks when measured by electromyography (EMG). [8,11,17,18] Decreases in muscle activity in both the vastus medialis oblique and gluteus medius have been found during squatting and stair ambulation tasks. [18,19] It has been suggested that these impairments alter patellar tracking and increase frontal plane movement during functional tasks, both of which may increase pressure of the patella on the trochlear groove during flexion based tasks. [11,20,21]

Impairments in both muscular strength and muscle activation have been suggested to influence aberrant movement patterns during functional tasks. [12] PFP patients present with an increase in hip adduction and internal rotation which increases stress on the patellofemoral joint and may result in an increase in pain. [22,23] Willson et al. reported that as the demands of functional tasks increase, so does the extent of hip adduction and internal rotation compared to healthy controls. [21] Clinicians target these altered movement patterns by supplementing movement retraining programs with traditional rehabilitation programs. [24-26] While retraining programs improve hip abduction and external rotation during specific trained task, there is limited carry over to additional tasks. [26]

Use of electrical stimulation is one potential intervention to reeducate the altered neuromuscular function in PFP patients. While traditional neuromuscular electrical stimulation treatments produce tetanus contractions, novel forms such as Patterned Electrical Neuromuscular Stimulation (PENS) incorporate a more natural muscle sequence and is more comfortable. PENS produces a precisely timed stimulus to these muscles based off healthy EMG firing patterns and is delivered to the agonist, briefly to the antagonist muscle and then again to the agonist. PENS has been previously utilized

to target both the gluteus medius and vastus medialis oblique in PFP patients. An intervention utilizing a single application PENS on PFP patients have been found to immediately increase gluteus medius activation by two-fold and decrease the amount of hip adduction for 32% of the task a lateral step-down task. [27]

Previous studies evaluating traditional rehabilitation for PFP report strength gains and improvements in patient-reported function. [28-30] Despite these findings, PFP often recurs and there are poor long term outcomes. [31] Traditional rehabilitation has not been shown to alter muscle activation or kinematics. [18,32] Therefore the purpose of this study is to determine the effect of PENS augmented rehabilitation on lower extremity movement patterns and muscle activity during functional tasks.

Methods:

Study Design

A double-blinded, randomized controlled laboratory study was conducted to evaluate the influence of 4-week rehabilitation program with PENS on lower extremity kinematics and EMG activity in PFP patients. Dependent variables were kinematics throughout 100% of each task, and EMG activity of the lower extremity. Independent variables were time (pre- and post-rehabilitation) and group (PENS and Sham).

Participants

16 females with PFP (Age: 23.3±4.9 years, Mass: 66.3±13.5kg, height 166.1±5.9cm) were recruited from a local university, sports medicine clinic, and local community. (Table 1) Participants were between 18 and 40 years old. Inclusion criteria required individuals to have 1) non-traumatic retro- or peri-patellar symptoms, 2) pain with two or more of the following activities: stair ambulation, kneeling, squatting,

jumping, prolonged sitting, running, quadriceps contraction, or pressure to the patella 3) pain for a minimal duration of 3-months and 4) <85 on the anterior knee pain scale for enrollment. A certified athletic trainer evaluated all participants to determine if inclusion/exclusion criteria were met for study enrollment. Exclusion criteria included 1) previous history of knee surgery, 2) ligamentous instability, 3) additional sources of anterior knee pain, 4) back or lower extremity injury within the last year, and 5) neurological involvement. Participants were also excluded contraindications to electrical stimulation: 1) implanted biomechanical devices, 2) hypersensitivity to electrical stimulation, or 3) infection to lower extremity. All participants completed written consent prior to enrollment, and the University's Institutional Review Board approved the study.

Instruments

Biomechanical Assessment

Three-dimensional kinematics was collected with a 12-camera Vicon motion analysis system (VICON motion systems, CA, USA) in conjunction with Motion Monitor software (Ascension Technology, Inc, Chicago, IL, USA). Rigid 4-cluster reflective marker sets were secured over the dorsum of each foot, lateral shanks, lateral thighs, the lumbar spine and upper thorax. Rigid marker sets were secured with Velcro straps and self-adhesive tape. Kinematic data was collected at 250Hz. A skeleton model was created by digitizing the top of the subject's head, C7, T-12, L-5, bilateral ASIS, medial and lateral knee joints, medial and lateral malleolus, and 2nd phalanx. All tasks were completed on a Bertec^{TM} Fully Instrumented Treadmill (Columbus, OH).

Electromyography

Electromyography (EMG) was collected simultaneously using the Trigno wireless surface EMG system (Delsys, Boston, MA, USA) integrated to the Motion Monitor Software. A 2000Hz-sampling rate was performed, with a 10-500Hz bandpass filter. Electrode preparation included shaving, debriding, and isopropyl alcohol cleansing over the muscle belly of interest on each participant. 37mm x 26mm x 15mm parallel-bar electrodes were placed on mid-belly of the biceps femoris (BF), gluteus maximus (GMax), gluteus medius (GMed), vastus lateralis (VL), vastus medialis oblique (VMO) and adductor longus (AL). Input impedance was $>10^{15}$ Ω/0.2pF with a signal to noise ratio of 1.2uV.

Patterned Electrical Neuromuscular Stimulation

PENS was administered with the Omnistim® Pro Electrotherapy System (Accelerated Care Plus, Reno, NV, USA). PENS is an asymmetrical biphasic square waved stimulus that has parameters of a pulse frequency of 50Hz, phase duration of 70μs, and stimulus train of 200-milliseconds. Opposing muscle groups were targeted based off manufacturer's recommendations. Channel A provided electrical stimulation to the gluteus medius and vastus medalis oblique, while channel B stimulated the hamstring and adductor muscles groups. Alternating stimulation was provided for channel A for 200 milliseconds, followed by a stimulus of channel B for 200-milliseconds, and an additional stimulus to channel A for 120milliseconds. A 40-millisecond stimulus overlap occurred between each alternating stimulus. Participants who received the PENS treatment received a strong motor treatment for 15-minutes. Clinicians increased the amplitude until a visible strong motor response was identified. Those participants

randomized into the Sham group received an identical setup with a 1mA subsensory treatment, also for 15-minutes prior to therapeutic exercise.

Procedures

Participants who met the inclusion/exclusion criteria were enrolled in the study and reported to the Exercise and Sport Injury Laboratory. A single researcher who was blinded to group membership of subjects completed all initial and final assessment measures (N.R.G). Participants completed the Anterior Knee Pain Scale, Activities of Daily Living Scale and pain assessment for current and worst pain over last 72-hour period. All participants were then allowed to warm-up for 5-minutes and then guided through an additional 5-minutes of stretching on their own. EMG sensors were placed over the BF, GMax, GMed, VL, VMO and AL according to SENIAM recommendations. [33] EMG electrode placement was confirmed with quiet standing and maximal voluntary isometric contractions during testing procedures.

Maximal voluntary isometric contractions (MVIC) and EMG data was collected simultaneously with a handheld dynamometer. Three-5 second contractions were collected for each muscle with manual muscle testing procedures for knee extension, hip abduction, adduction, and extension. [34] If MVIC was greater than 10% variability, an additional trial was conducted. [34]

Following EMG and motion analysis set-up a bipedal quiet standing trial was recorded for 5-seconds and served as normalization for EMG and for determining kinematic excursion during the functional tasks. Following setup, two functional assessments were conducted, a SLS and an anterior SDT. Participants were provided verbal instructions to complete the task and three practice trials of each were provided.

The SLS involved participants to stand on the limb of interest with their arms across their chest. Participants were instructed to lower themselves as low as possible for two seconds and return to a fully extended knee position for two seconds. A metronome was utilized to provide auditory feedback for the duration of the task. Three individual trials were conducted with a 30-second rest period between each trial. Following the third squat, individuals were asked to assess their knee pain during the SLS with the visual analog scale.

Following the SLS task a one-minute break was provided. During this time, participants were provided instructions for the anterior SDT. Participants were also provided three practice attempts. Participants stood on a 21cm step that was next to a non-conductive forceplate (Bertec). They stood on the step with their pathological limb and maintained their hands on their hips. Individuals lowered themselves until the heel of their contralateral limb came in contact with the forceplate and then they raised themselves back to the starting position. Participants were instructed to just touch the forceplate and not transfer their full weight onto the forceplate. Individuals completed ten consecutive step-down tasks at a self-selected rate. The average of three trials were used for data analysis.

Interventions

Individuals completed a 4-week rehabilitation program (3 supervised visits a week) that targeted quadriceps, gluteus medius, and core strengthening, stretching, and balance training using an impairment-based paradigm. This rehabilitation program is a modified program that produced improvements in strength and subjective function in PFP patients.[28] The MVIC strength measures at baseline were used to determine the strength

paradigm, with percentages of each participant's maximal strength being their starting resistance values for therapeutic exercises. A single certified athletic trainer (A.N.S) completed all electrical stimulation treatments and progression of all exercise throughout the duration of the study. Participants were continuously assessed on difficultly of each exercise and progressed throughout the 4-weeks based off of the clinical judgment of the athletic trainer. This was conducted to mimic clinical practice on the progression of individual being treated for PFP.

Reassessment:

Participants returned to the laboratory within 96 hours of the completion of the final rehabilitation session. Identical testing procedures including MVIC, EMG, and biomechanical assessment. Participants completed 3 SLS and 10 consecutive anterior step-downs with VAS scores for each task, for the post-rehabilitation measures.

Data Processing

Strength was assessed by normalizing the average of three trials (N) by the participant's body mass (kg). Root mean squared EMG activity and kinematics were reduced to 100 data points from the initiation of knee flexion to full knee extension for each task. The data was exported from Motion Monitor software and the average of three trials was completed for each task. EMG variables were all normalized to a quiet standing trial for all 6 muscles. Peak EMG and area under the curve(AUC) for each muscle was calculated for both the SDT and SLS.

Statistical Analysis

Continuous

Curve analyses were constructed for lower extremity EMG activity and kinematics across the entire task for both the SLS and SDT. Group means were plotted for the duration of the tasks with 90% confidence intervals. Significant differences were identified when the confidence intervals did not overlap for three consecutive data points between the two groups.

Discrete

Repeated measure analysis of variance were conducted for EMG and kinematics between groups for both pre and post-intervention. EMG discrete variables were peak activity and AUC for the 6 muscles across each task. Kinematic excursions completed for the frontal and sagittal plane for the knee, hip and trunk. Pearson correlations were conducted between changes in EMG activity with changes in frontal and sagittal kinematics during each respective tasks. Alpha was set *a priori* at $p<0.05$.

Results:

No significant differences were identified between the PENS or Sham groups for any anthropometric variables. At baseline, we found no significant differences in the continuous EMG or kinematics variables in the SLS (Figure 1 and 2) or SDT (Figure 3 and 4) between the PENS and Sham groups. No baseline differences were seen in discrete kinematic variables between groups for the single leg squat (Table 2) or the step down (Table 3).

Continuous variables

EMG Activation

A 37% decrease in gluteal activation was seen in the PENS group during the SLS task. (Figure 5) Those in the PENS group decreased GMax activity by 0.89 activity

above quiet standing between 8-28% and 1.3 30-39% of the SLS and a decrease of 3.52 in GMed activation for 71-75% of the task. There was also a decrease in muscle activation of both the BF (13-18[1.3], 21-39[2.7], 43-48[3.4], 56-67[3.17], and 95-99%[3.18]) and 6.52 less activity the VL (63-71%) of the SLS. No pre post-rehabilitation changes were seen in EMG during the SLS in the sham group.

Those who received rehabilitation with PENS had a decrease in BF activation during 1-15% and 40-46% of the SDT. (Figure 6) No other statistical differences were seen in the PENS group for the other 5 muscles, and no differences were seen in the sham group.

Frontal Plane Kinematics

We found significant improvement in frontal plane hip kinematics for individuals allocated into the PENS treatment group. A 4.6°decrease in hip adduction was seen between 29-47% of the SLS task (Pre: 14.97±1.63° Post: 10.35±1.20°) (Figure 7) and a 6.6°decrease in hip adduction was seen for 43-69% of the SDT(Pre: 24.10±0.74° Post: 17.54±0.81°) (Figure 8) No differences in trunk or knee frontal plane kinematics were seen in the PENS group. The rehabilitation group with sham electrical stimulation produced no changes in knee, hip or trunk kinematics for both the SLS and SDT.

Sagittal Plane Kinematics

Changes in sagittal kinematics were found following 4-weeks of rehabilitation with PENS in each of the two tasks. An increase in hip flexion was seen during the SDT for 10-42% (Pre: 19.09±11.10° Post: 25.90±11.59°) and 94-100% (Pre: 2.44±1.20° Post: 8.16±0.77°) of the task. A decrease in knee flexion was seen for 11-26(Pre: 41.49±7.22° Post: 34.76±6.99°), and 66-81(Pre: 53.33±18.14° Post: 44.17±7.23°) and 86-100%(Pre:

12.69±6.19° Post: 7.48±7.60°). of the SLS. (Figure 7) A 10.91° difference were seen in trunk flexion across the entire SDT (0-100%) in those in the PENS group (Pre: 14.58±2.58° Post: 3.67±0.91°).(Figure 8) No differences were seen in the Sham group for either task.

Discrete Variables

EMG

A significant time main effect was seen in VMO peak activation (Pre:197.85± 131.1, Post: 258.52± 149.88, P=0.42) and peak gluteus maximus activity (Pre:17.9± 8.3, Post: 12.0± 7.4, P=0.012) during the step down task. No significant group-main effects or group by time interactions were seen in EMG activity during either task between the PENS or sham groups.

Kinematics

No statistical improvements were seen in sagittal plane kinematic excursions in either group. (Table 2) There was a significant improvement in frontal plane hip kinematic excursion in the PENS group (Pre:17.51±4.5, Post: 11.02 ±6.39, P=0.04) during the step down task, with a large clinically meaningful differences (d=1.2(0.10, 2.30). A trend towards significance was also seen in single leg squat hip adduction in the PENS group as well (Pre:12.31±6.4, Post: 6.48 ±5.5, P=0.08), with a meaningful large effect(d=1.08 (0.00, 2.17).

Relationships between the pre-post changes in both muscle activity and kinematic excursions were evaluated in both tasks. Moderate correlations were seen in the single leg squat, between knee abduction and adductor AUC muscle activation (r=0.553,

P=0.032) and adductor peak activation (r=0.542, P=0.037). A moderate relationship was also seen with hip adduction and peak adductor activation (r=0.573, P=0.026).

During the step down task, an increase in gluteus medius AUC activation had a strong relationship with hip flexion (r=0.712, P=0.003). and a moderate relationship with knee flexion(r=0.635, P=0.011). There was also a moderate relationship between gluteus maximus AUC activation and trunk flexion (r=0.532, P=0.041).

Discussion:

The purpose of this study was to evaluate an impairment based rehabilitation program augmented with PENS on lower extremity muscle activity and kinematics in PFP patients. We found improvement in both frontal and sagittal plane hip kinematics and a decrease in muscle activity with individuals who received rehabilitation with PENS. Moderate relationships were also seen with changes in muscle activity and kinematics during the tasks. All of these participants did have an increase in self-reported function, strength, and range of motion, without differences being identified between groups.[35]

Clinicians have placed a great deal of focus on therapeutic exercises to address these strength, muscle activity and movement patterns. Strength focused rehabilitation has been found to improve lower extremity strength, decrease pain and improve subjective function. [18,36,37] However, gluteus medius strengthening programs have not altered muscle activity of the gluteus medius during stair tasks. [18] Traditional rehabilitation also did not improve the altered movement patterns in those with PFP. When specific tasks were implemented into the rehabilitation, there were improvements in those tasks; but the functional tasks tested in our program were not specifically

integrated into the therapeutic exercise program. Traditional rehabilitation including gluteus medius strengthening programs typically do not improve EMG activation during these functional tasks, suggesting additional interventions may be required to address these impairments. [18]

Both groups presented with similar baseline EMG activity across both tasks. While the sham group did not have any changes, we found a decrease in muscle activity in many of the lower extremity muscles in both tasks for the PENS group. With the noted improvement in lower extremity kinematics, we theorized that the decrease in activity may be related to changes in the neural drive. Improvements in the neuromuscular control of the hip abductors may require less motor unit activation to be recruited to complete tasks like squatting and stair use. While there were improvements in the kinematics for both tasks, the increase in efficiency of the muscular contraction may be due to the underlying neural reeducation with the precisely timed recruitment of the gluteus medius and VMO from the PENS treatment.

Previous studies are conflicting on changes in muscular activity following rehabilitation-based studies. While improvements have been seen, these studies often use healthy individuals and complete a greater duration of strength training, over 20 weeks. [38,39] Shorter studies in a pathological population have not produced changes in muscles activity of the quadriceps or gluteus medius muscles. [18,40] A proposed suggestion for the inconsistency in neural changes may be due to the population being assessed. PFP patients have been found to have inhibition of their quadriceps muscle and potentially may be an explanation for gluteus medius weakness. [41] Prospective studies have not found gluteus medius weakness in individuals before the development of PFP, suggesting

the weakness is a cause of the pathology and not a risk factor.[42] Inhibition to muscles besides the quadriceps should be examined in the future as to determine potential neurophysiological impairments in this population.

PENS has been previously found to improve gluteus medius activation by 2-fold and decrease hip adduction by 8° during a lateral step down task in PFP patients following a single application.[27,43] There was also an immediate increase in the duration of activation in the gluteus medius during the same task.[27] However, no differences were seen in either EMG or kinematics during a SLS task. We did see that 4-weeks of rehabilitation with PENS did produce improvement in both squatting and step down task, suggesting that long-term application of the modality may be needed to improve altered movement patterns. These improvements in frontal plane movements were similar to the decrease following a single intervention of PENS, with both improving hip abduction between 6-8°.

A 4.6-6.6° decrease in hip adduction across the task and a 5.8-6.6° hip adduction excursion were reduced follow rehabilitation with PENS. While strength training has not been consistently beneficial, real-time retraining programs have been another avenue to improve the altered movement patterns. Noehren et al.[26] conducted real-time gait retraining for 2-weeks with rehabilitation and found improvement in hip adduction and internal rotation while running. They found a decrease of 5°, which is similar to our reduction of 6° in both tasks.[26] However, their improvements were only seen within the trained task, as a reduction in hip adduction was not found during a SLS task. Willy et al.[25] saw similar results, as mirror training with the SLS improved squatting mechanics but not with a running task. Finding treatment options that have a carry-over effect on

multiple pain provoking activities may be one method to decrease the long-term presentation of PFP symptoms and improve the quality of life for these individuals.

It is of interest that those in the PENS group had improved hip adduction during both tasks, but not the sham group. Both groups had improved subjective function when assessed by the Anterior Knee Pain Scale and Activities of Daily Living Scale, as well as improvement in both current and worse pain levels.[35] There was also improvement in the gluteus medius strength, however no differences post-rehabilitation were identified between groups.[35] These improvements in subjective function and increased hip abduction strength did not seem to play a role on the altered movement patterns, as only those with the PENS treatment group noted improvement. The underlying mechanism of neuromuscular retraining may be one proposed mechanism for these altered movement patterns. PENS has been suggested to replicate neural drive that occurs during locomotion, due to the rhythmical contraction of the PENS.[44]

Recent attention has been placed on the role of the trunk during functional tasks in PPF patients.[9,45] Females have been found to have a 3.6° increased trunk excursions during tasks like the SLS.[9] We found similar amounts of trunk flexion between both groups during the SD task. However, post-rehabilitation differences were found in the PENS group, where participants reduced their trunk flexion by over 10° over the duration of the SD. Trunk flexion has been suggested to result as a protective mechanism for individuals who present with lower extremity weakness, such as with PFP.[45,46] If quadriceps weakness is present, an increase in trunk flexion decreases the external moment needed by the quadriceps to complete the task.[46] This adaptation may also play a role in reducing pain, as a decrease in quadriceps force may be accompanied by

changes in patellofemoral joint stress.[46] While we did not evaluate changes in quadriceps strength and trunk kinematics, there may be a potential relationship present in strength gains and improvements trunk movement patterns. Additional attention should be evaluated on the role on muscle strength gains and trunk kinematics during functional tasks.

We identified a moderate correlation with adductor muscle activity and increases in hip adduction and knee abduction pre to post rehabilitation. Altered activity of the adductors have been found in stair ambulation, as an increase in adductor duration of activation and linked to knee abduction moments in a PFP population.[47] Previous authors have suggested that an increase in adductor muscle activity may be a consequence of altered activity of the VMO.[47,48]While there is a large focus on the lateral hip musculature; there is little evidence on the role of the adductor muscles within this population. An increase in their activation may pull the hip into a more adducted position, reinforcing the altered movement pattern in this population.

There are some limitations of the current study. We conducted a RCT with a relatively small sample size, which may decrease the generalizability of our findings. Due to the heterogeneous presentation of impairments of PFP patients, a larger small sample size would provide additional insight into the effectiveness of this modality. Our participants also had substantial altered frontal plane movement during the functional tasks and a large sample size would allow potential sub analyses depending on severity of the task. We also utilized a strict inclusion criteria for this study, which may decrease the generalizability of our results to all individuals suffering from PFP.

Long-term follow up on these individuals would provide insight into the effectiveness on PENS during these functional tasks. While self-reported function has been tracked for the short-term following rehabilitation, measures of muscle function or movement patterns has not been evaluated following rehabilitation interventions. While outcomes of PFP treatment is less than optimal, [4] evaluating persistent changes in movement patterns following would provide insight into the use of PENS for PFP. Longitudinal tracking would also provide greater understanding on the chronicity of PFP, and appropriate ways to intervene if progression of muscle weakness, altered movement patterns or pain changes over time.

Conclusion

Significant differences were found in gluteal muscle activation and lower extremity and trunk kinematics in individuals who received rehabilitation with PENS. Utilization of PENS in conjunction with rehabilitation may be helpful for clinicians who commonly treat PFP. This suggests that a potential link between changes in muscle activity may be responsible for improved kinematics during common pain provoking activities.

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Table 2.1. Baseline anthropometric, subjective, and objective characteristics

Demographics	PENS (n = 8)	Sham (n = 8)	p-value
Age, yrs	23.0±6.0	23.5±4.0	.85
Height, cm	166.8±5.7	165.3±6.4	.62
Mass. kg	65.7±9.6	66.8±17.3	.88
Duration, months	28.0±30.6	24.5±31.3	.82
C-VAS	0.8±0.9	2.2±2.1	.12
AKPS	77.7±6.5	71.8±8.1	.13

Yrs= Years, cm=centimeters, kg=kilograms, C-VAS= Current Visual Analog Scale, AKPS= Anterior Knee Pain Scale

Table 2.2. Single Leg Squat Kinematics between Group Pre/Post Rehabilitation

Muscle	Group (Mean±SD) PENS Pre	PENS Post	Cohen's d Effect Size with 95% Confidence Intervals	Group (Mean±SD) Sham Pre	Sham Post	Cohen's d Effect Size with 95% Confidence Intervals
Knee Flexion	61.7±11.7	59.4±6.3	0.24 (-0.78, 1.26)	69.4±15.1	63.3±15.1	0.40 (-0.59, 1.39)
Knee Abduction	1.0±2.2	4.9±5.6	-0.94 (-2.01, 0.13)	0.4±8.4	0.1±8.4	0.04 (-0.94, 1.02)
Hip Flexion	51.5±22.9	41.9±9.3	0.53 (-0.50, 1.57)	66.5±16.2	50.5±16.2	0.99 (-0.05, 2.03)
Hip Adduction	12.5±6.3	6.2±5.2[a]	1.08 (0.00, 2.17)	13.3±10.0	8.0±10.0	0.53 (-0.47, 1.53)
Trunk Flexion	17.5±11.9	11.6±7.6	0.58 (-0.45, 1.62)	24.1±13.3	15.0±8.7	0.81 (-0.21, 1.83)
Trunk Lateral Flexion	0.5±1.7	1.5±1.8	-0.57 (-1.61, 0.46)	1.2±2.2	1.2±2.5	0.00 (-0.98, 0.98)

[a]: Significant difference between groups, $p<.05$

Table 2.3. Step Down Kinematics between Group Pre/Post Rehabilitation

Muscle	Group (Mean±SD) PENS Pre	PENS Post	Cohen's d Effect Size with 95% Confidence Intervals	Group (Mean±SD) Sham Pre	Sham Post	Cohen's d Effect Size with 95% Confidence Intervals
Knee Flexion	71.2±3.9	77.1±10.5	-0.77 (-1.82, 0.28)	71.8±10.5	74.3±5.1	-0.30 (-1.29, 0.68)
Knee Abduction	2.0±3.8	2.2±5.6	-0.05(-1.07, 0.96)	5.9±5.0	0.1±13.0	0.58 (-0.42, 1.58)
Hip Flexion	45.7±5.5	46.7±7.3	-0.16 (-1.17, 0.86)	41.5±12.6	39.4±11.4	0.17 (-0.81, 1.16)
Hip Adduction	17.5±4.5	11.0±6.3[a]	1.20 (0.10, 2.30)	11.7±5.7	7.9±10.6	0.45 (-0.55, 1.44)
Trunk Flexion	6.8±13.3	5.6±9.2	0.10 (-0.91, 1.12)	7.3±8.9	4.9±10.2	0.25 (-0.73, 1.23)
Trunk Lateral Flexion	1.6±4.3	4.7±12.0	-0.35 (-1.36, 0.71)	0.4±3.4	0.2±3.8	0.06 (-0.92, 1.04)

[a]: Significant difference between groups, $p<.05$

Figure 2.1 Baseline PENS and Sham Single Leg Squat Muscle Activity

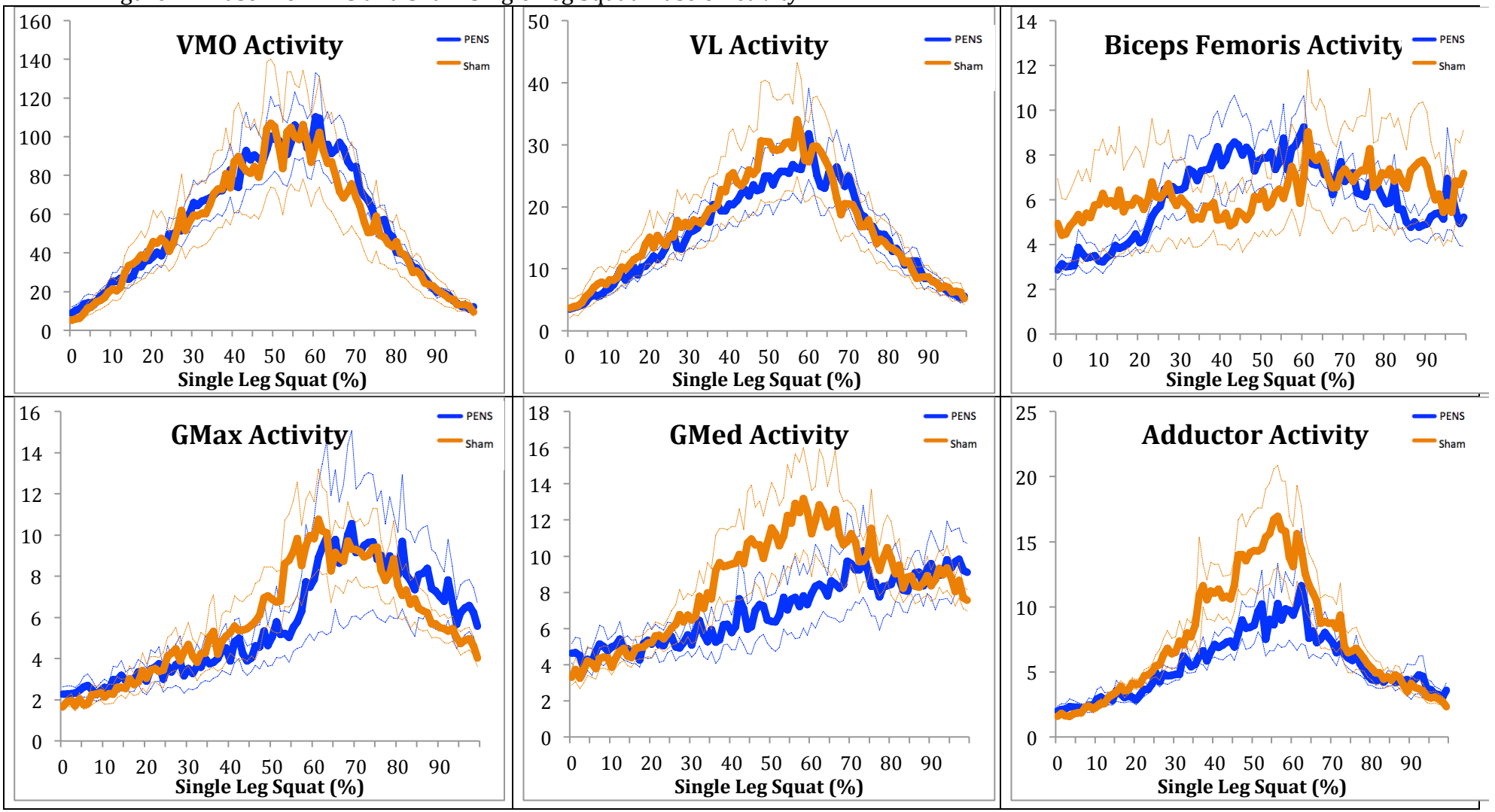


Figure 2.2 Baseline PENS and Sham Single Leg Squat Kinematics

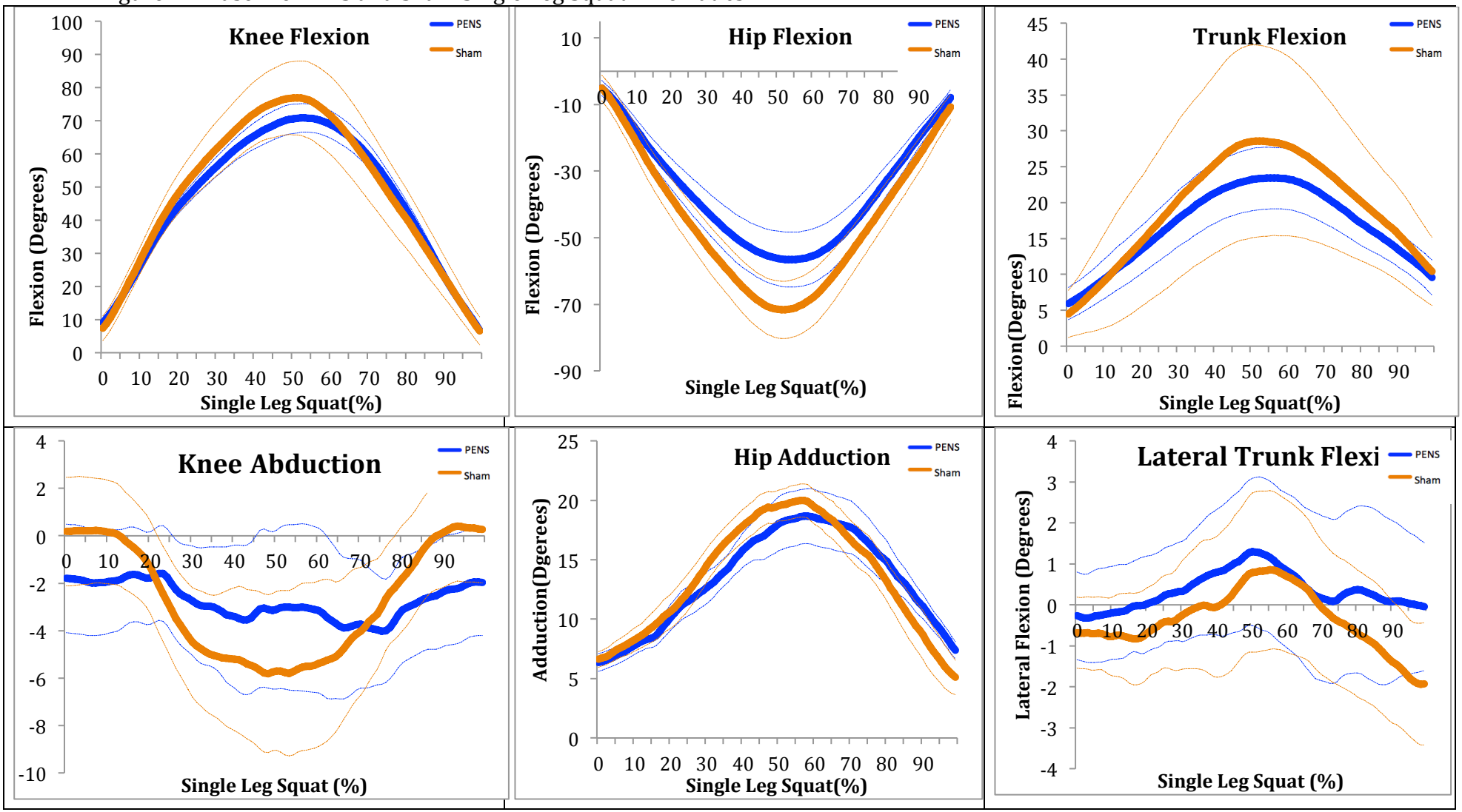


Figure 2.3 Baseline PENS and Sham Step Down Muscle Activity

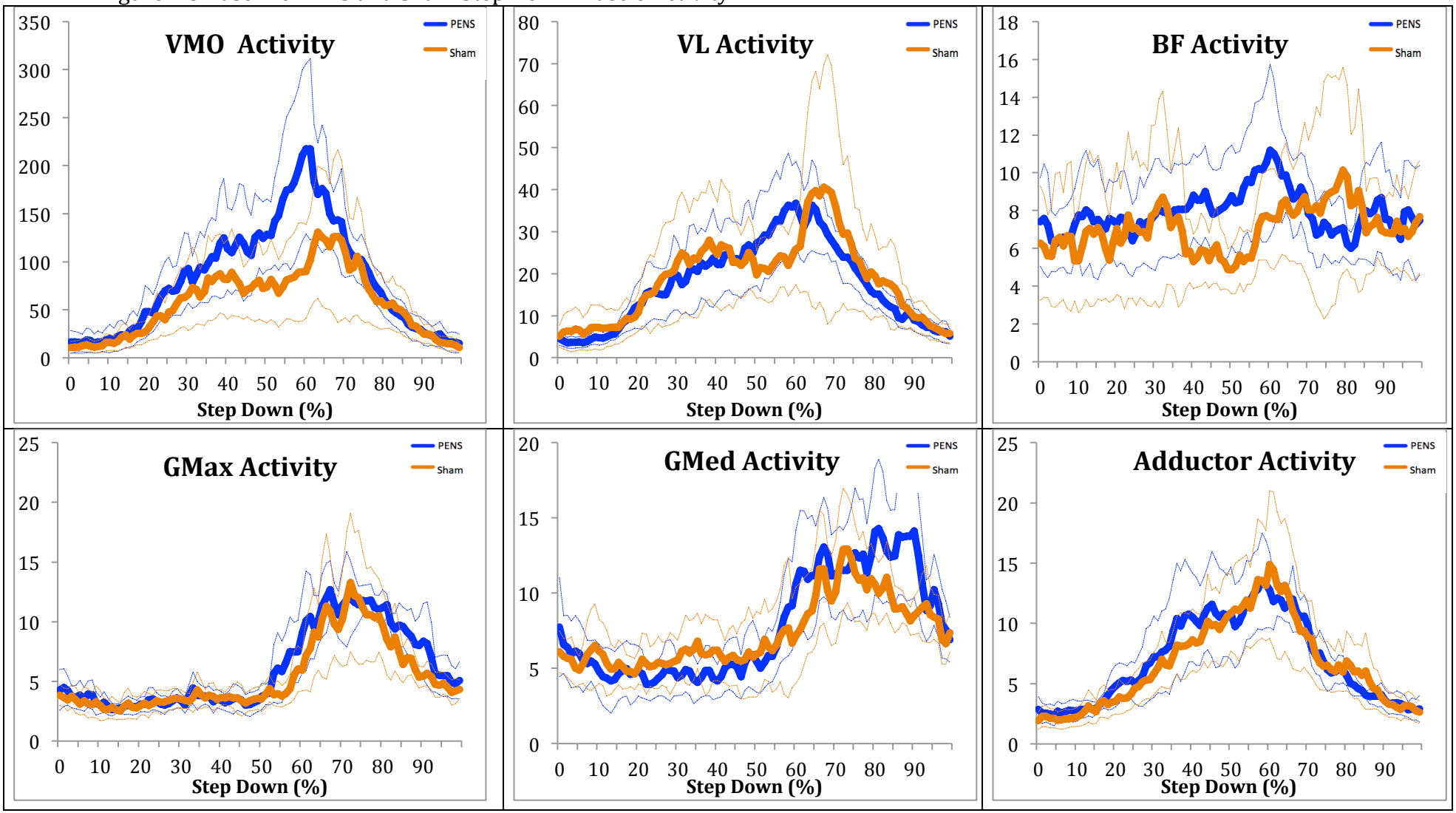


Figure 2.4 Baseline PENS and Sham Step Down Kinematics

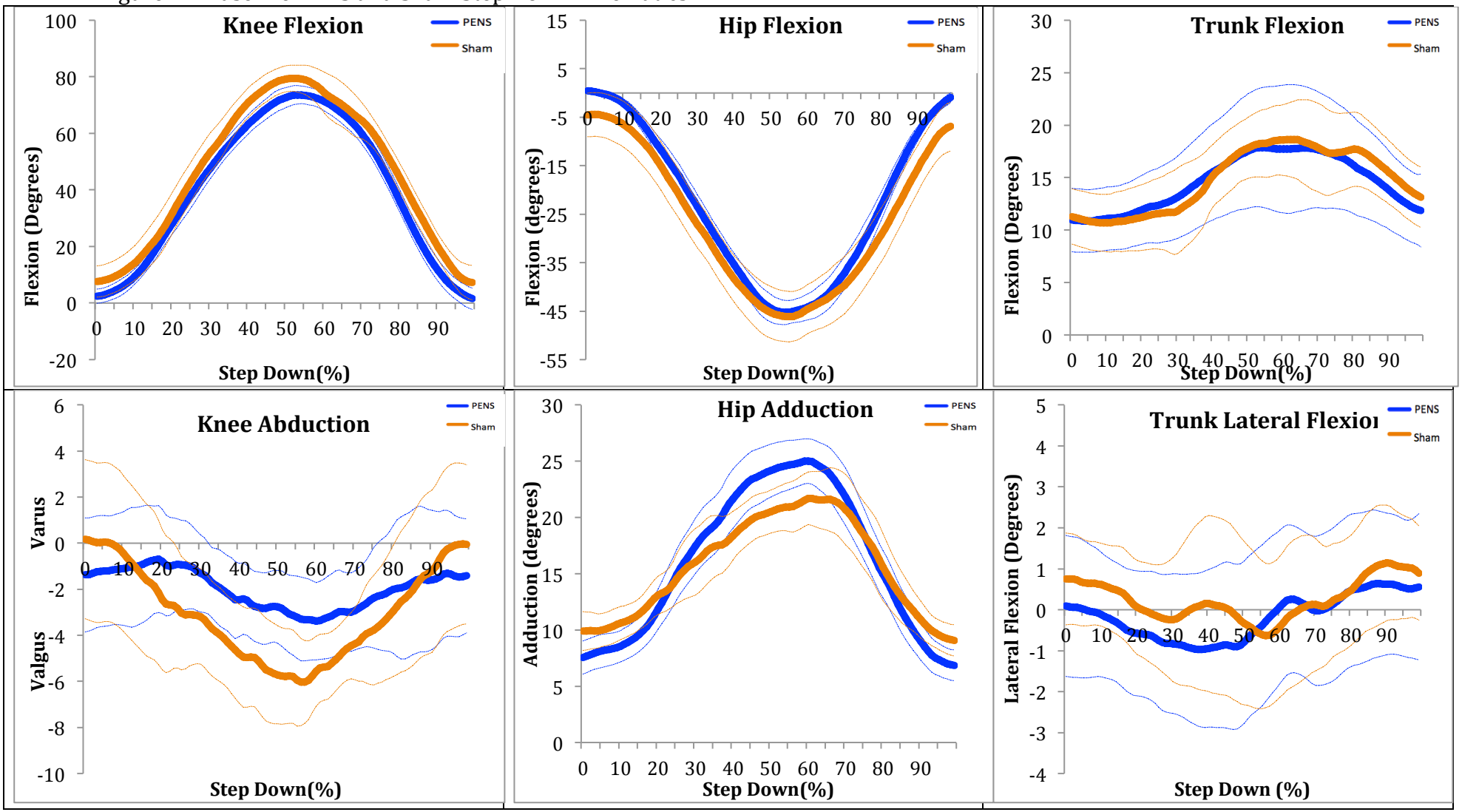


Figure 2.5 Pre Post-Rehabilitation with PENS Single Leg Squat Muscle Activity

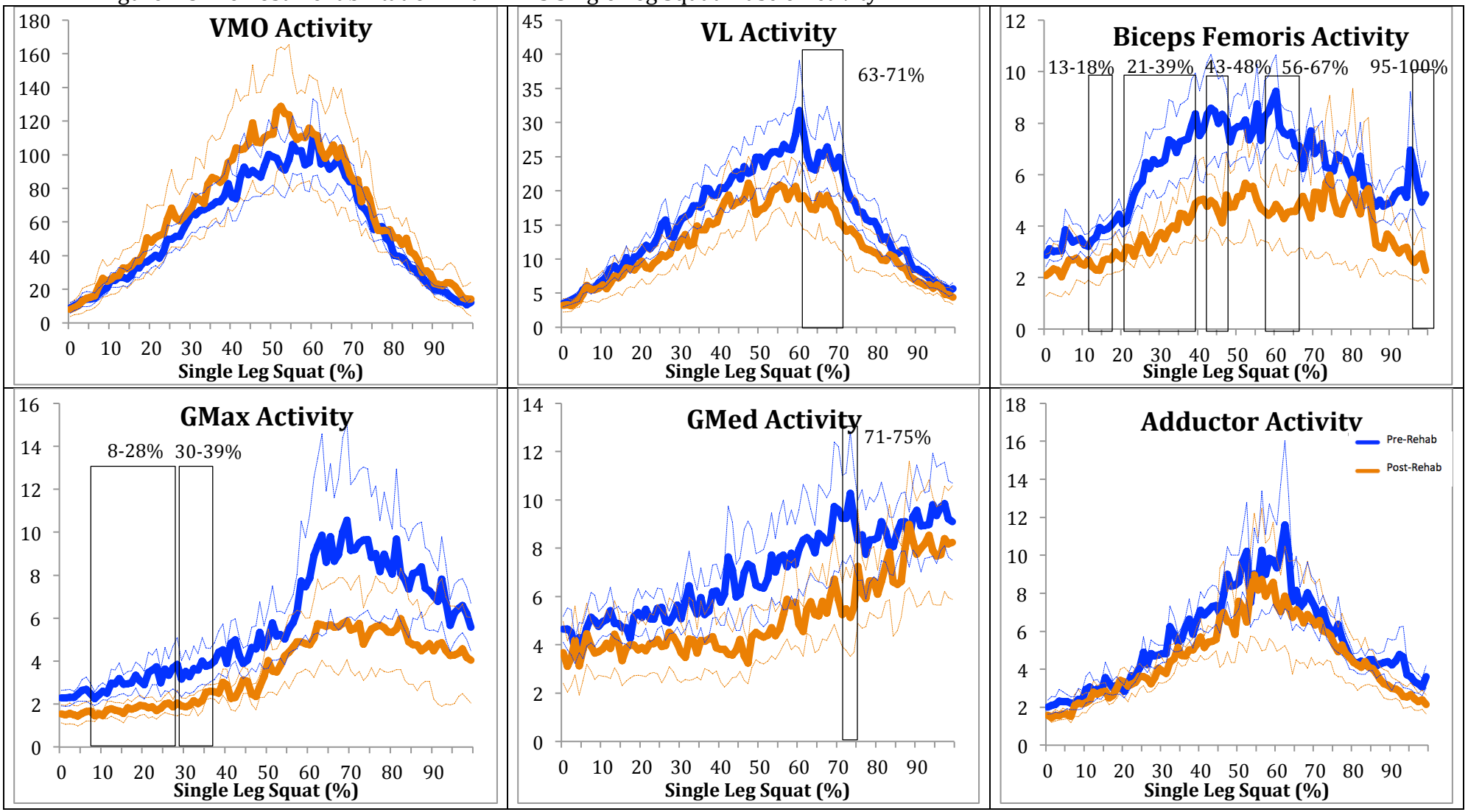


Figure 2.6 Pre Post-Rehabilitation PENS Step Down Task Muscle Activity

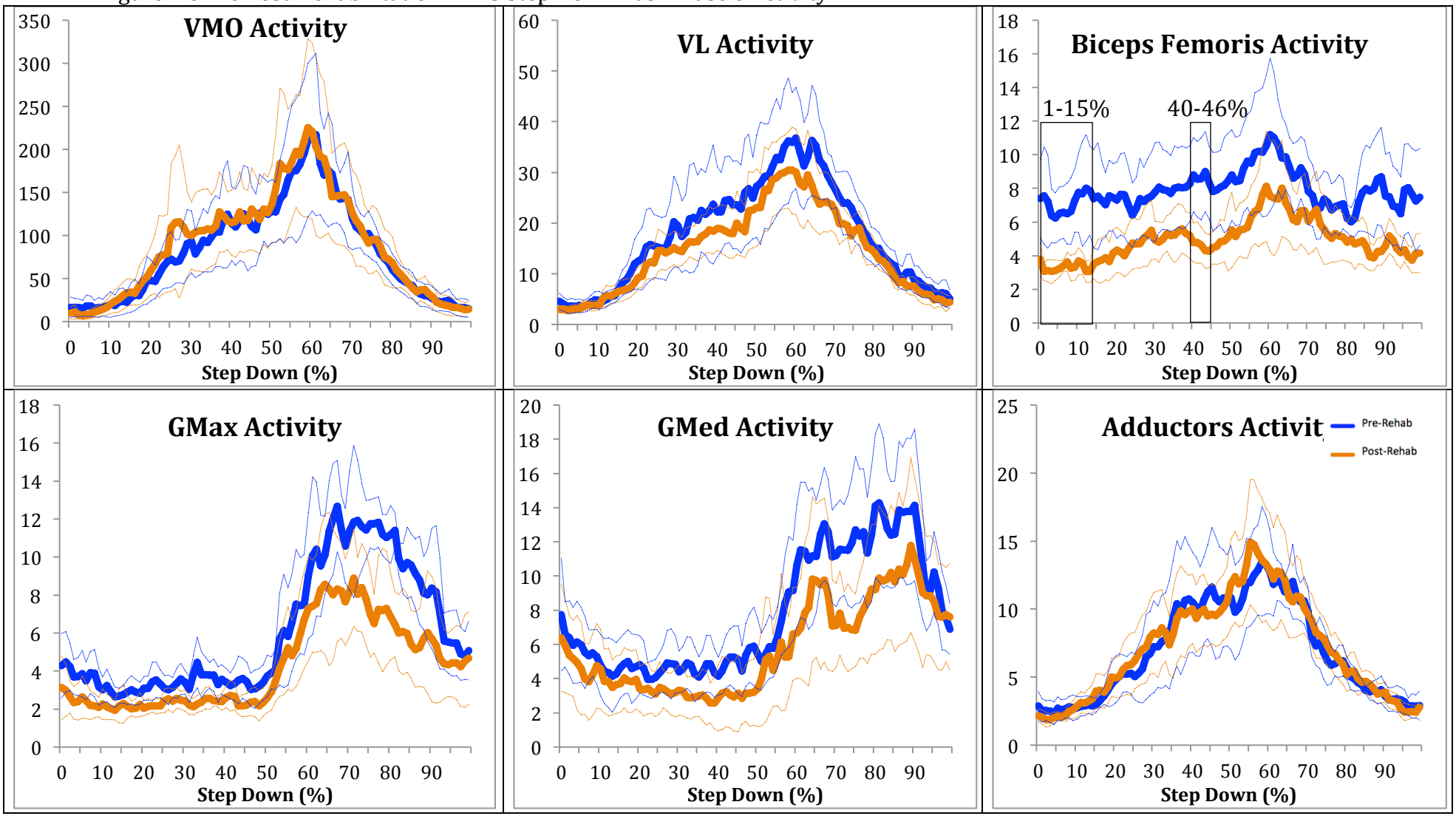


Figure 2.7 PENS Pre Post-Rehabilitation Single Leg Squat Kinematics

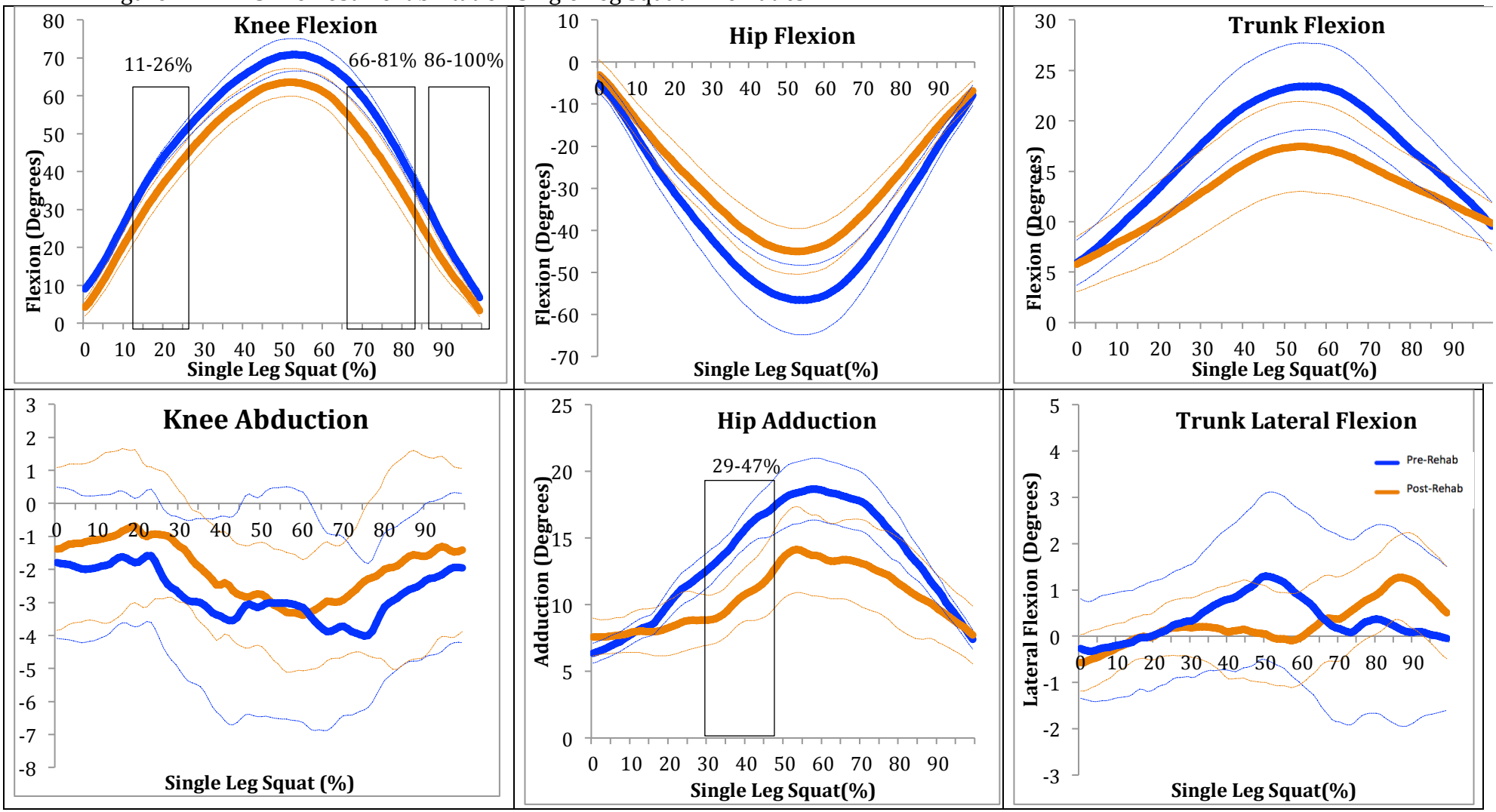
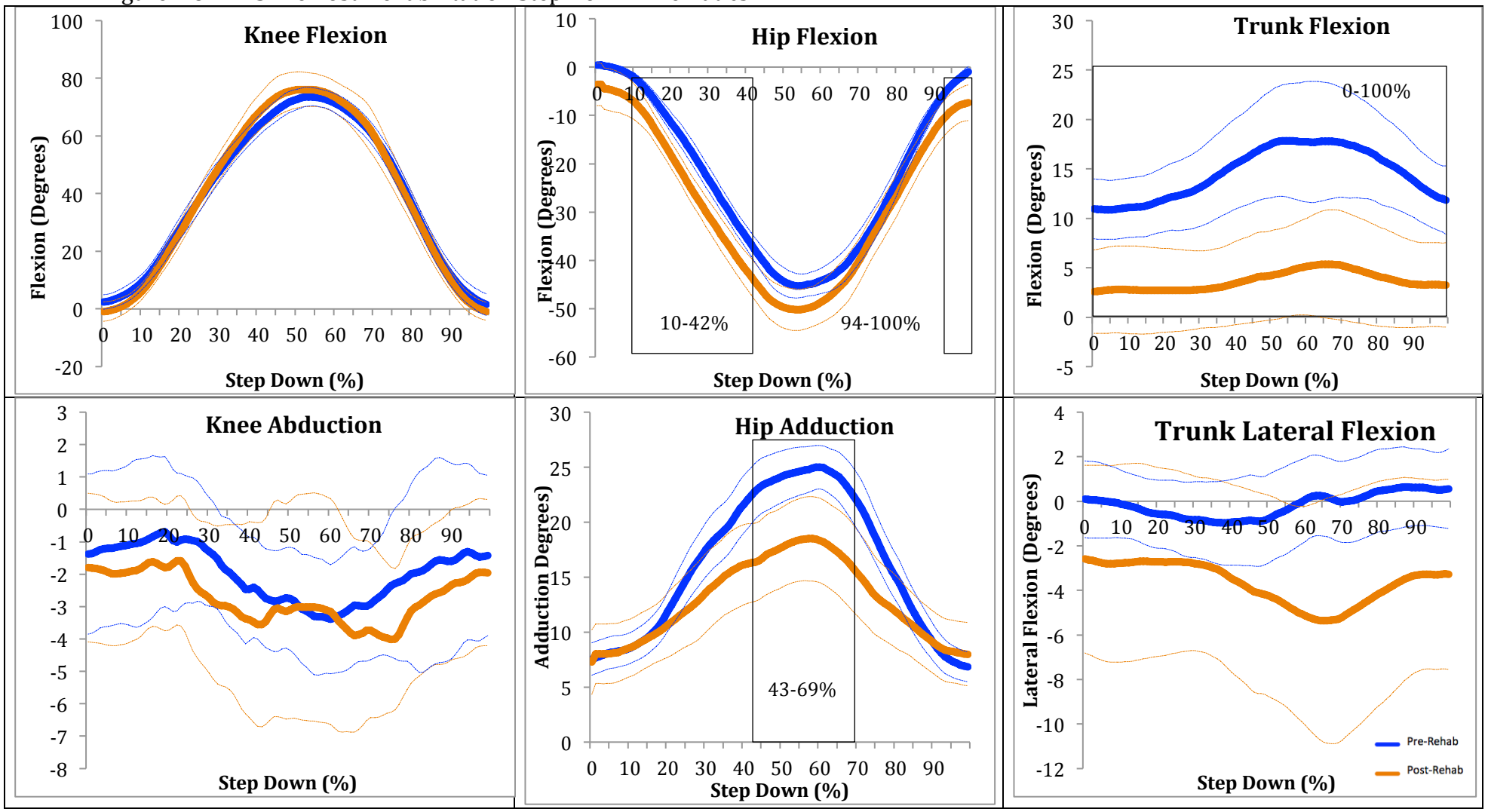


Figure 2.8 PENS Pre Post-Rehabilitation Step Down Kinematics



SECTION II: MANUSCRIPT III

EFFECT OF REHABILITATION WITH PATTERNED ELECTRICAL NEUROMUSCULAR STIMULATION ON JOGGING KINEMATICS, KINETICS, AND EMG IN PATIENTS WITH PATELLOFEMORAL PAIN

Abstract

Context: Altered kinematics, kinetics, and EMG activity are seen during gait in individuals with PFP. The chronic repetition of these impairments may be one explanation for the long-term deficits experienced by individuals with PFP. Use of patterned electrical neuromuscular stimulation (PENS) has been found to improve altered kinematics and EMG during stair tasks, but more challenging tasks, such as jogging, have not been evaluated. **Objective**: To determine the effect of a 4-week rehabilitation program with PENS on jogging kinematics, kinetics and EMG in individuals with PFP. **Design**: Double-blinded randomized controlled trial. **Settings**: Laboratory. **Patients or Other Participants**: 16 females with PFP (Age: 23.3±4.9 years, Mass: 66.3±13.5kg, height 166.1±5.9cm). **Main Outcome Measures:** Lower extremity kinematics, kinetics, and muscle activity were evaluated during jogging before and after a 4-week impairment based rehabilitation with or without electrical stimulation. Group means were plotted across the entire gait cycle with 90% confidence intervals for all dependent variables in both the frontal and sagittal plane. **Results:** No baseline demographic differences were found in participants between the two groups. A significant difference was found at baseline between groups, as those in the PENS group had a 2-fold increase in adductor activity in 96-100% of the jogging task. Participants who received rehabilitation with PENS had a 5.8° decrease in hip adduction motion for 88-100% of the task and a 47% decrease in adductor EMG activity for 93-100% of the gait cycle. A 2.7N/kg reduction in vertical ground reaction force was seen in the sham group for 16-28% of the stance phase. **Discussion** We found a decrease in hip adduction in the final phase of the swing phase before initial contact in individuals with PFP. Improving the position of the limb before initial contact may decrease the magnitude of excursion during a jogging task.

Word Count: 295

Key Words: Gait, Movement Patterns, Muscle Activity

Introduction

Patellofemoral pain is one of the most common pathologies treated within sports medicine clinics. [1,2] It is seen in both active and adolescent populations, with females twice as likely to develop this chronic condition. [3] It often presents with retro or peri patellar pain during weight bearing activities that load the patellofemoral joint, such as jogging. One of the challenges with PFP is the chronicity of the pathology; with recurrent rates as high as 91% up to 16 years following their initial diagnosis. [4,5]

With these high recurrence rates, it is essential that clinicians identify factors that influence the development and progression of PFP and provide appropriate treatment. Altered lower extremity kinematics is one such factor that has been seen in females with PFP. [6,7] Previous research has found an increase in hip adduction and internal rotation during gait tasks among PFP patients. [8-11] This suboptimal kinematic movement pattern has been theorized to increase stress placed on the patellofemoral joint. [6,7] This joint stress is of concern when the frequency of repetition in activities such as jogging is taken into consideration for the integrity of the joint. With the longevity of PFP symptoms lasting for up to 16 years following initial diagnosis, the potential for exponential stress on the joint over time may lead to structural damage. This repetitive loading may be one of the explanations for the link between a history of PFP and the development of patellofemoral osteoarthritis. [12,13] These altered movement patterns need to be improved to minimize to the cumulative stress placed on the joint.

Clinicians and researchers often perform rehabilitation programs to help improve the factors related to PFP. [14-17] While these conservative treatments have been found to have positive short-term results, the long-term outcomes are less than optimal. Over half

of all PFP patients have reported they are not satisfied with their knee function following rehabilitation; suggesting modifications to the current standard of care may be warranted. [18] Novel treatments have been evaluated to improve the movement patterns in individuals with PFP with moderate success. [14-16] One of the limitations is that previous interventions only provide improvements to activities that are focus on during the treatment, and no crossover effects are seen in other pain provoking tasks. [14,15] Use of electrical stimulation is one treatment option that has been found to improve movement patterns and muscle activity for functional tasks in females with PFP. [19,20] However, the tasks evaluated have been laboratory-based measures, such as a step down task and single leg squat. It is currently know how use of this modality with rehabilitation can influence more functional tasks such as jogging in individuals with PFP. Therefore, the purpose of this study was to evaluate the effect of PENS in conjunction with a 4-week impairment based rehabilitation program on lower extremity kinematics, kinetics and EMG during gait in individuals with PFP.

Methods:

Study Design

We performed a randomized controlled, double blinded study to evaluate the effects of a 4-week supervised rehabilitation program with or without patterned electrical neuromuscular stimulation on knee, hip and trunk kinematics, kinetics, and EMG activity of the vastus lateralis (VL), vastus medialis oblique (VMO), gluteus maximus (GMax), gluteus medius (GMed), adductor longus (Add), and biceps femoris (BF) during jogging in females with patellofemoral pain. This study was part of a larger laboratory study that evaluated lower extremity function and neuromuscular control during a variety of

functional tasks. [21,22] The study was approved by the University's institutional review board and all participants completed informed consent prior to study participation.

Participants

Sixteen females with PFP were recruited from the university and local community and participated in this study. Participants were included if they were between the ages of 18-40, had non-traumatic retro- or peri-patellar pain for at least 3-months with 2 or more of the following activities: stair ambulation, kneeling, jumping, squatting, running, palpation to the patella or contraction to the quadriceps. Participants were also required to complete the Anterior Knee Pain Scale and score <85/100 for enrollment. Those participants whom met this inclusion criterion were also evaluated by a certified athletic trainer to confirm PFP diagnosis. Exclusion criteria included history of knee surgery, ligamentous instability, additional sources of anterior knee pain, injury to lower extremity or low back within the previous 1 year, or neurological conditions. Participation exclusion also included electrical stimulation contraindications; biomedical implanted devices, hypersensitivity to stimulation, infection or muscular abnormalities to the lower extremity.

Neuromuscular and Gait Analysis

Kinematics, kinetics and surface EMG were collected simultaneously using Motion Monitor Motion capture software (Innovative Sports Training, Inc., Chicago, IL). Three-dimensional joint kinematics of the knee, hip and trunk were measured using a passive marker system using 12 Bonita Vicon cameras with a sampling rate of 250Hz. Reflective marker clusters were secured with self-adhesive tape over bilateral dorsal feet, lateral shanks, lateral thighs, lumbar, and thorax. (Figure 1). Digitization was completed

for C7, T12, L5, left and right ASIS, medial and lateral knee and ankle joints, and 2nd phalanxes. Ground reaction force data was collected with two imbedded treadmills (Bertec, Columbus, OH) and vertical ground reaction forces were sampled at 1000Hz. A 16-channel surface wireless electromyography system (Trigno EMG System, Delsys, Boston, MA) collected muscle activation at 2,000Hz. Wireless parallel bar electrodes (37mm X 26mm X 15mm) were placed over the muscle belly of the VMO, VL, GMed, GMax, BF, and Add following shaved, debrided, and cleansed skin.

A quiet, bipedal standing trial was conducted for 5-seconds for sEMG normalization. Participants jogged on a split-belt treadmill for 2.55m/s for kinematic and kinetic data collection. One trial of 30-seconds was collection to ensure a minimum of 10 full gait strides were recorded. Knee pain during the run was collected with a VAS immediacy following the trial.

Rehabilitation Protocol

Participants completed a 4-week rehabilitation program that focused on quadriceps, gluteus medius and core strengthening therapeutic exercises, stretching, balance, and movement retraining. Impairments such as muscle weakness and soft tissue restriction were addressed with a rehabilitation program that was continuously progressed for the duration of the study. The study was double-blinded, with the primary researcher (NRG) conducted all baseline and post measurements. A single certified athletic trainer(ANS) completed all rehabilitation sessions and progressed participants based off the participants self-reported difficultly of tasks and any reported pain to mimic clinical practice. This athletic trainer also administered all electrical stimulation treatments prior

to the therapeutic exercise for all participants. Participants were also blinded to allocation into the PENS or Sham treatment that was receive during rehabilitation.

Post-rehabilitation Collection

Participants returned within 96 hours from their final rehabilitation sessions to the laboratory for the post-rehabilitation assessment. Identical testing procedures were conducted from the initial assessment for kinematic, kinetic and EMG measures during the jogging task. VAS score was also completed following the jogging trial.

Data Reduction

All analyses were performed for the entire gait cycle for jogging tasks. Initial heel contact was defined with a threshold of vertical ground reaction force greater than 20N. Each gait cycle was reduced to 100 frames, with each frame representing 1% of the stride length.[23] Ten strides were averaged for each participant to evaluate knee, hip and trunk kinematics, kinetics and EMG activity of the VMO, VL, GMed, GMax, BF and, Add.

Knee, Hip, and Trunk Kinematics and Kinetics

Kinematic data was processed with a low-pass 4th order, Butterworth filter with a 14.5Hz cut-off frequency. Kinematics of the knee and hip were calculated using the Euler rotation method (Y, X, Z) to calculated flexion/extension, and adduction/abduction. Trunk kinematics were defined relative to the global axis system using Euler (X, Y, Z) to calculate flexion/extension and trunk lateral flexion.[24] Vertical ground reaction force (vGRF) was calculated in newton's (N) and normalized to the body mass (kg) of each participant. Kinetics were calculated with internal joint moments normalized to the height and mass(N*m/kg) of each participant.

Surface Electromyography

Data was filtered with a 10-500 band pass filter, a 50Hz notch filter, and with a 50-sample moving root mean square (RMS) smoothing algorithm. An input impedance of $>10^{15}$ W/0.2pF and a signal to noise ratio of 1.2uV was utilized. EMG was normalized to quiet standing and was plotted across the entire gait cycle.

Statistical Analysis

Frontal and sagittal kinematic, kinetics, and EMG were plotted across the entire gait cycle for jogging. Group means for each group and 90% confident intervals were plotted for the 100 data points across the gait cycle. Statistical significant was identified when confidence intervals did not overlap for 3 consecutive data points. Paired t-tests were conducted for VAS scores during jogging, with alpha set *a priori* at $P<0.05$.

Results:

We found no difference in baseline anthropometric or self-reported function between the PENS and sham group. When evaluating differences at baseline between groups, no differences were found in kinematics, (Figure 1) or kinetics. (Figure 2) A significant difference at baseline in adductor activity was seen in the EMG, with double the activation in the PENS group for 96-100% of the task.(Figure 3) There were no differences in pain levels during jogging in either group.

Following rehabilitation, we found a 5.8° decrease in hip adduction motion in the PENS group for the last 12% of the gait cycle. (Figure 4) No differences were found in frontal or sagittal plane kinematics across the gait cycle in the sham group. No differences in knee or hip kinetics were seen in either group following the rehabilitation intervention. A 47% decrease in the adductor muscular activity was seen for the final 8%

of the gait cycle in the PENS group when compared to their baseline activity. (Figure 6) We also found a 2.9 N/kg decrease in vGRF in the sham group for 16-28 % of the gait cycle, however there were no differences in the vGRF were seen in the PENS group. (Figure 7)

Discussion:

The purpose of this study was to evaluate the effect of rehabilitation with PENS on lower extremity kinematics, kinetics and EMG activity across the gait cycle. To our knowledge, this is the first study that examined the use of electrical stimulation with rehabilitation on lower extremity neuromuscular function during treadmill jogging in individuals with PFP. We did see an improvement in hip abduction motion and a decrease in hip adduction EMG activity during the end of the swing phase in individuals who received PENS with their rehabilitation program compared to those in a sham electrical stimulation group. No differences in self-reported function or strength was identified between groups following the 4-week rehabilitation program, as both groups improved self perceived function and increased their lower extremity strength.[21] Similar improvements were also identified in the PENS group, as they also decreased their hip adduction during a single leg squat and stair ambulation following the rehabilitation program.[22]

Following rehabilitation, a reduction in hip adduction motion during the latter portion of the swing phase (88-100%) in gait was found in the PENS group but not in the sham group. This is an interesting finding, as both groups improved their gluteus medius strength, without any significant differences between groups, however only those in the PENS group had an improvement in their jogging mechanics.[21] Those who received

PENS had a decrease of approximately 4° from their baseline values, and were at approximately 4° of hip adduction at initial contact. Healthy females have also been reported to be at 4° of hip adduction during the same task. [10] This decrease in hip adduction prior to heel contact may allow individuals with PFP to be placed in a more optimal position during stance, and bring the pelvis into a neutral position at heel strike. This change in lower extremity position may decrease the stress placed on the patellofemoral joint and minimize the extent of excursion during the task.

We found similar movement patterns between groups at baseline in frontal plane hip motion adduction during the stance phase (0-40%) of the gait cycle. However, it is difficult to compare the changes of the entire gait cycle to other research, as the majority of the evidence does not examine limb position during the swing phase. [10,25] Willson et al. did find differences in hip adduction between PFP and healthy females during a running task for initial contact and the majority of stance phase; however the swing phase was not reported. [10] It may be possible that differences prior to initial contact exist, however they did not report swing phase kinematics. Due to the limited research it is difficult to compare our findings with others on this improved frontal plane position prior to initiating a weight bearing activity. However, other pathologies who present with altered kinematics during functional tasks have identified similar trends, specifically individuals within the chronic ankle instability literature during both gait[26] and single-leg jump landing[27] tasks.

Many other studies have conducted rehabilitation programs in an attempt to improve lower extremity kinematics and kinetics with the PFP population. [14-16] Changes in kinematics have been found when implementing real-time feedback with mirror

biofeedback retraining during specific tasks that present with altered movements patterns. [14-16] However, no carry over is seen when these participants completed additional tasks as part of their overall therapeutic exercise program. While the role of motor learning may provide some explanation for those findings, we did see changes in a non-trained task, jogging. We believe this is the first study to identify improvement in functional tasks when a targeted intervention was not specific to the activity. While our rehabilitation program included some mirror retraining with squatting and stair tasks, jogging retraining was not included. The use of electrical stimulation that is delivered in a rhythmical pattern may be one explanation for these changes. The PENS was directed to the abductor muscle group and the VMO with the aim of re-educating these muscles. The alternating stimulus between the agonist and antagonist muscles has been suggested to stimulate muscle stretch receptors and motor neurons, which replicate spinal alterations that are seen during movement. [28,29] Thus, our results suggest that the addition of stimulation helped position the hip more optimally at heel strike.

No differences were seen in lower extremity kinetics during gait between the two groups. While we had a relatively small sample size, a great deal of variance is present in the two groups for both knee and hip kinetics. There may be a possibility that various strategies to complete jogging tasks may be present within this population. Ferber et al. found that individuals with PFP have large variability in gait kinematics during gait; however this theory has not been examined for lower extremity kinetics. [30] Ferber et al. found a range of 12° in genu valgum angles between PFP patient strides during gait, all of which may result with different kinetic values with each stride. [30] Future research to

evaluate the possibility of kinetic variability in the PFP population during functional tasks would provide additional information for clinicians who often treat this condition.

We did see a 16.9% decrease in vGRF in the sham group, for 16-28% of the gait cycle. While there was no significant difference in pain levels between groups at baseline, those in the sham group had greater levels of pain running (1.3 units) when assessed by the VAS compared to the PENS group. These individuals also had a clinically significant difference in the reduction of VAS by 1.9 units following the rehabilitation program. We did not see any interactions between the groups from pre-post rehabilitation in either self reported function or pain levels at rest.[21] These differences raise the question on causation; does pain reduction decrease vGRF or does a decrease in vGRF influence pain level? Caution should be taken, due to the small sample size included in this study when making inference on the changes in vGRF.

There was a decrease of 47% in adductor activation prior to initial contact in the PENS group. There may be a possibility that the decrease in adductor activity may have allowed the hip to maintain a more abducted position prior to initial contact. However, when we consider that no changes in kinetics occurred, it is difficult to make this link. It should be noted that a between group baseline difference was also present during a similar phase, which may be responsible for the change.

This study does have limitations that influence the findings of this study and may limit generalizability for clinical recommendations. First, we had a low sample size, which play a role in the large deviation in lower extremity moments and vGRF in the two groups. Secondly, we included individuals from the general population in this study and did not specifically recruit recreational runners. Individuals who have developed PFP

from running may present with different movement patterns than individuals with PFP that have pain while running. We also did not control for the strategy of running or shoe wear in our population either between subjects or between the pre and post-rehabilitation assessments. Recent evidence supports that rearfoot strikers have lower vGRF and muscle activity while running.[25] Lasting effects of the improved hip abduction during gait are also unknown, as long-term follow up for these variables are not present.

Conclusion:

The results of this study indicate that females patients with PFP who complete a rehabilitation program with PENS have a decrease in hip adduction prior to heel contact during a jogging task. Beginning the stance phase in a less adducted position may decrease stress placed on the patellofemoral joint and allows individuals with PFP to demonstrate a more normal movement pattern.

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Figure 3.1 Baseline Jogging Kinematics

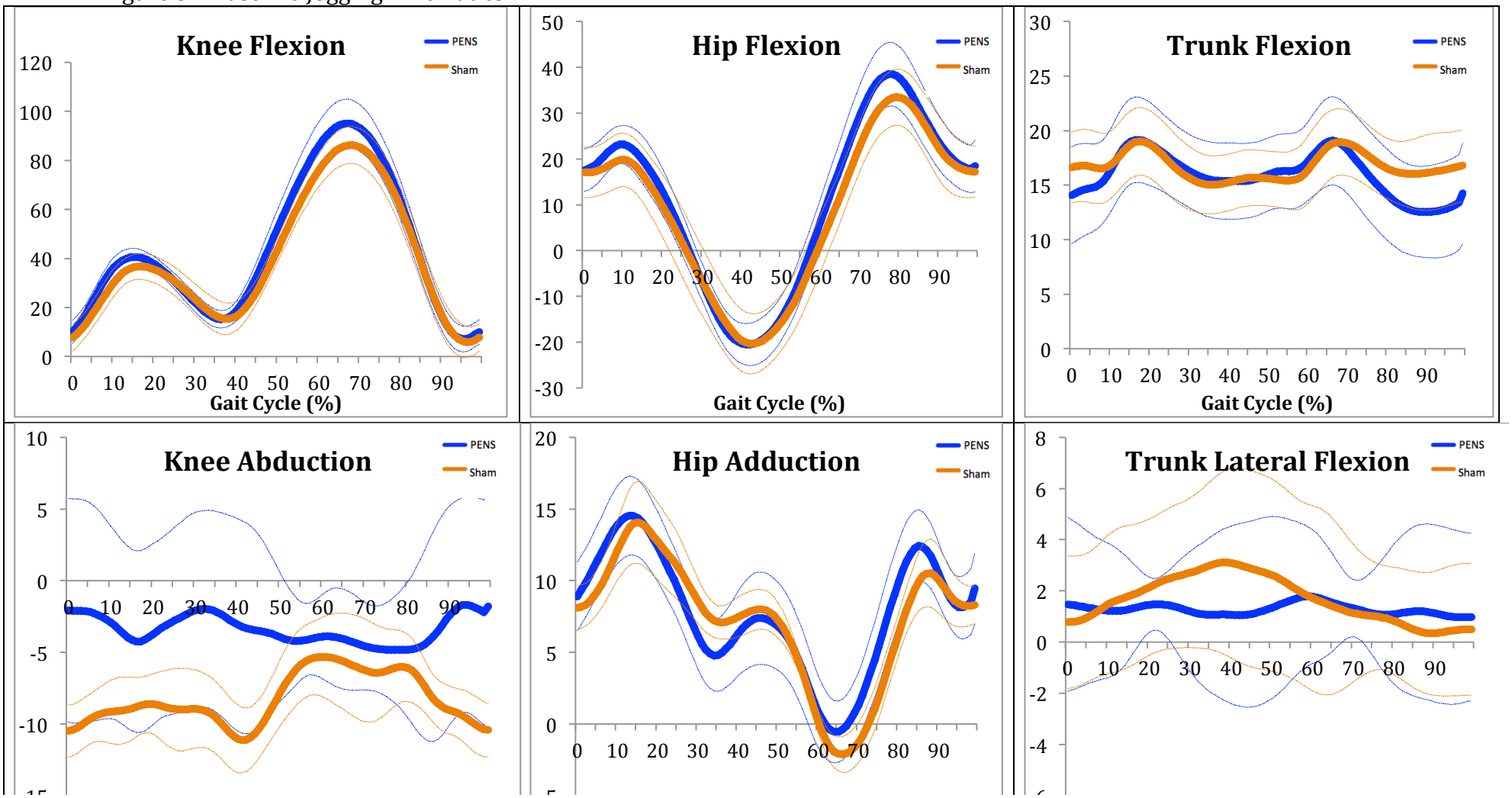


Figure 3.2 Baseline Jogging Knee and Hip Kinetics

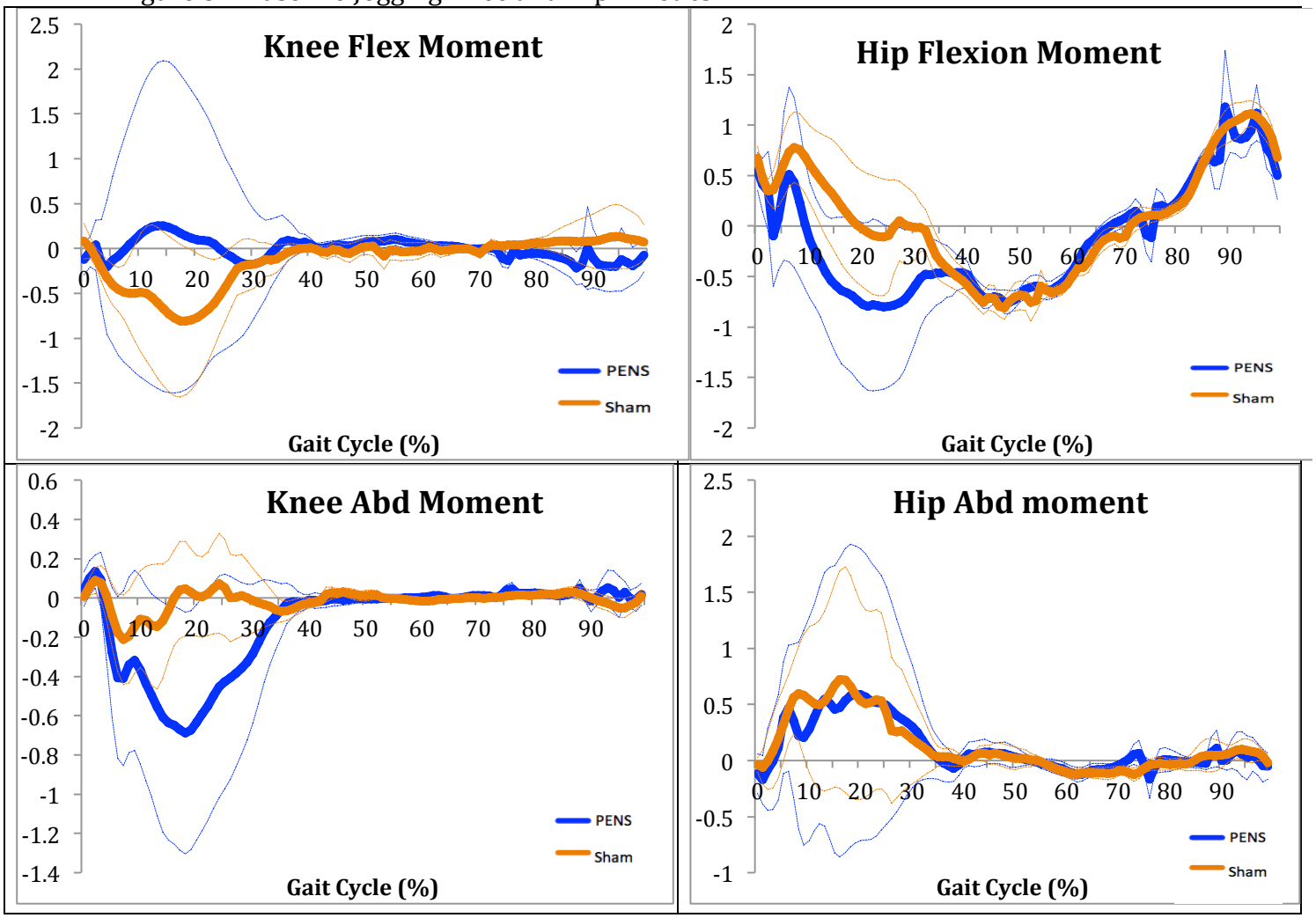


Figure 3.3 Baseline PENS and Sham Jogging Muscle Activity

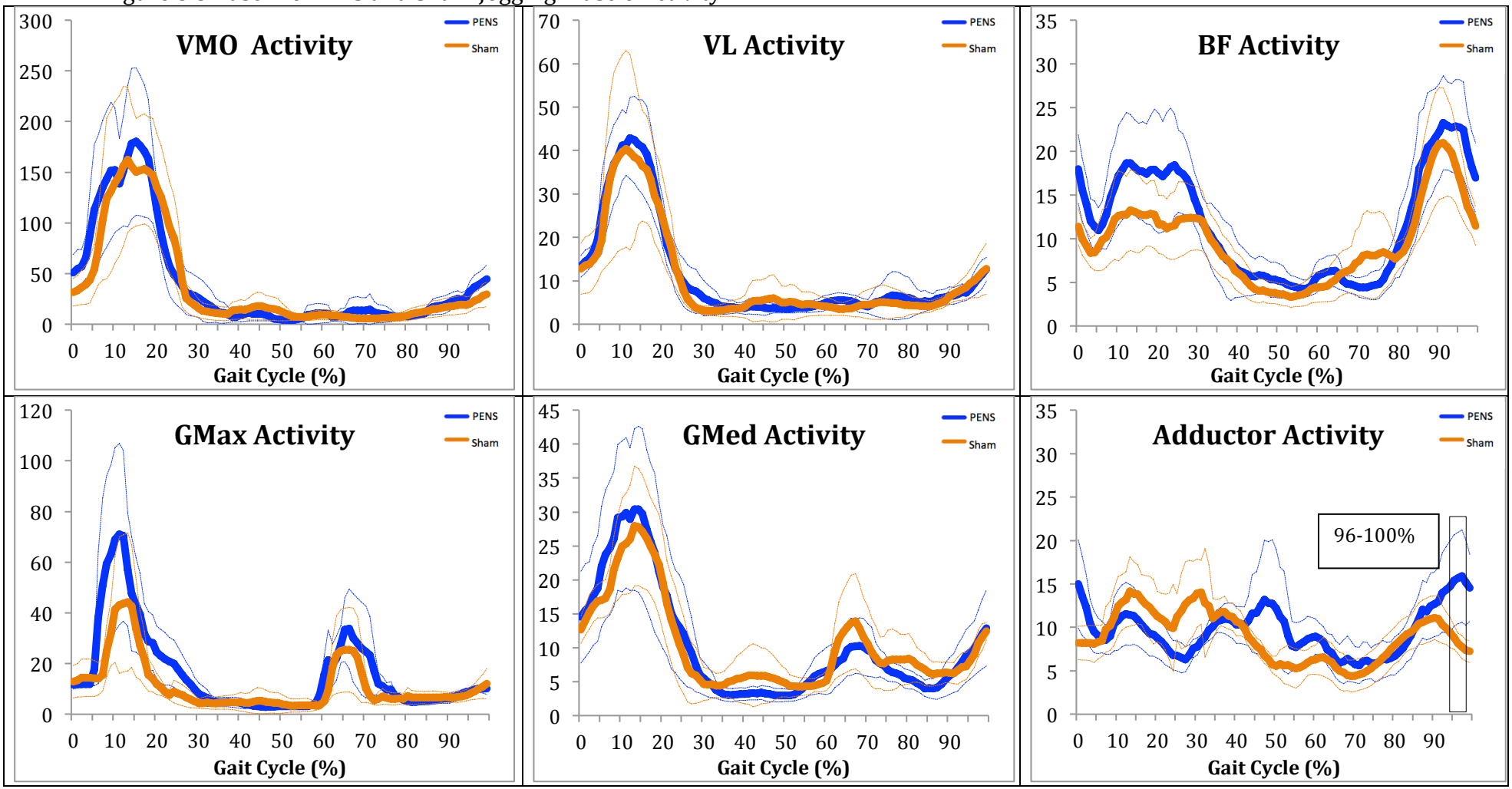


Figure 3.4 Pre Post Rehabilitation with PENS Jogging Kinematics

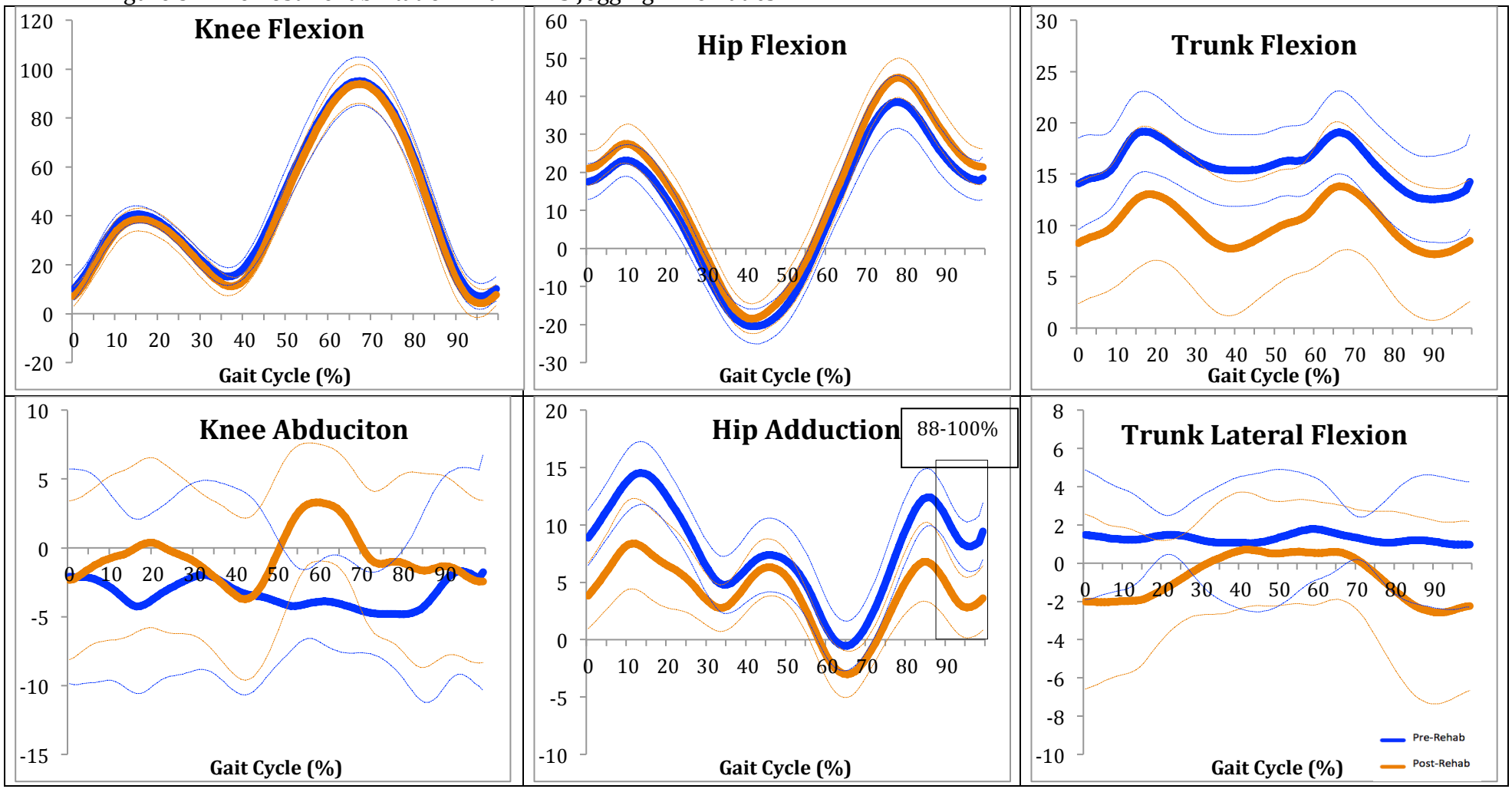


Figure 3.5 Pre Post PENS Jogging Knee and Hip Moments

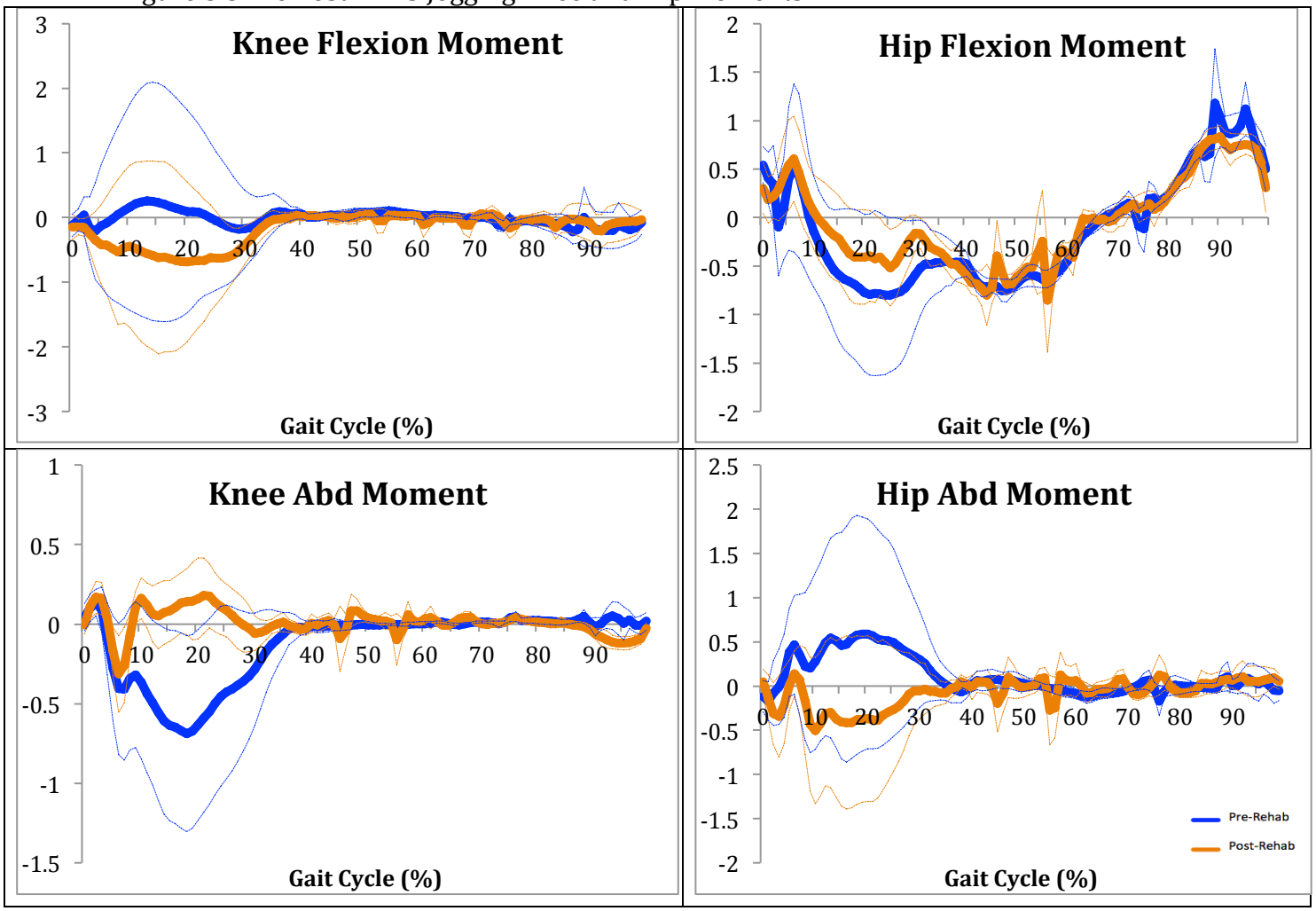


Figure 3.6 Pre Post Rehabilitation with PENS on Jogging Muscle Activity

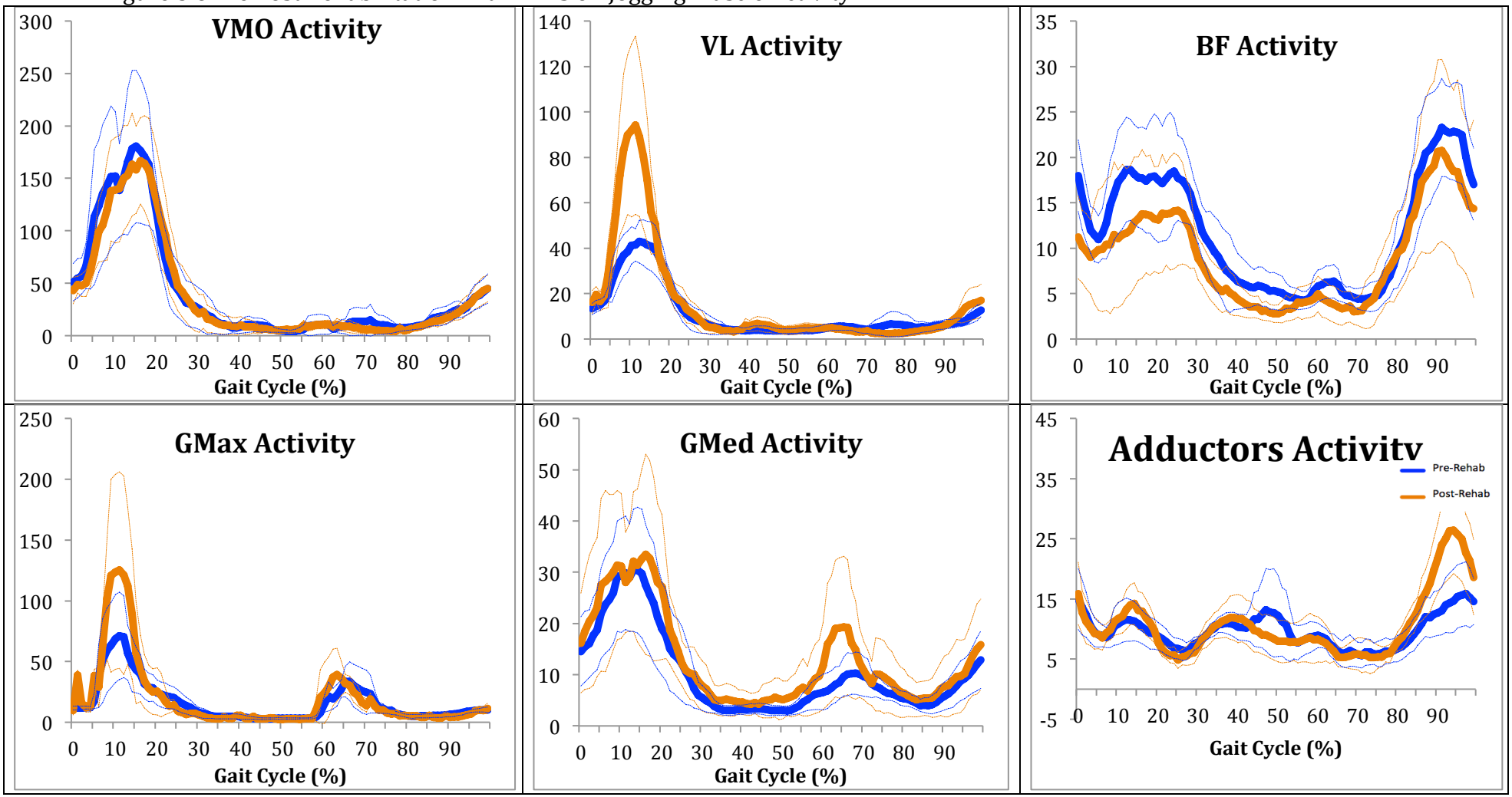
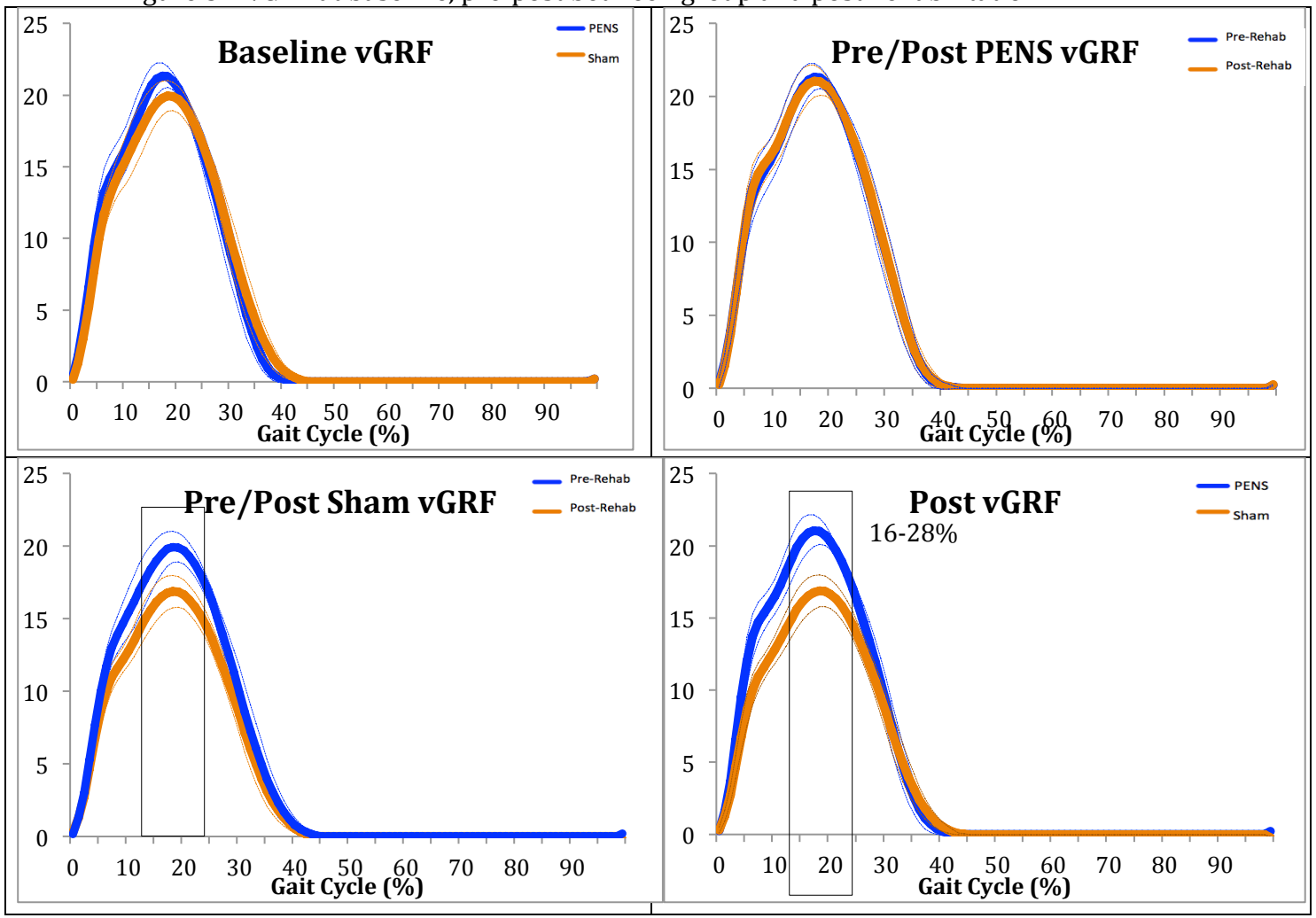


Figure 3.7 vGRF at baseline, pre-post between group and post-rehabilitation.



SECTION III: APPENDICES

APPENDIX A

The Problem

Statement of the Problem

Patellofemoral pain is a common orthopedic pathology that is seen within the active, general and military population.[1-8] The occurrence rates have been reported between 7.3 and 25% of those individuals seeking medical care receiving a diagnosis of patellofemoral pain.[1,2] It is often termed an activity limiting condition, as individuals diagnosed with PFP often have major implications on their activities of daily living.[3,4] Seventy four percent of those individuals with PFP will decrease or stop their activities due to increased pain.[8] PFP presents with pain to the retro or peri-patella during activities such as squatting, jumping, kneeling, prolonged sitting and running. The etiology of the condition is unknown, since there is no traumatic event but pain often lasts between months and years. [4]

While much uncertainty exists on the underlying cause of PFP, there has been a plethora of purposed reasons for those experiencing this pathology. Increased patella contract pressure has gained a strong amount of support to explain the reason for pain during so many functional activities. Soft-tissue restriction to the lateral reticulum and lower extremity muscles, such as the quadriceps, hamstrings and gastrocnemius/soleus complex have also been purposed.[9-11] Others suggest muscle weakness in the quadriceps, hamstrings and external rotators of the hips as the primary cause for PFP. The muscle weakness has been targeted during rehabilitation interventions by clinicians, however strengthening exercise often does not change altered movement patterns and the sub-

optimal long-term outcomes commonly seen with this condition.[17-19] One purposed explanation for these poor results may be due to altered neuromuscular activation between the vastus medialis, vastus lateralis and the gluteus medius. While the strengthening programs may improve force output, the firing patters recorded by electromyography often do not change.

Common treatment strategies often focus on quadriceps and gluteus medius strengthening programs. This originates due to the literature supporting muscle weakness in these muscles groups within the PFP population when compared to the general population. However, the long-term outcome for conservative treatment is often subpar. Quadriceps strengthening has been examined more extensively within the population, but those studies report recurrent rates as high as 96%. While proximal focused interventions to treat PFP have gained a great deal of attention, there is limited evidence evaluating the long-term effectiveness of reducing pain and improving subjective function. While these programs help strengthen the proximal and local musculature, there is minimal evidence that has examined interventions designed to improve the altered neuromuscular firing patterns; most studies aim to decrease pain and improve functional movement patterns during challenging activities.

The inability to correct or address a faulty firing or activation pattern of the hip and knee musculature may explain the poor outcomes in individuals with PFP. One purposed intervention to address the altered firing patterns is with a novel form of electrical stimulation, termed patterned electrical neuromuscular stimulation (PENS). PENS is a precisely timed electrical stimulation that is used to replicate firing patterns based off healthy EMG activity data. By inducing an electrically stimulated contraction

of key muscles has been shown to improve the firing pattern of the problematic muscles. The goal is to improved neuromuscular control and correct altered biomechanical movement patterns that occur with painful activities. To date, PENS has not been studied as part of a comprehensive rehabilitation program for PFP.

Therefore, the purpose of this study was to examine the effect of PENS treatments in conjunction with a 4-week impairment based rehabilitation program in individuals with PFP compared to a similar rehabilitation program without PENS (sham treatment). Main outcomes were 1) pain and self-reported function; 2) electromyography (EMG) activity and lower extremity kinematics during functional tasks; and 3) lower extremity strength.

Research Questions

1. Does self-reported function improve in patients with PFP after a 4-week intervention that incorporates PENS (experimental group) compared to a 4-week intervention that does not incorporate PENS (Sham group)?
2. Do clinical measures of ankle, knee and hip ROM, and strength improve in patients with PFP after a 4-week intervention that incorporates PENS compared to a 4-week intervention Sham electrical stimulation?
3. Does pain improve and does pain relief occur faster in a 4-week intervention that incorporates PENS compared to a 4-week intervention Sham electrical stimulation in patients with PFP?
4. Does peak EMG activity of lower extremity muscles during functional tasks such as stair ambulation, single leg squatting, walking and running change following a 4-

week intervention that incorporates PENS when compared to a 4-week intervention Sham electrical stimulation in patients with PFP?

5. Does muscle activation, as measured by EMG activity, of the vastus medialis, vastus lateralis and gluteus medius during functional tasks; such as stair ambulation, single leg squatting, walking and running change following a 4-week intervention that incorporates PENS compared to a 4-week intervention Sham electrical stimulation group?
6. Do lower extremity kinematics during functional tasks; such as stair ambulation, single leg squatting, walking and running change following a 4-week intervention that incorporates PENS compared to a 4-week intervention Sham electrical stimulation group?

Experimental Hypothesis

1. Self-reported functional improvement will occur in both treatment groups, with greater gains in the impairment rehabilitation program that utilizes PENS with the rehabilitation protocol.
2. Clinical measures of lower extremity ROM, strength and balance will improve in both groups. We expect increased strength in the experimental group, but we do not expect differences in ROM.
3. Pain reduction will occur in both groups, with greater pain reduction occurring sooner in the PENS group than in the sham group during the rehabilitation protocol.
4. The PENS group will have increased peak EMG activity during stair ambulation, single leg squat, walking and running.

5. The PENS group will have improved onset of activation and duration of activation will occur between the vastus medialis, vastus lateralis and gluteus medius during stair ambulation, single leg squatting, walking and running.
6. The PENS group will have an increase kinematics of their hip abduction and hip external rotation, decrease in knee abduction during functional tasks.

Assumptions

- Surface EMG is a reliable and valid method to assess muscle activity.
- Quiet standing is a reliable and valid method to normalize EMG.
- Subjects will provide accurate responses on the patient reported questionnaires and visual analog pain assessments.
- Repeated pain assessments will not influence subject responses on future assessments.
- Subjects will provide maximal effort during their rehabilitation sessions and testing sessions.
- Equipment will be functioning properly and will be calibrated for all subjects through the duration of the study.
- Electrode placement for the EMG and PENS electrodes will be consistent across the subjects during the duration of the study.
- Subjects will be provided detailed instructions for all testing procedures and will understand how to perform functional tasks, strength measurements and subjective assessment.

- Standardizing rate of speed for the stair ambulation tasks, single leg squat, walking and running will not influence ability of subjects to complete the task or pain levels.

Delimitations

- Number of subjects
- Participant inclusion will be a combination of both self-reported patellofemoral pain and clinical diagnoses from healthcare provider:
    a. Subjects were between the ages of 15-45yr and free of previous knee surgery, ligamentous instability, other source of anterior knee pain such as tendonitis, bursitis, plica, etc., history of neuropathy, presence of biomedical devices, muscular abnormalities, hypersensitivity to electrical stimulation, active infection around the quadriceps, hamstring, adductors or gluteus medius, or involved in a physician-prescribed rehabilitation program.
    b. Subjects were included if they report pain greater than 3 on a standard visual analog scale, pain lasting longer than 3 months, scored less than 85 on the anterior knee pain scale and report pain with at least three of the following activities to qualify for this study: stair ascent or descent, running, kneeling, squatting, prolonged sitting, jumping, contraction of the quadriceps and pressure on the patella.
- Maximal voluntary isometric contractions were utilized prior to testing to establish confirmation of electrode placement to minimize potential EMG cross talk for processing and data analysis.

- Subjects were matched by gender between the PENS and Sham group to ensure equal males and females in each group.
- Randomization between the PENS and Sham treatment groups were counterbalanced using a 4-block scheme.
- A metronome was used during the squatting tasks at a rate of 60 beats per minute.
- Subjects were advised to abstain from NSAIDs and medication during testing sessions and rehabilitation sessions to minimize altering pain levels during assessment.
- An average of 3 trials was utilized for the functional tasks, gait, strength, and lower extremity assessments.

Limitations

- Patellofemoral pain is great enough to enroll within this study, yet would not influence testing sessions or prevent the ability to complete rehabilitation sessions.
- Patellofemoral pain variability on functional limitations, duration of pain, and time of testing may influence rehabilitation exercises and group result.
- Performance of the rehabilitation progression was dependent on meeting specific outcomes but could have variability due to the clinician.

Significance of the Study

PFP is a challenging pathology for clinicians to treat due to its heterogeneous patient population and plethora of functional limitations. While there have been many studies evaluating interventions to improve flexibility, strength, movement patterns, core, muscle activation patterns, or a combination of interventions, the long term outcomes for this

pathology are poor. Previous studies have produced specific improvements dependent on the focus of the program, however current research has identified specific impairments between sex and patients with PFP. The variability suggests the need for impairment based rehabilitation program for those with PFP. The utilization of PENS to the gluteus medius was used in conjunction with this impairment based rehabilitation program to examine its intervention on altered neuromuscular control of multiple lower extremity muscle activity patterns. We believe these interventions would produce improvements in both clinical measures (strength, range of motion, pain) but also in kinematics during functional tasks, which current rehabilitation studies have failed to change in this population.

APPENDIX B

Literature Review

Introduction

Patellofemoral pain is chronic condition that affects almost 8% of the general population within the United States.[1] The prevalence is even greater within athletic and military populations, with over 25% of all reported diagnoses in sports medicine facilities and running clinics being PFP.[2,3] While this condition is a common pathology seen within a diverse population, the etiology is unknown. Current research suggests that individuals with PFP have altered loading on the patellofemoral joint.[4] While multiple factors have been purposed to contribute to the development PFP, the presentation of symptoms is fairly common; peri- or retro patellar pain during functional activities such as running, squatting, jumping, and prolonged sitting.[5-7]

Individuals who are diagnosed with PFP have many consequences on their quality of life and chronic long-term knee pain. Over 74% of individuals with PFP modify or cease activity due to their knee pain.[8,9] The concern for decreased activity due to PFP is compounded with the chronicity of pain, which has been cited to persist for over 5 years following the initial diagnosis.[8,10] A linear relationship has also been found between the amount of physical limitations with levels of anxiety and fear-avoidance during their activities.[11] While the result of repetitive long-term altered loading on the patellofemoral joint has not been clearly studied, there is growing concern at the potential progression from PFP to the development of patellofemoral osteoarthritis.[12]

Multiple impairments have been identified in patients with PFP, such as deficits in, range of motion, strength,[13] postural control[14], quality of movement during functional tasks and lower extremity anatomical or structural variations. While clinicians cannot intervene on all known impairments during the rehabilitation process, researchers have examined the effect rehabilitation has on improving the strength, movement patterns and patient reported outcomes of those with PFP. However, the long-term outcomes of rehabilitation are less than optimal, current evidence supports that fewer than 30% of individuals who have PFP will be become pain free following rehabilitation. [15]

While the treatment of PFP has not been effective within the research setting, it should be emphasized that a disconnect between clinical practice and study design within PFP research studies exists. It is possible that this may be one of the explanations for the poor outcomes. The variance in previous study design on sessions per week, duration of rehabilitation, duration of treatment session, and exercises conducted varies vastly between studies.[16-18]Some studies attempt to address the majority of PFP impairments while others only examine strengthening of a single muscle group.[19,20]The majority of these studies closer resemble the latter study design, which does not mimic clinical practice and suggests the need for advancement in rehabilitation studies addressing PFP.

To complicate the treatment of PFP even more, emerging evidence has identified a heterogeneous presentation of impairments within individuals with PFP between sex and age. Altered movement patterns have been suggested to increase joint contact forces differently during a variety of tasks between females and males

with PFP.[6] Both sexes demonstrate increased hip adduction, while females present with increased internal rotation and males have altered pelvic movements. Long-term outcomes between adolescents and adults also vary, presenting the need for individualized treatment for those presenting with this chronic condition.[21]

Current Treatment for PFP

Clinicians who treat individuals with PFP should assess common impairments when establishing a rehabilitation program. Range of motion, strength, movement patterns, balance and core stability have all been identified to be less optimal within a pathological population compared to healthy controls. However, those with PFP do not always present with identical deficits, stressing the importance of individualized treatment plans. We suggest the need for a detailed assessment of these deficiencies with targeted interventions to improve both objective and subjective measurements.

Range of Motion

Range of motion deficits have been found within the PFP population for much of the lower extremity. Evidence has identified arthrokinematic restrictions in the quadriceps[22-24], hamstrings[22,23], plantar flexors,[22,24] IT Band/tensor fascia latae[22,25,26] and osteokinematic restrictions for the lateral retinaculum.[27]. The restriction in these associated muscle groups or anatomical structures may limit normal range of motion and place increased stress on the patellofemoral joint.[11] Clinicians should assess the patient's range of motion and perform appropriate stretching and mobilization techniques to improve these restrictions. Reassessment

should be conducted to evaluate the effectiveness of the stretching program and make modifications as needed.

Quadriceps tightness

Quadriceps tightness has been evaluated in both retrospective[23,25,28] and prospective[24] studies with consistent findings, those with PFP present with tightness when compared to healthy controls. This soft-tissue restriction is believed to increase the pull of the patella resulting in a superior migration, which increases stress placed on the patellofemoral joint during functional tasks[11]. Cross sectional studies have found those with PFP to have approximately 10° less knee flexion when compared to healthy controls.[11,23,28] Withrouv et al. identified that quadriceps tightness was a risk factor for the development in PFP, with those who developed the condition to have 8° less mobility.[24]

Quadriceps stretching has been a frequency treatment option in PFP rehabilitation studies over the last 20 years, either as an isolated treatment[29] or in conjunction with additional stretching and strengthen therapies.[30-32] Isolated quadriceps stretching has been found to improve quadriceps muscle flexibility, it has not been found to improve patient function.[29] More in depth rehabilitation programs commonly include lower extremity stretching exercises, including the quadriceps, however it is difficult to determine its benefit with the additional exercises.[30-32]

Treatment options for quadriceps stretching are traditional exercises utilized in clinical practice. Standing or prone positions with active or passive knee flexion to end ranges of range of motion should be utilized to improve flexibility. Peeler et al.[29]

found improved flexibility within 3 weeks when performing five-30 second repetitions daily. Variations of dynamic or proprioceptive neuromuscular facilitation stretching has yet to be examined within this population, as well as variation in the duration and frequency of stretching required to produce optimal results. Reliability of the quadriceps have been found to be excellent, with ICC values of 0.91, within the PPF population.[33]

Hamstring tightness

Hamstring flexibility has been examined within the PFP population with less concrete findings than other soft tissue restrictions. Tightness in the hamstrings have been theorized to prevent full knee extension, which can increase contract pressure on the patella.[11] There is also some concern that restriction in the hamstring muscle group may result in an increased force production in the quadriceps, which can also produce increased contact pressure on the patellofemoral joint. Like the quadriceps, the hamstrings have also been studied in both prospective[24] and retrospective studies.[11,22,23]

Hamstring has been identified to be present in those with PFP when compared to healthy controls in some studies[22,23], while it has not been identified in others.[24] Piva et al.[22] found those with PFP had a 9° deficit in their hamstring flexibility. Witvrouw et al.[34]prospectively examined individuals who developed PFP, yet hamstring tightness was not found to a significant predictors, as those who developed PFP only had a 3° restriction. However, it should be noted that differences in measuring hamstring restrictions vary between studies; some utilize a supine testing position with a straight leg raise task[24] while others use a seated knee

extension task.[23] No studies have evaluated isolated hamstring stretching programs on improving outcomes in those with PFP, however it is still a very common prescription within the rehabilitation literature.[17,30,32,34]

Hamstring range of motion assessment has produced high reliability between clinicians; Piva et al. found an interclass correlation value of 0.92 when assessing individuals with PFP.[33] In clinical practice, a variety of stretching positions have been utilized in rehabilitation programs, ranging from supine straight leg raise, supine 90° hip flexion with knee extension[35], to seated knee extension tasks.[36]

Plantar flexion tightness

Soft tissue restriction in the triceps surae complex has gained a great deal of attention recently, as researchers have placed a distal emphasis on the shank and foot in those with PFP.[37,38] Limited dorsiflexion due to tightness in both the gastrocnemius and soleus has been theorized to result in changes up the kinetic chain. Increased pronation from the subtalar joint can occur when there is a restriction in dorsiflexion, which can increase shank internal rotation, placing increased stress on the patellofemoral joint during functional tasks.[33,39]

While there are conflicting findings if those with PFP have tightness in their plantar flexors, recent results support the soft-tissue restriction.[22,24,40] Tightness in the triceps surae complex has been evaluated in both weight-bearing[22] and non-weight bearing assessment methods.[24] Those with PFP have been found to have 10° of limited gastrocnemius flexibility, and 8° in soleus flexibility when compared to healthy controls in a non weight-bearing assessment.[22] Restriction in both the

gastrocnemius and soleus have been suggested to provide unique information between those with and without PFP.[22] Weight-bearing gastrocnemius tightness has also been identified as a risk factor for developing PPF, with only a difference of 3° necessary to distinguish pathological and healthy individuals.[24] Reliability of non weight-bearing gastrocnemius and soleus measurements in those with PFP have been found to be 0.92 and 0.86, respectfully.

IT Band/ TFL tightness

Tightness in the IT band plays a unique role in those with those with PFP due to its lateral attachment to the patella.[41] It has been suggested that tightness in the IT band results in a lateral pull on the patella, placing it in a suboptimal position.[42] A relationship has also been found with IT band tightness and patella mobility in those with PFP.[41,43,44] Soft tissue restriction in the IT band has been found to be a common limitation in those with PFP and has been found to result in a decrease in medial patellar glide.[25,26,41,44] Tightness has also been suggested to affect contact pressure of the patella during functional activities.[43] IT band stretching in conjunction with traditional rehabilitation has been identified to greatly improve flexibility of the IT band when assessed by the Ober test.[45] Reliability of assessing IT band range of motion within a PFP population has produced excellent results, with an ICC value of 0.97.[33]

Lateral retinaculum

Articulation of the patella in the trochlear grove varies depending on the degree of knee flexion.[46] The patellar facets have a predictable pattern with which facet contacts the trochlear. However hypomobility or hypermobility of the patella

may increase altered pressure on the articular surface in a repetitive nature depending on individual's activity levels. These altered contact forces have been theorized to be a potential cause for the chronic nature of PFP and why pain-provoking activities vary during many functional tasks. Since hypo- and hypermobility of the patella can have an influence on osteokinematics, evaluating patella mobility should be performed during clinical evaluation and appropriate treatment should be provided.

Assessment of the patella should be performed to determine both its position within the trochlear grove and its mobility. Patellar positioning can be assessed as described by Herrington et al; 20 degrees of knee flexion (ensuring the patella is within the trochlear grove) and marks placed on the medial femoral epicondyle, lateral femoral epicondyle, and mid-point of the patella. [47] Two distances are measured; the distance between the patella tick mark and each individual epicondyle mark. [47] This method has been found to be reliability by experienced clinicians and has been used to identify a more lateral position in those with PFP.[47,48]Patella position should be equidistant to both femoral epicondyles, as differences greater than 5mm has been identified to alter function of the VMO. [49,50] Patellar mobility should be used to assess mediolateral mobility of the restraints on the patella. [51] The patella should be divided into four quadrants and should be glided medially from a starting rested position. [51] If there is greater than three quadrants of displacement the patella is considered hypermobile, while displacement less than one quadrant is considered hypomobile.[51]

Limited mobility of the patella should be assessed within all patients with PFP during the initial evaluation. This valuable information provides insight into utilizing patellar mobilization for a treatment option. Soft tissue restriction or scar tissue to the lateral retinaculum can prevent the patella position from being equidistant to the femoral condyles.[49,51] Loudon et al.[52] utilized patellar mobilization with a traditional rehabilitation program and found positive results when compared to a control group.

A decrease in lateral retinaculum and other restraints of the patella prevents precise tracking during functional movements. Without these restraints an increase in superior/inferior and medial/lateral, or any combination, can arise during movement. Clinicians have used a variety of bracing and taping methods to minimize excess movement with varying results. One of the most widely utilized methods has been McConnell taping, which uses superficial application of tape to pull the patella into a more optimal position. McConnell taping has been suggested to correct different suboptimal orientations of the patella; tilt (anterior or medial), medial glide, and rotation.[42]

Strength

Individuals with PFP have been found to often present with weakness to the quadriceps, gluteus medius and hamstring. The majority of these studies have evaluated females with and without PFP retrospectively and have identified that weakness of these muscles may be risk factors for developing PFP. While current prospective studies have questioned if hip weakness is actually a risk factor or a repercussion of the development of PFP itself, additional studies are need to

evaluate this in more depth.[53] It should also be noted that strength differences have not been identified in adolescents with PFP for both the knee and the hip.[54]

Quadriceps

The quadriceps have long been considered a focus for clinicians who treat PFP.[18,24,30,45,55-58] Weakness in knee extension has been both identified in pathological and healthy individuals, but also as a risk factor for developing the painful chronic condition.[55-57] Van Tiggelen et al.[55] and Duvigneaud et al.[56] both have found weakness in concentric and eccentric isokinetic testing at both 60°/sec and 240°/sec, suggesting that both those with PFP might have both strength and endurance deficits. Isometric knee extension has also been found to be a risk factor for naval recruits who develop PFP.[57] These findings are similar Lankhorst et al. who found knee strength when assessed by knee torque to be a risk factor for PFP in a recent systematic review.[59] Isometric and isokinetic testing differences are not the only measures of quadriceps force production, as those with PFP have decrease performance with both a vertical jump task[24] and a triple single leg hopping task.[60] Recent evidence also supports that weakness in knee extension torque is not just isolated to females as males also present with this deficit, suggesting the need for sex specific rehabilitation.[61]

Those with PFP have also been found to present with an inhibition of their quadriceps muscle, when assessed by the central activation ratio. Those with PFP were found to have approximately 20% inhibition of their maximal quadriceps force production when compared to healthy controls.[62] These impairments have been found to have over 10% more inhibition and almost a 150N decrease in isometric

knee extension when compared to healthy controls when assessed multiple times over three weeks. [63]

Torque production has not been the only assessment of the quadriceps atrophy in those with PPF, as muscle volume has been measured in both ultrasound and MRI settings. [64-68] Ultrasound imaging of the VMO have been found to be smaller in size in both males and females with PFP when compared to their healthy counterparts. [64,67,68] The pathological limb in those with PFP also had a smaller cross-sectional area of the VMO when compared to their non-pathological limb. [67] Similar findings have been found when examining quadriceps cross sectional area when assessed with MRI. The pathological limb demonstrated atrophy with compared to a non-dominate limb with a smaller quadriceps volume, smallest cross sectional area of the quadriceps, and a deficit when assessing the largest cross sectional area of the quadriceps. [65] These deficits were also present when these limbs were functionally assessed, with a decrease in torque production and hopping distance.[65]

Clinicians and researchers have frequently utilized a quadriceps strengthening programs when treating PFP, and it is often considered the "gold standard" of treatment. Quadriceps strengthening programs vary a great deal within the literature, using isolated quadriceps strengthening programs [19,20,34]and programs that use quadriceps strengthening in conjunction is additional exercises, such as hip strengthening[17,35,69], taping[70,71], bracing[72], balance[73], joint mobilization[74], core[17,30], patient education training. [30] The majority of these studies have produced positive findings following the conclusion of the training program, with both

decreases in pain and improvement in function. The long-term results have been inconclusive, as the majority of studies that conduct follow-up assessments have limited with poor results, with a decrease in pain but no change in function.[75,76] A systematic review by Kooiker et al.[77] did find benefits to a quadriceps-strengthening program when treating PFP, suggesting the need to continue targeting quadriceps weakness within this population.

Gluteus Medius

Gluteus medius weakness has been found consistently in the literature in females with PFP when assessed by hip abduction and external rotation,.[7,13,78-83] The gluteus medius' role has been found to have a positive relationship with the extent of hip adduction during running.[84] When evaluating hip abduction isometric strength, those with PFP have been found to have a 27% reduction in torque production.[57,80,81] This decrease in hip abduction strength has also been identified when assessed in both an eccentric[7,13] and concentric contraction.[13] Similar trends are seen in hip external rotation strength, with isometric deficits between 24-36%[80,81,83] and 23% in both eccentric and concentric.[13] While these deficits are noted in females with PFP, the same weakness has not been found in their male counterparts.[61]

Hip focused strengthen programs have gained a great deal of attention over the last decade, as the number of rehabilitation studies focusing on the hip has increased steadily.[17,18,30,35,36,58,85] Ferber et al.[58] examined a hip and core focused rehabilitation program to a quadriceps focused program, finding improved strength and function with a decrease in pain in both groups over 6-weeks. However, those

in the hip and core group had increased strength in hip abduction and extension, as well as having a significant decrease in pain sooner than the quadriceps only group.[58] Hip strengthening programs have also produced similar results when compared to a quadriceps program, with greater reduction in pain and greater functional improvement.[18] Dolak et al.[32] also found a significant reduction in pain sooner in patients who performed a hip focused program before quadriceps strengthening.

Additional Muscle Weakness

The literature supports both quadriceps and gluteus medius weakness in those with PFP, there has also been some attention placed on additional muscle weakness in a variety of studies, such as the hamstrings, hip adductions and hip flexors. Hamstring strength has the most support that those with PFP have weakness in both isometric hip extension and knee flexion.[57,78] Isometric knee flexion strength was also found to be less in those who went on to develop PFP.[57] Baldon et al. did find increased hip adduction during eccentric isokinetic testing.[79] Those with PFP have also been found to have a 14% decrease in hip flexion strength in their pathological limb when compared to their ipsilateral limb.[45]

Functional Tasks

Altered kinematics during functional tasks have been found in a variety of activities within individuals with patellofemoral pain, such as running, single leg squat, stair ambulation, and jumping tasks.[5,78,86,87] Females have been identified to have increased hip adduction and internal rotation, which may increase the stress placed on the patellofemoral joint with the majority of these tasks.[78,87] Males have also demonstrated increased hip adduction with afferent trunk movements.[88] These

impairments should be identified as faulty movement patterns and exercises to retrain movement patterns should be conducted for these individuals.

Strength training of the gluteus medius muscle would appear to be the initial logical step, due to its role in both hip abduction and external rotation. However, while strength training of the lateral hip musculature improves pain and strength, it has not transitions into changes in kinematics[17,18,31]. The underlying mechanism as to why strength training to a targeted muscle does not produce improved movement patterns has not been identified; clinicians should explore additional training programs to address the altered afferent movement strategies.

Both clinical based and biomechanical analysis within laboratory settings have been used to both quantify and qualify increased joint angles and quality of movement.[6] These evaluations have identified altered movement patterns within the pathological population that should be addressed within the rehabilitation process. Promising results have been seen with both short duration and long term retraining sessions. These positive results have also been found by utilizing a limited number of therapeutic exercises, presenting a benefit from minimal time needed to help those with PFP.

To understand the proposed benefit to gait retraining, it is important to understand some basic theory in motor re-learning. The use of mirror training provides assistant in developing changes in motor learning. Gentile et al. divides motor learning into two phases, explicit and implicit, both being required to change an individual's movement pattern.[89] The explicit phase provides the individual time to learn their current movement strategies and take feedback from the clinician to

make learn the appropriate movement strategy to complete the task.[89,90] Utilization of the mirror allows the individual to see their movement and provides immediate feedback when they make adjustments. Limitations in range of motion and strength might provide some insight into challenges completing this task and should first be addressed. Once the individual can perform the task correctly, repetition of successful trials should be performed to reinforce the correct movement pattern, the implicit phase.[89,91] During this phase, the individual should be challenged with both external forces (resistant bands used by Willy et al.[6] and Baldon et al.[30]) or slight variations in the task(depth of a squat or utilizing unstable surfaces).

Providing rehabilitation exercises that focus on proper movement patterns during common pain provoking activities has also become common in PFP rehabilitation studies.[6,30] These studies often utilize a mirror to provide immediate feedback to the patient to identify and modify afferent movement. As these patients progress, an external force is applied to exaggerate a faulty position that require the patient's to resist the force and perform the task with proper hip and knee movement.[6] This provides benefits two-fold, providing an eccentric contraction to the gluteus medius during a functional task and repetitive training to help introduce and develop a new movement pattern. Willy et al. found improvements in single leg squatting for hip adduction and internal rotation in those who conducted a hip-strengthening program with motor learning exercises.[6] However, the improvements in those participants did not carry over to a running task, which suggests training should be conducted on painful tasks for each individual.

Gait retraining during running in those with PFP, while limited, has produced promising results at improving afferent movement patterns. Willy et al.[92] and Noehren et al.[16] both conducted a 2-week program on gait retraining mechanics during running in those with PFP. Both retraining programs produced decreases in hip adduction, hip internal rotation and contralateral pelvic drop.[16,92] These kinematic changes have been suggested to decrease stress placed on the PFJ, which may minimize pain. This suggestion holds true, as pain was decreased following the training study in both groups by 86%[16] and 90%.[92] Pain reduction in these studies was also significantly greater than other traditional rehabilitation studies treating those with PFP[17,31]. Noehren et al. also found a decrease in both average loading rates and instant loading following the 2-weeks of training.[16] The most positive benefit of these two studies is the long-term retention of their gait retraining, as these individuals retained their improved hip kinematics for 1-3 months.[16,92]

Patient education has also been a recent addition to traditional rehabilitation programs with promising results. Rathleff et al.[93]compared patient education to patient education with exercise in one of the largest rehabilitation studies conducted on individuals with PFP. Patient education consisted of one-on-one education on pain management, strategies to minimize load on the painful limb, and proper pacing for activity.[93] While isolated education produced some decrease in pain, superior results were found in the group with the combination program.[93] A 2-year follow up was conducted and those in the combination group had a steady increase in self-reported recovery, with success as high as 44%.[93] This value is much greater than other long-term follow up studies, which have failed outcomes

and recurrent PFP symptoms in up to 96% of individuals.[8] Rathleff et al. also identified a dose-response between successful outcomes and adherence to exercise, stressing the necessity of rehabilitation in those with PFP.[93]

Additional Potential Factors

A multifactorial approach for treating PFP has been suggested by researchers for clinical treatment, due to the heterogeneity of impairments for these patients. This suggestion has produced novel emerging research that has examined both distal and proximal factors. Distal factors have looked at foot type and neuromuscular control during balance tasks, while proximal factors have started looking at the core and trunk during functional tasks.[37,38,58,94,95]

Proximal Factors

Core

The lumbo-pelvic-hip complex has been recently examined in those with PFP due to its importance in the kinetic chain.[96] Altered core stability has also been found to play a role in performance during a single leg squat task, as weakness was found in those with worse performance.[96] Impaired neuromuscular recruitment has also been seen in the core muscles during a perturbation task, with altered patterns in the transverse abdominus, external oblique and erector spinae muscles.[95] To date, there are no known cross sectional or case control studies that evaluated core endurance or strength in between healthy individuals and those with PFP. Additional research should be placed on examining if differences in core function exist between those with PFP and those without.

However, core strengthening has been included in a variety of rehabilitation studies, with noted improvement in core stability and endurance following the training regimen.[17,58] Ferber et al.[58] used core training with hip exercises to compare the effectiveness to a traditional quadriceps only program. Yilmaz et al.[97] examined knee rehabilitation with and without a postural stabilization. Significant improvements in pain, strength, and function were seen in the group who had additional postural stabilization programs included.

Trunk

Hip weakness has been suggested to result in compensated altered movement patterns in the pelvic and trunk, specifically an increase in trunk lean.[84] This altered trunk movement has, in fact, been identified during a variety of functional tasks.[7,60,84] Differences in trunk movement appear to be related to the demands of the task, as triple single limb hopping has also identified increased trunk flexion and decrease in trunk rotation, while stair ambulation has not produced any differences.[60] During challenging tasks, the time to peak trunk flexion, ispilateral flexion and rotation also differ from healthy controls, suggesting both trunk excursion and duration to reach the maximal excursion are present in those with PFP.[60] Trunk lean might also play an important role on PF joint stress, as it was found to provide unique variance on loading of the knee during gait in individuals with knee OA.[98] A positive relationships has also been seen by Teng et al. between PFJ stress and trunk flexion in healthy individuals during running tasks.[99] While caution should be placed in comparing relationships between the trunk and knee across pathologies and in a healthy population, it does present with the

possibility to provide insight into this altered movement in individuals with PFP. The potential to use this information to screen those with increased risk for developing PFP as well as the potential to use trunk lean as a re-training methods to decrease PFJ stress should be examined.

Distal Factors

Balance

Static and dynamic balance has limited evidence when examining differences between PFP and healthy individuals.[100-102] However, impairments in balance have been found in the pathological group in both types of balance.[100-102] Due to the functional applications of single limb stance during daily activities, single limb balance has been evaluated in PFP.[100,101] Those with PFP have been found to have decreased stability in an anteroposterior movement, and significantly less stability on their pathological limb.[100,101] A decrease in functional balance has also been identified during the modified star excursion balance test in those with PFP, again with their pathological limb being worse.[102,103] Due to the chronic pain response in those with PFP, the influence of pain on balance has also been identified to correlation with each other.[103] Interventions that decrease pain have been found to have an influence on balance; Aminaka et al. found such improvements in the SEBT following application of McConnell taping.[102]

Foot Type

Mobility of the navicular has been examined in various PFP studies, due to its role on subtalar pronation.[37,38,57] Individuals with PFP have been found to have increased foot mobility, a more pronated position and increased navicular drop and

drift when compared to healthy counterparts.[38]. Navicular drop has also been found to be a risk factor for developing PFP.[57] This extra mobility may result in a more supinated position, which increases shank internal rotation and placing additional stress on the PFJ. Utilization of orthoses has produced promising results at immediately decreasing pain and improving function and producing long-term benefits in pain.[37,104] Orthotic use has also been found to have immediate improvement in kinematics, a decrease in hip adduction and internal rotation and improve muscle activity.[94] Positive findings have also been seen in patellofemoral contact stress during running, with a delay in time to peak stress.[105]

Rehabilitation of Patellofemoral Pain

The wide range of impairments seen in individuals suffering from patellofemoral pain has made the treatment somewhat challenging for clinicians, as PFP is often described as an orthopedic enigma.[106] Outcomes have been less than optimal, with long-term pain and symptoms lasting up to 16 years following initial PFP diagnosis.[10,107] This prolonged pain has also been suggested to result in the development of patellofemoral osteoarthritis.[108] Clinicians have employed a variety of strengthening programs to address the impairments of patients with PFP. While the outcomes are suboptimal, interventions to improve subjective and objective function of these patients have explored additional interventions. Electrical stimulation is one intervention that clinicians can use to treat PFP.

Electrical Stimulation with Rehabilitation in Patellofemoral Pain stimulation

The use of electrical stimulation on individuals with PFP is limited to applications to the quadriceps muscles, primarily addressing the VMO. Callaghan et

al. conducted two separate studies examining two forms of electrical stimulation to the quadriceps in individuals with PFP.[109, 110] His first study examined daily treatments over 6 weeks between an asymmetrical biphasic pulse with a 20μs pulse duration and 1:5 duty cycle to an asymmetrical biphasic pulse that varied phase durations between 250-350μs and pulse rates between 3 and 35Hz. found a decrease in VAS scores of 1.2 and 1.5 between the two groups.[109] With his second study, Callaghan et al. administered 60-minute daily stimulus treatments over 6 weeks between a standard 35 Hz, 300μs, 10:50 duty cycle and 100mA biphasic rectangular waveform to an experimental treatment that utilized an asymmetrical biphasic pattern with a frequency of 2 and 83 HZ and a 200μs pulse duration with 8-500ms interpulse intervals at 90mA, 10:50 duty cycle.[110] Callaghan et al. did find a reduction of 33% of pain in those individuals with PFP, however the VAS change scores was only 1 on the VAS scale.[110] Bily et al. was the one study that produced greater pain relief, however examined a group receiving standard physical therapy (pain reduction of 2.8cm) and one with physical therapy and electrical stimulation (reduction of 3.4).[111] While this study produced a greater reduction in pain, it is difficult to ascertain if the pain reduction was just from the electrical stimulation or with the therapeutic exercise that participants also performed during the 12-week protocol.[111]

While the number of interventions utilizing NMES and PFP is limited, there is some emerging evidence utilizing Patterned electrical neuromuscular stimulation (PENS). PENS utilizes a rhythmical pattern that is derived from healthy EMG activities during functional tasks.[112,113] The stimulus pattern of PENS has been

purposed to provide neuromuscular re-education of the altered motor impairments seen within those with PFP. Administering a stimulus pattern to apposing muscle groups has been suggested to replicate muscle stretch receptors and motor neuron stimulation that traditionally occur during lower extremity movements.[114] The benefits of PENS is that this electrical stimulation is applied to both the VMO and gluteus medius muscles as the agonist muscles, which have both been identified to have altered firing patterns during functional tasks.[53,83,115] In addition to the rhythmical pattern of PENS, it has been found to not produce muscle fatigue that is traditionally seen following NMES interventions.[116-118]

Single applications of PENS have been evaluated on muscle function, kinematics, and pain in individuals with PFP.[119,120] Following a single application of PENS in PFP patients, an increase in gluteus medius EMG activation was seen by over 100% during a lateral step down task.[120] When the kinematics during functional tasks were examined, females in this study demonstrated an improvement in movement strategies with PENS application compared to a sham treatment.[119] Those who received PENS had a decrease in hip adduction for 30% of the task during the lateral step down. The deviation of hip adduction in the PENS group was less than 9 degrees, which is a similar value to healthy individuals.[7,121,122] This decrease in hip adduction may be due to the decrease in patellofemoral stress commonly seen when hip adduction is in the 15-20 degree range. Significant reduction in pain during both a single leg squat and stair ambulation was immediately seen following PENS, 1.8 and 2.3 on the VAS respectfully.[119] This pain reduction is not only statistically significant, but also clinically relevant as they are

greater than the minimal change in difference of 1.3 for individuals with PFP during functional tasks.[123]

While no training studies have been conducted within the PFP population to date, there has been a single training study evaluating the influence of PENS on vertical jump in college students. [124] A 6-week training study with PENS was found to improve vertical jump height by greater than 9%, where no differences were seen in the control or sham group.[124]The improved jump height was also retained for 2-weeks after the PENS intervention training had ended, while no statistically significant differences were seen in the sham or control groups.[124]

APPENDIX C
Additional Methods

Table C1: University of Virginia Institutional Review Board Approved Protocol (#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.

<u>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.</u>

<u>Investigators Experience</u>

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

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?

46 subjects

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

46 subjects

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

- 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

2. List the criteria for exclusion

- 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 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.

Task	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)

VISIT 1A: CONSENT AND SCREENING

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.

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:

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 s 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 six muscles to be recorded are gastrocnemius, quadriceps (at 2 locations), hamstrings, adductor muscle group, and lateral hip muscle.
- 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.

ULTRASOUND IMAGING

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

- 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.

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

VISITS 2-13 (Treatment sessions 1 to 12)

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:

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. This will take no longer than 2 hours

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?

Payment

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 ITC: if breach involves electronic data UVa Police if breach includes items that are stolen	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

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

►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

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.

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.

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

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.

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

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 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*)

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 Patellofemoral Pain Group (#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 your 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 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.

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:

- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- 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 Paticipant

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

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 Consent Form Healthy Group (#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 what strength, range of motion, movement during functional activities, muscle activity and patient reported outcomes look like in healthy individuals.

You are being asked to be in this study as a healthy individual. You will have your flexibility, strength, muscle function and movement of your hip, knees and ankles evaluated during many tasks. These tasks include squatting, stair climbing, walking, jogging, lunging, jumping, squatting and balancing.

Up to 40 people will be in this study at UVA

What will happen if you are in the study?

The test and all procedures 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 enrolled in the study

VISIT 1 B STUDY TEST AND PROCEDURES: *(*will last about 2 hours)

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 Motions 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 2-weeks. Following the 2-week you will turn it back over to the research team.

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 up to 2- testing visits (we can split these as needed). You will also need to come back to the laboratory in 2-weeks to return the pedometer (FitBit).

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. .

Will you be paid for being in this study?

You will not receive compensation for completion in this study.

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

d) The Principal Investigator is concerned about your health due to increase pain while performing the functional tasks
e) pregnancy .
f) 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:

- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- 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 Paticipant

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

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 C4: 17909 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 C5: Pre-Intervention Data Collection Form

ROM		**Left**			**Right**	
Hip Flexion						
Hip Extension						
Hip Add						
Hip Abd						
Hip IR						
Hip ER						
Knee Flexion						
Knee Extension						
Ankle Inversion						
Ankle Eversion						
Dorsiflexion (Gastroc)						
Dorsiflexion (Soleus)						
Plantarflexion						
IT Band						
Great Toe Flexion						
Great Toe Extension						

Strength	Left Moment Arm		**Left**		Right Moment Arm		**Right**	
Hip Flexion								
Hip Extension								
Hip Add								
Hip Abd								
Hip IR								
Hip ER								
Knee Flexion								
Knee Extension								
Ankle Inversion								
Ankle Eversion								
Dorsiflexion (Gastroc)								
Dorsiflexion (Soleus)								
Plantarflexion								

Table C6: Post-Intervention Data Collection Form

ROM		**Left**			**Right**	
Quads						
Hamstring						
IT Band						
Gastroc						

Strength	Left MA		**Left**		Right MA		**Right**	
Hip Extension (HS)								
Hip Ext (GMax)								
Hip Add								
Hip Abd								
Hip IR								
Hip ER								
Knee Flexion								
Knee Extension								
Ankle Inversion								
Ankle Eversion								
Dorsiflexion								
Plantarflexion								

Table C7: VAS Data Collection Form

Visual Analog Scale
Please rate your current pain by marking the line below:

No pain _____ *Worst Imaginable*

Please rate your worst pain in the last 24-hours by marking the line below:

No pain _____ *Worst Imaginable*

Please rate your pain during the single leg squat by marking the line below:

No pain _____ *Worst Imaginable*

Please rate your pain going up the steps by marking the line below:

No pain _____ *Worst Imaginable*

Please rate your pain going down the steps by marking the line below

No pain _____ *Worst Imaginable*

Please rate your current pain during the lunge by marking the line below:

No pain _____ *Worst Imaginable*

Please rate your pain during DVJ by marking the line below:

No pain _____ *Worst Imaginable*

Please rate your pain during jogging by marking the line below:

No pain _____ *Worst Imaginable*

Table C8: Summary Collection Form

Dominant Limb	L / R	
Treatment Limb	L / R	
PRO	**Pre**	**Post**
VAS-C		
VAS-W		
VAS During SLS		
VAS During Stair Ambulation		
VAS During Lunge		
VAS During Jogging		
ADLS		
Tegner		

	Week 1	**Week 2**	**Week 3**	**Week 4**
Godin Leisure				
AKPS				
FABQ				

Session	**Pre-Rehab VAS**	**Post-Rehab VAS**
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		

Table C9: PENS 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 C10: Week 1-2 Rehabilitation Form

NAME: Group: Session #:

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 C11: Week 3-4 Rehabilitation Form

NAME: Group: Session #:

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			

NAME: Group: Session #:

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 C12: Rehabilitation VAS Scoring Form

Pre Rehab

Please rate your current pain level by marking the line below:

No pain _____ *Worst Imaginable*

Post Rehab

Please rate your current pain level by marking the line below:

No pain _____ *Worst Imaginable*

Table C13: Exercise and Sport Injury Lab Medical Questionnaire: Lower Extremity

Exercise and Sport Injury Lab

Medical Questionnaire: Lower Extremity

Subject Number:_____ **IRB#** _____

Activities of Daily Living

Please check below if you have difficulty with any of the following:

- ☐ Sitting
- ☐ Standing
- ☐ Walking
- ☐ Walking up stairs
- ☐ Walking down stairs
- ☐ Running
- ☐ Sprinting
- ☐ Other: _____

Please explain any checked items:

_____

_____

Orthopedic

Regarding your lower extremity (hips, thighs, knees, shins, ankles, feet) please answer the following questions:

Do you have a history of any broken bones?

Please explain the extent of the injury including the date and severity:

_____

_____

Do you have a history of any torn or sprained ligaments?

Please explain the extent of the injury including the date and severity:

_____

_____

Do you have a history of any dislocations?

Please explain the extent of the injury including the date and severity:

_____

_____

Do you have a history of any muscle or tendon strains or tears?

Please explain the extent of the injury including the date and severity:

_____

_____

Version Date: 12/2/13

Exercise and Sport Injury Lab

Pain
Please check below any boxes which describe your pain:

- ☐ Burning
- ☐ Stinging
- ☐ Aching
- ☐ Tingling/Numbness
- ☐ Tightness
- ☐ Pinching
- ☐ Other: _____

Please explain any checked items:

_____

_____

Please rate the frequency of your pain:

- ☐ Every day
- ☐ Few times per week
- ☐ Few times per month
- ☐ Few times per year

Please explain any checked items:

_____

_____

How do you reduce your pain level? _____

_____

What activities or motions reproduce your pain? _____

_____

How long does your pain last?

- ☐ All day
- ☐ Half a day
- ☐ Few hours
- ☐ One hour
- ☐ Several minutes
- ☐ Less than one minute
- ☐ Other_____

Please explain any checked items:

_____

_____

Please rate your current pain by marking the line below:

No pain _____ *Worst Imaginable*

Version Date: 12/2/13

Table C14: 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 C15: 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
- ☐ Abnormal
- ☐ Nearly Normal
- ☐ 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
- ☐ Abnormal
- ☐ Nearly Normal
- ☐ Severely Abnormal

7- Over the past 24 hours, how bad has your pain been?

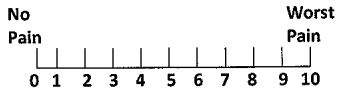


Table C16: Godin Leisure-Time Exercise Questionnaire

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 C17: 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.

SURGICAL HISTORY

Have you had any additional surgeries to your knee other than those performed by Dr. Stone?

Yes / No

If Yes:

What procedure(s) were performed? _____

When was the surgery performed?_____

Who performed the surgery?_____

Table C18: 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 C19: SF-12 Health Scale

SF-12 Health Survey

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. **Answer each question by choosing just one answer.** If you are unsure how to answer a question, please give the best answer you can.

1. **In general, would you say your health is:**

☐1 Excellent ☐2 Very good ☐3 Good ☐4 Fair ☐5 Poor

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	YES, limited a lot	YES, limited a little	NO, not limited at all
2. **Moderate activities** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	☐1	☐2	☐3
3. Climbing **several** flights of stairs.	☐1	☐2	☐3

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	YES	NO
4. **Accomplished less** than you would like.	☐1	☐2
5. Were limited in the **kind** of work or other activities.	☐1	☐2

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	YES	NO
6. **Accomplished less** than you would like.	☐1	☐2
7. Did work or activities **less carefully than usual.**	☐1	☐2

8. **During the past 4 weeks, how much did pain interfere with your normal work (including work outside the home and housework)?**

☐1 Not at all ☐2 A little bit ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

These questions are about how you have been feeling during the past 4 weeks.
For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm & peaceful?	☐1	☐2	☐3	☐4	☐5	☐6
10. Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5	☐6
11. Have you felt down-hearted and blue?	☐1	☐2	☐3	☐4	☐5	☐6

12. **During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?**

☐1 All of the time ☐2 Most of the time ☐3 Some of the time ☐4 A little of the time ☐5 None of the time

Table C20: 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, re creational 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 C21: Global Rating Change Score

Subject #:_____

PATIENT GLOBAL RATING

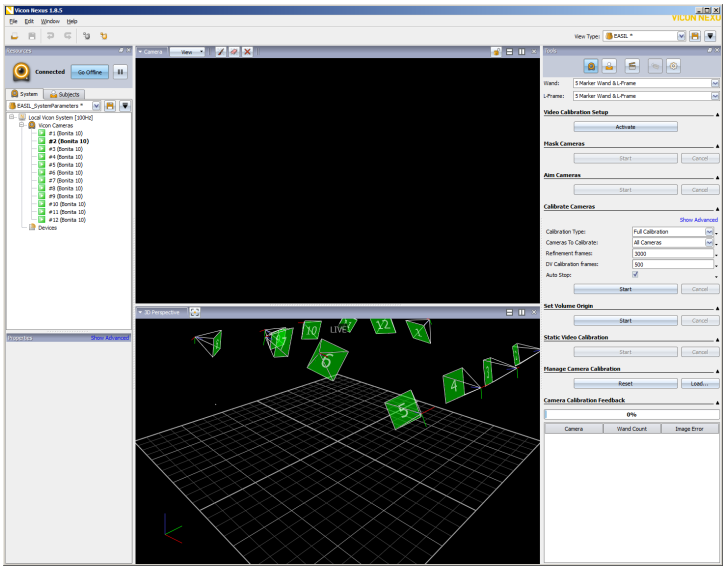
Date:_____/_____/_____
mm dd yy

Please rate the overall condition of your knee ***from the time that you began treatment until now*** (check only one):

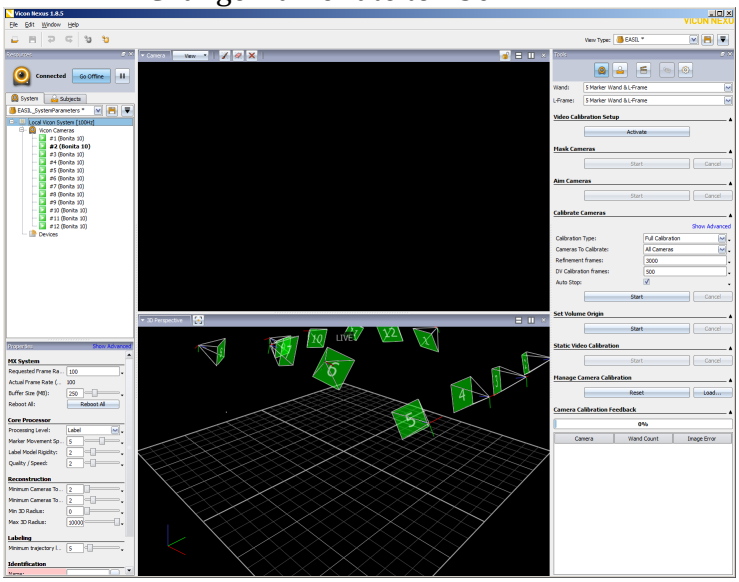
□ A very great deal worse	□ About the same	□ A very great deal better
□ A great deal worse		□ A great deal better
□ Quiet a bit worse		□ Quiet a bit better
□ Moderately worse		□ Moderately better
□ Somewhat worse		□ Somewhat better
□ A little bit worse		□ A little bit better
□ A tiny bit worse (almost the same)		□ A tiny bit better (almost the same)

Table C22: Vicon and Motion Monitor Data Collection Procedures

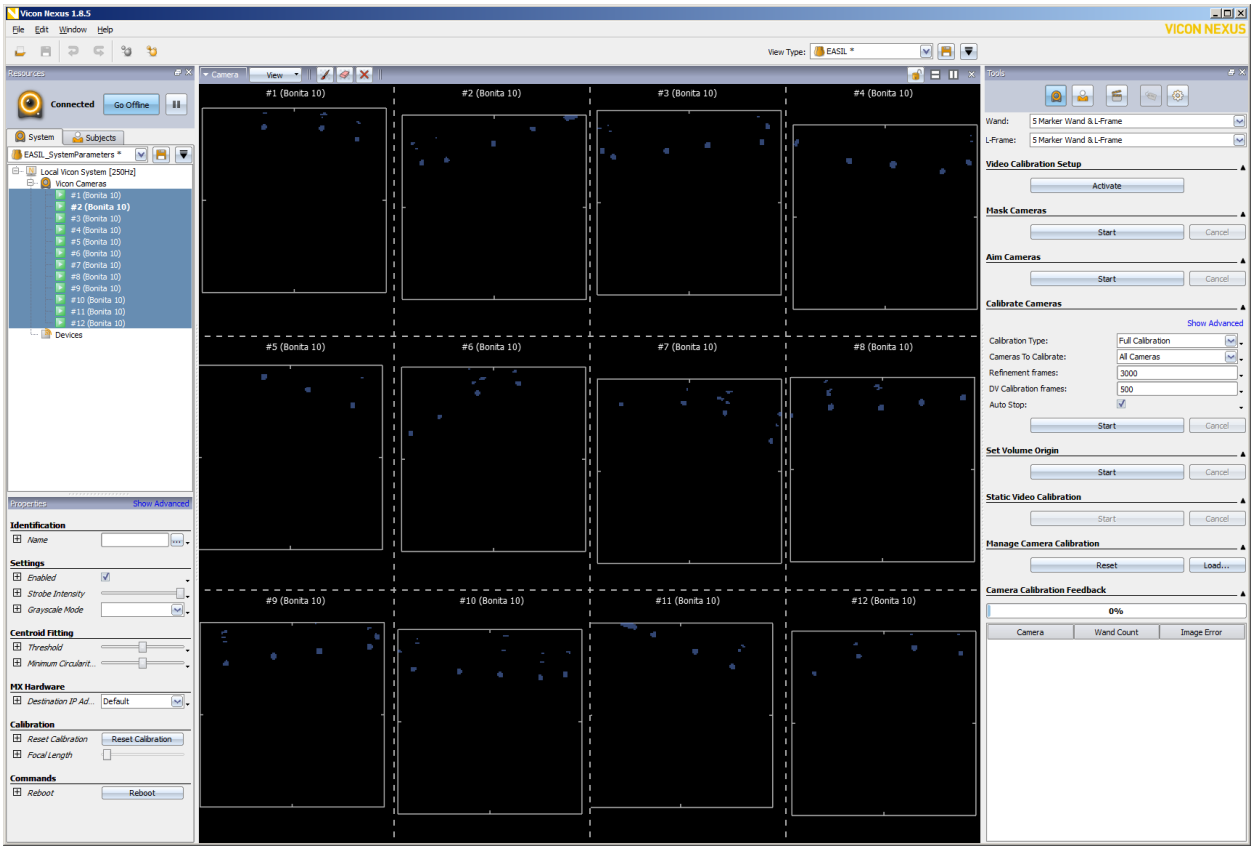
1. Turn on computer and open Vicon Nexus
    a. Make sure all cameras are green
    b. If any cameras are not green, unplug and reinsert corresponding camera cable



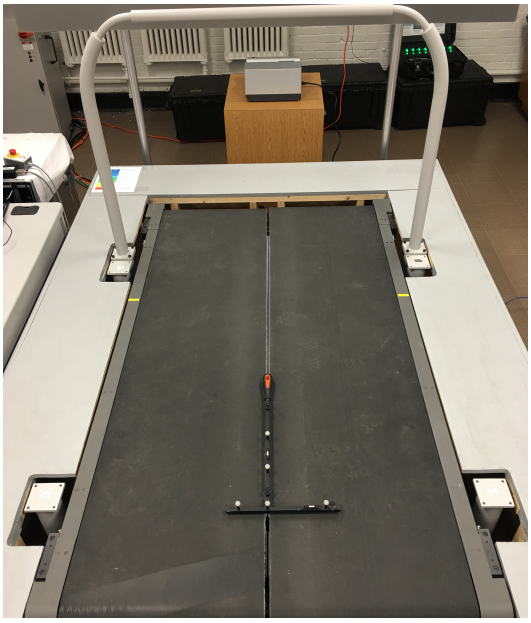
2. Change frame rate to 250 Hz.



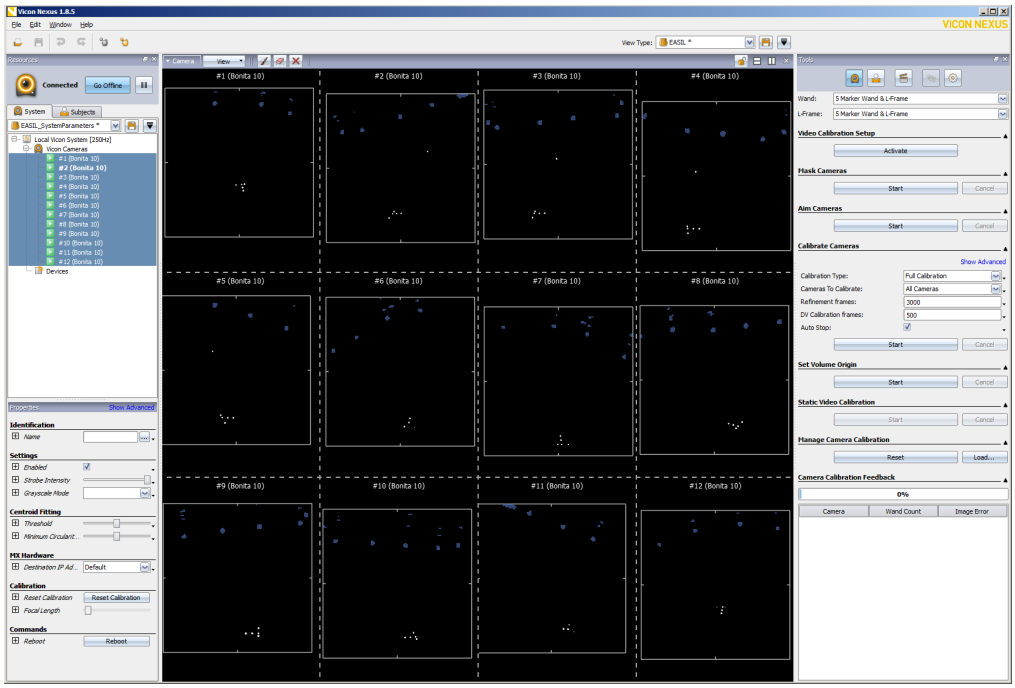
3. Select all cameras and change view to camera view
4. Remove all markers from the field
    a. If an unknown marker is in the field, try to locate it before masking cameras
5. Mask cameras
6. Select STOP once all reflectors in the field have changed to blue



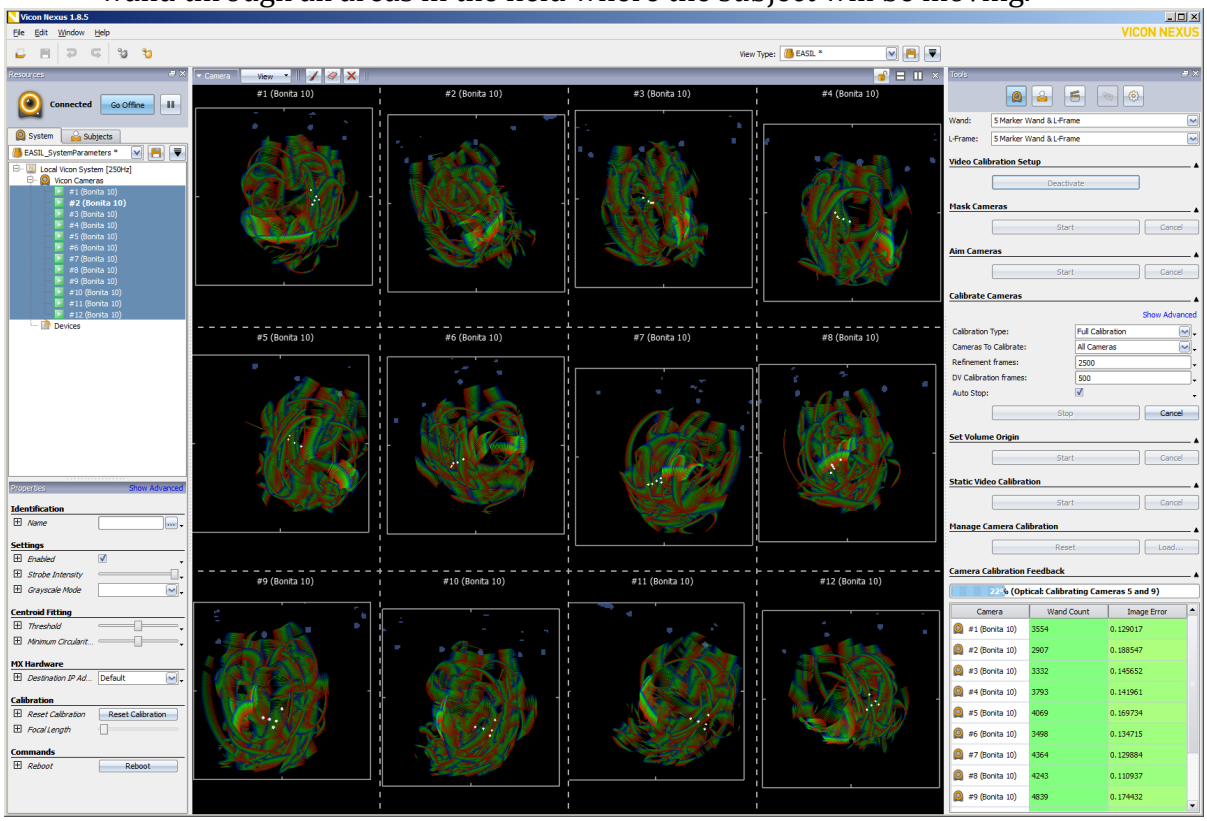
7. Place the L-wand in the field at the edge of the force plates



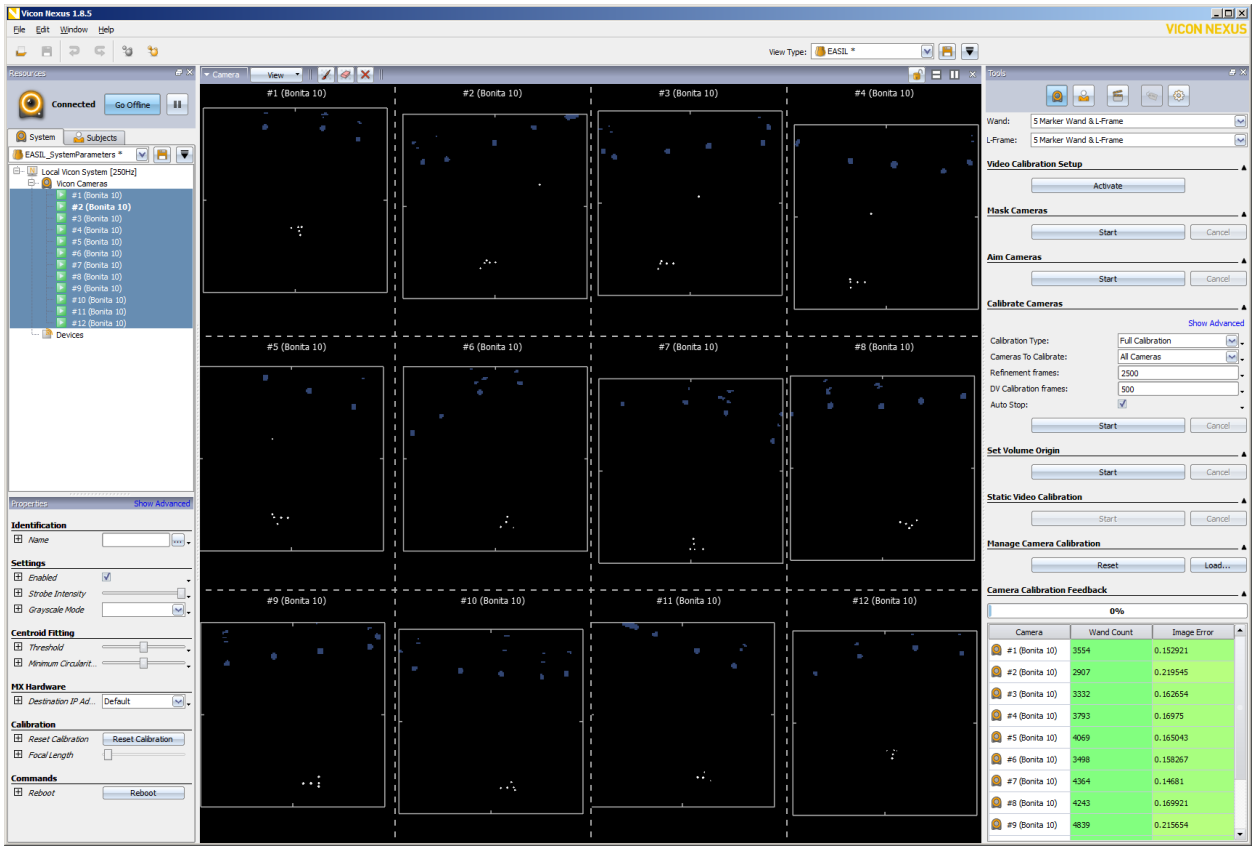
8. Aim Cameras



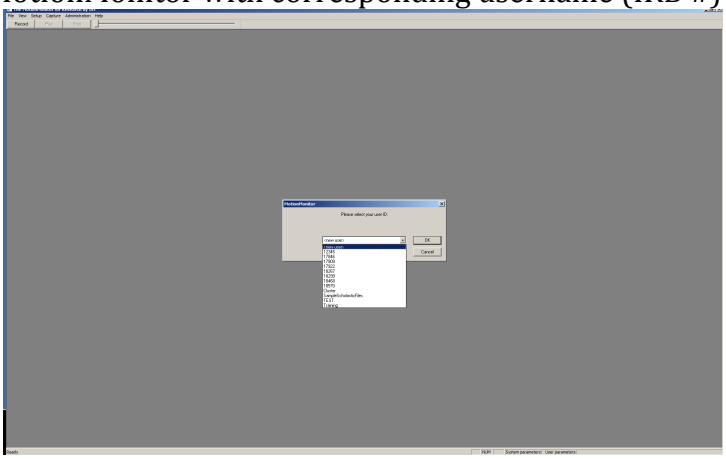
9. Calibrate cameras using 2500 refinement frames. Make sure to move the wand through all areas in the field where the subject will be moving.



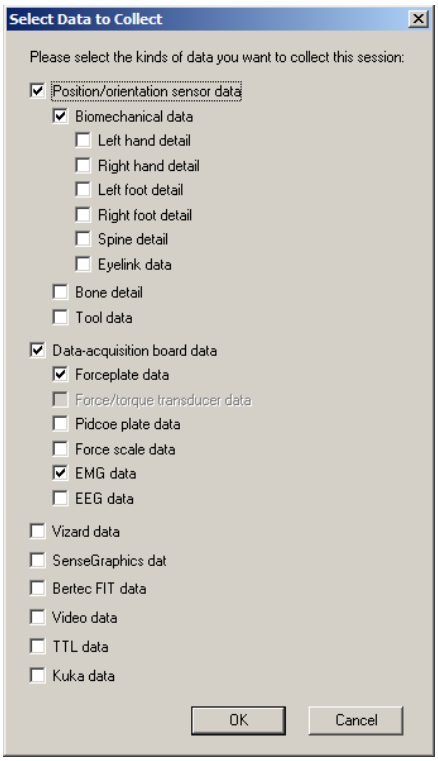
10. Check Image Error for any error greater than 0.25 – this may require recalibration
11. Replace the wand in the field (see picture in Step 7)
12. Set Volume Origin



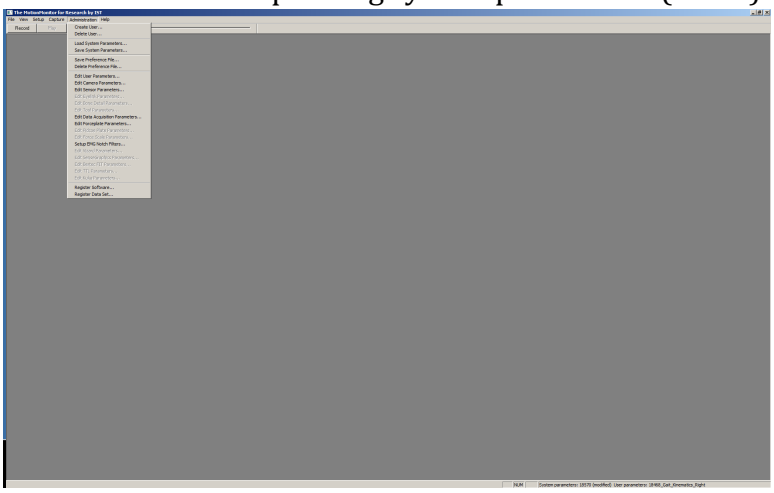
13. Select “Data Management” and select appropriate protocol for data collection
14. Select “Subjects’ tab to verify cluster files have loaded.
    a. Press Control-R and markers on participant will be recognized to create model.
15. Open MotionMonitor with corresponding username (IRB #)



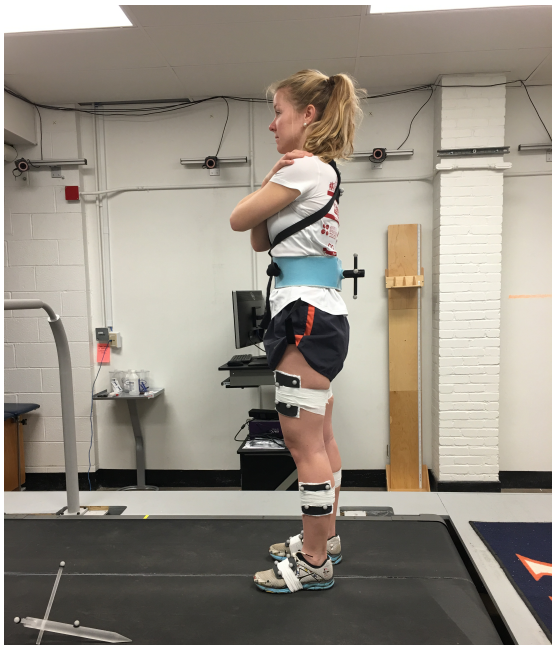
16. Select data to collect: Make sure Position/orientation sensor data, Biomechanical data, Data-acquisition data, forceplate data, and EMG data are checked.



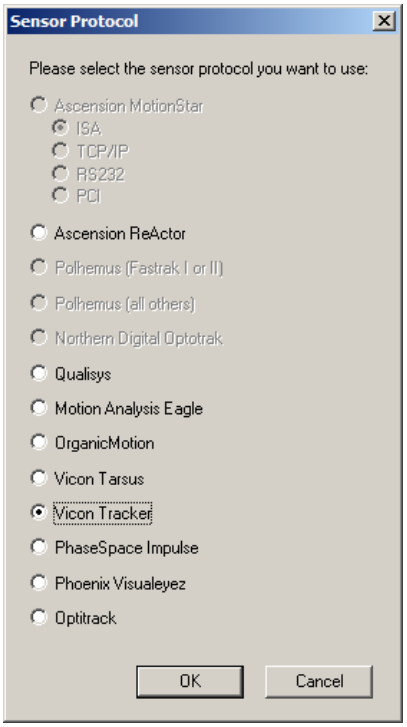
17. Go to the top menu and select Administration and Load System Parameters. Load corresponding system parameters (IRB #).



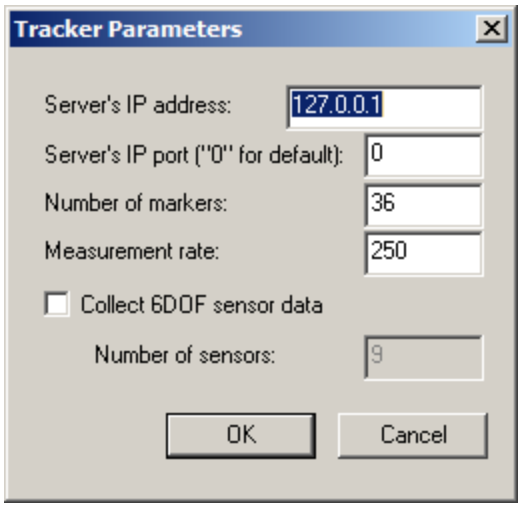
18. Go to the top menu and select File and Preference File. Load appropriate preference file.
19. Subject should enter the field (stand on the treadmill) with all clusters attached and the stylus need to be placed within the field.



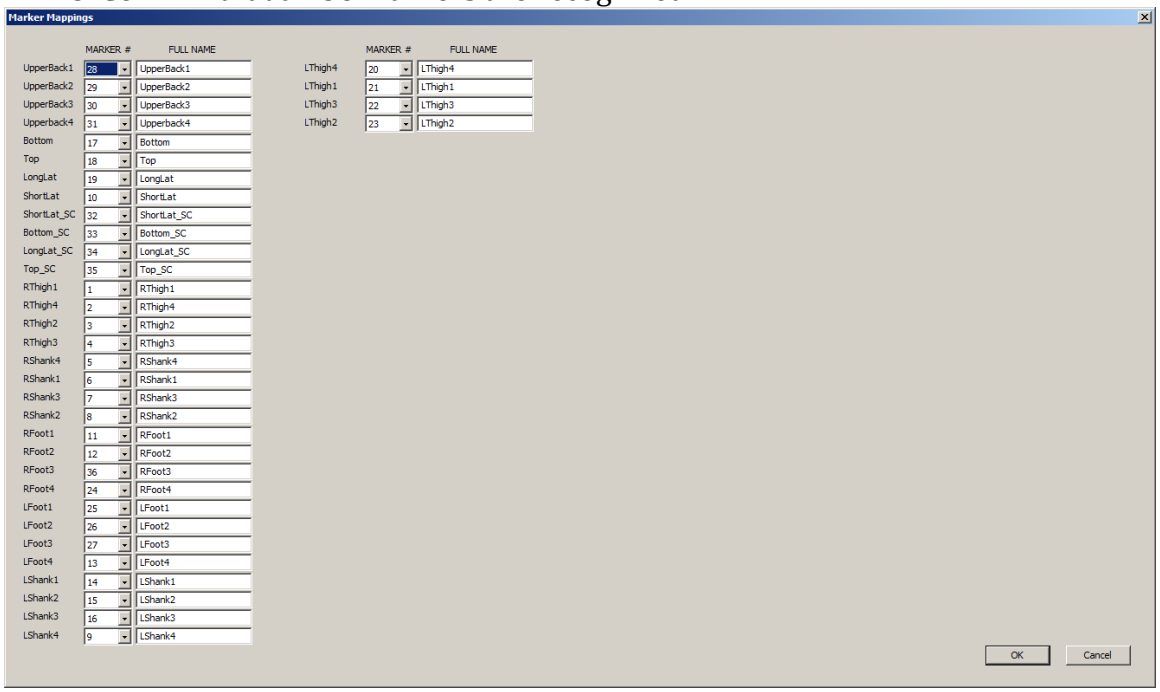
20. Go to the top menu and select Administration then select Edit Sensor Parameters.
21. Select Vicon Tracker

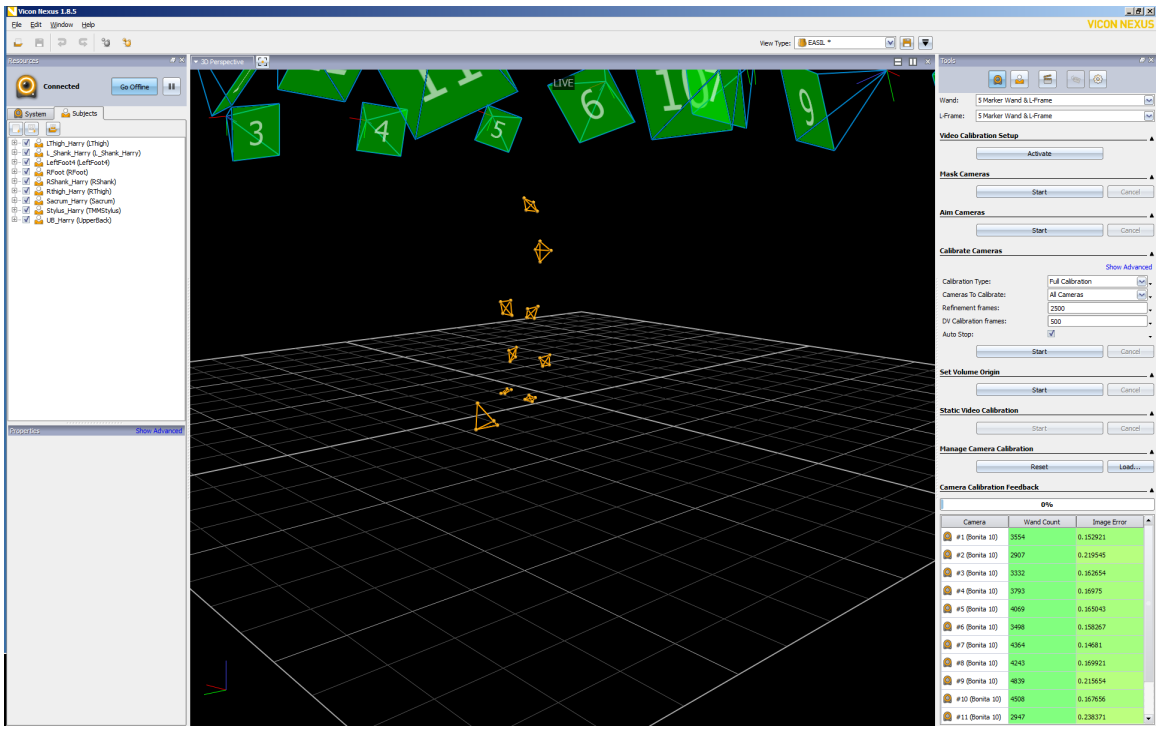


22. Confirm that number of markers = 36 and measurement rate = 250Hz

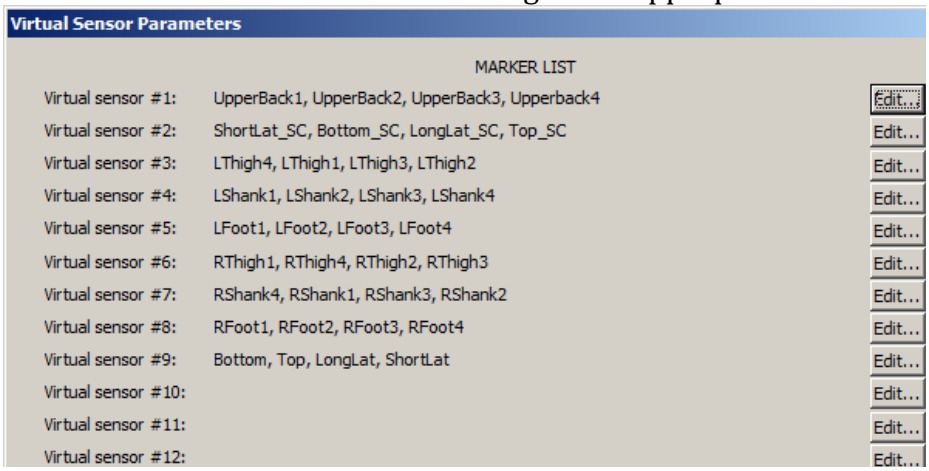


23. Confirm that all 36 markers are recognized

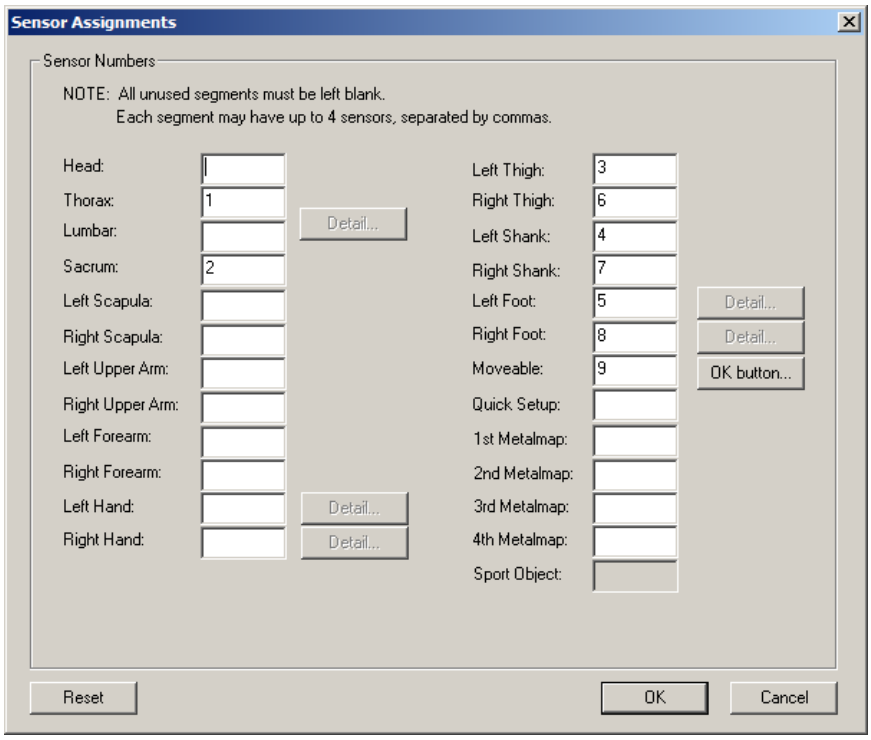




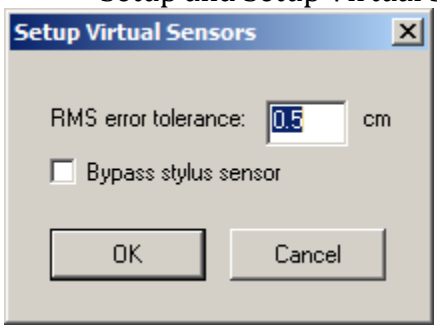
24. Confirm all clusters are assigned to appropriate virtual sensor.



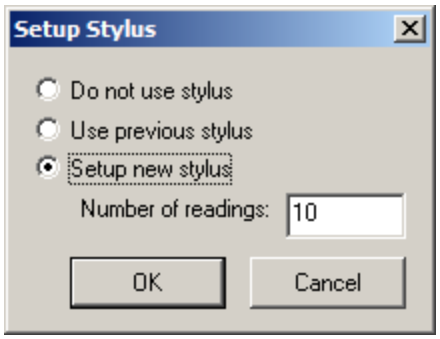
25. Go to the top menu and select setup and Edit Sensor Assignments. Sensor assignments listed should match assignments in virtual sensor parameters (see previous step)



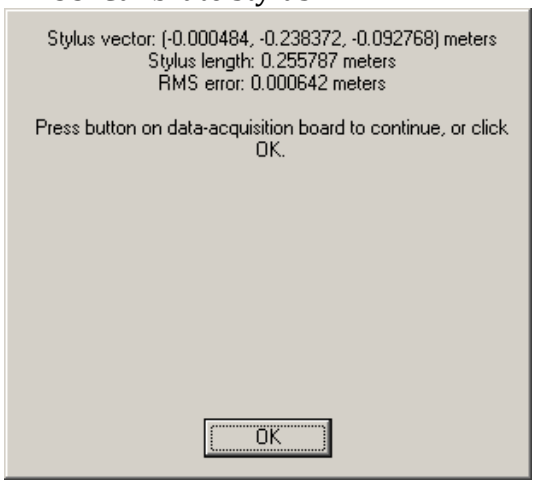
26. Ask the subject to stand still with hands crossed on the shoulders
27. Go to Vicon Nexus window and press Control-R
28. Return to MotionMonitor window and go to the top menu and select Setup and Setup Virtual Sensors



29. If you DO NOT receive an error, continue to step 28. If you DO receive an error, go back to step 18.
30. Ask Subject to step onto the mat behind the treadmill.
31. Select Setup and Select Data to Collect. Uncheck EMG data.
32. Select Setup and Setup Stylus. Setup a new stylus with 10 readings.

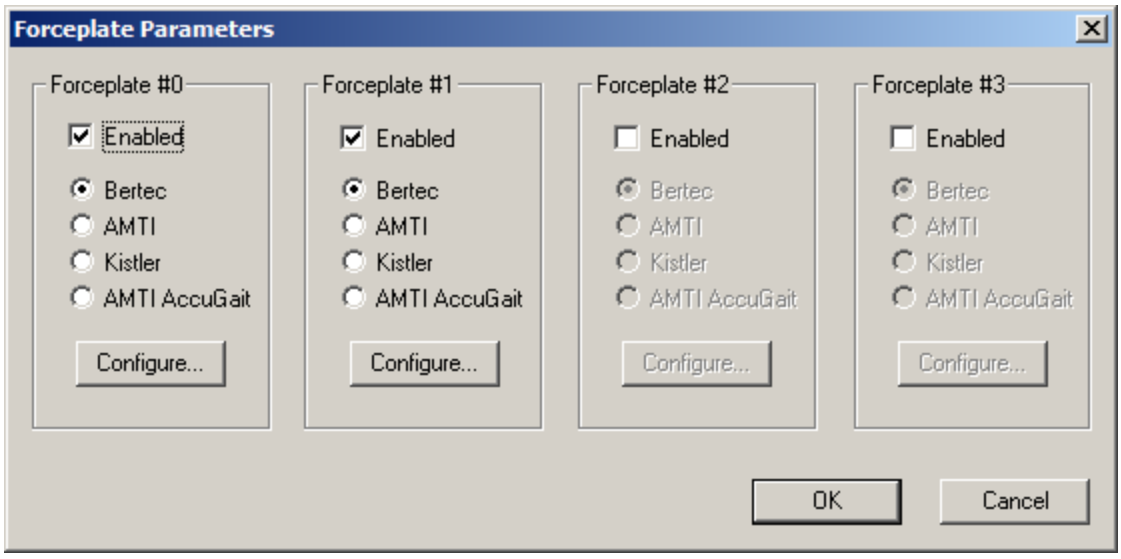


33. Calibrate stylus

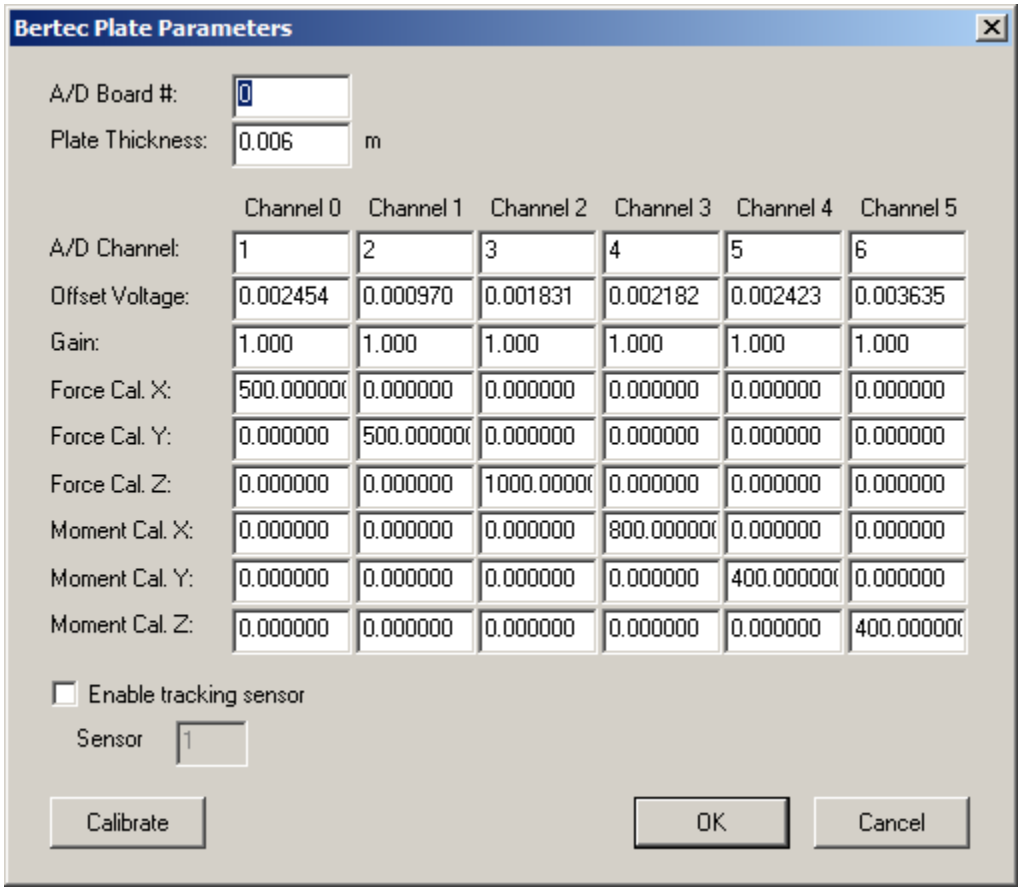


34. Remove all weight from forceplates. Zero the forceplates in the hardware.
35. Go to Administration and Edit Forceplate Parameters.

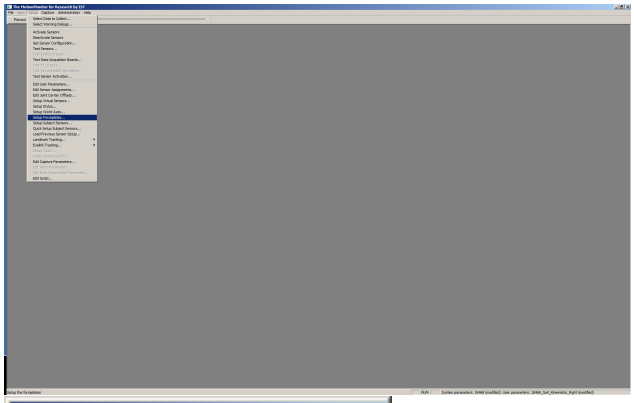
36. Select Configure for Forceplate #0

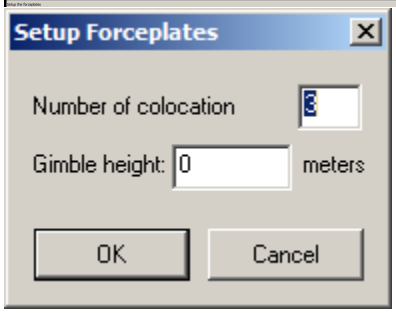


37. Select Calibrate

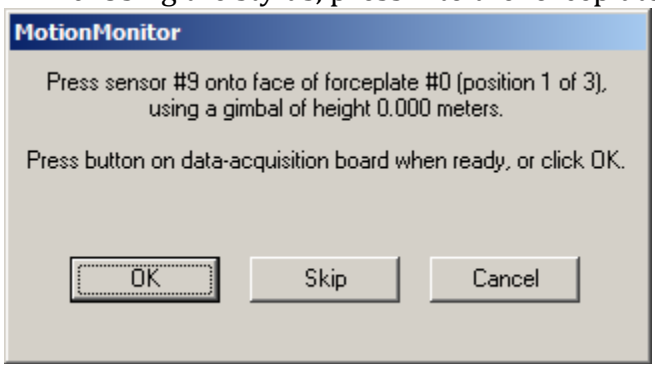


38. Select OK and repeat steps for Forceplate #1
39. Go to the top menu and select Setup and Setup Forceplates

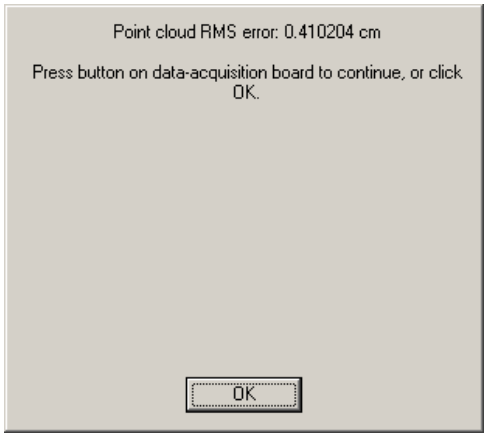




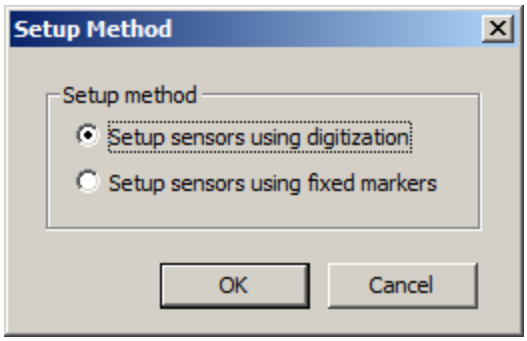
40. Using the stylus, press into the forceplate at three non-linear locations.

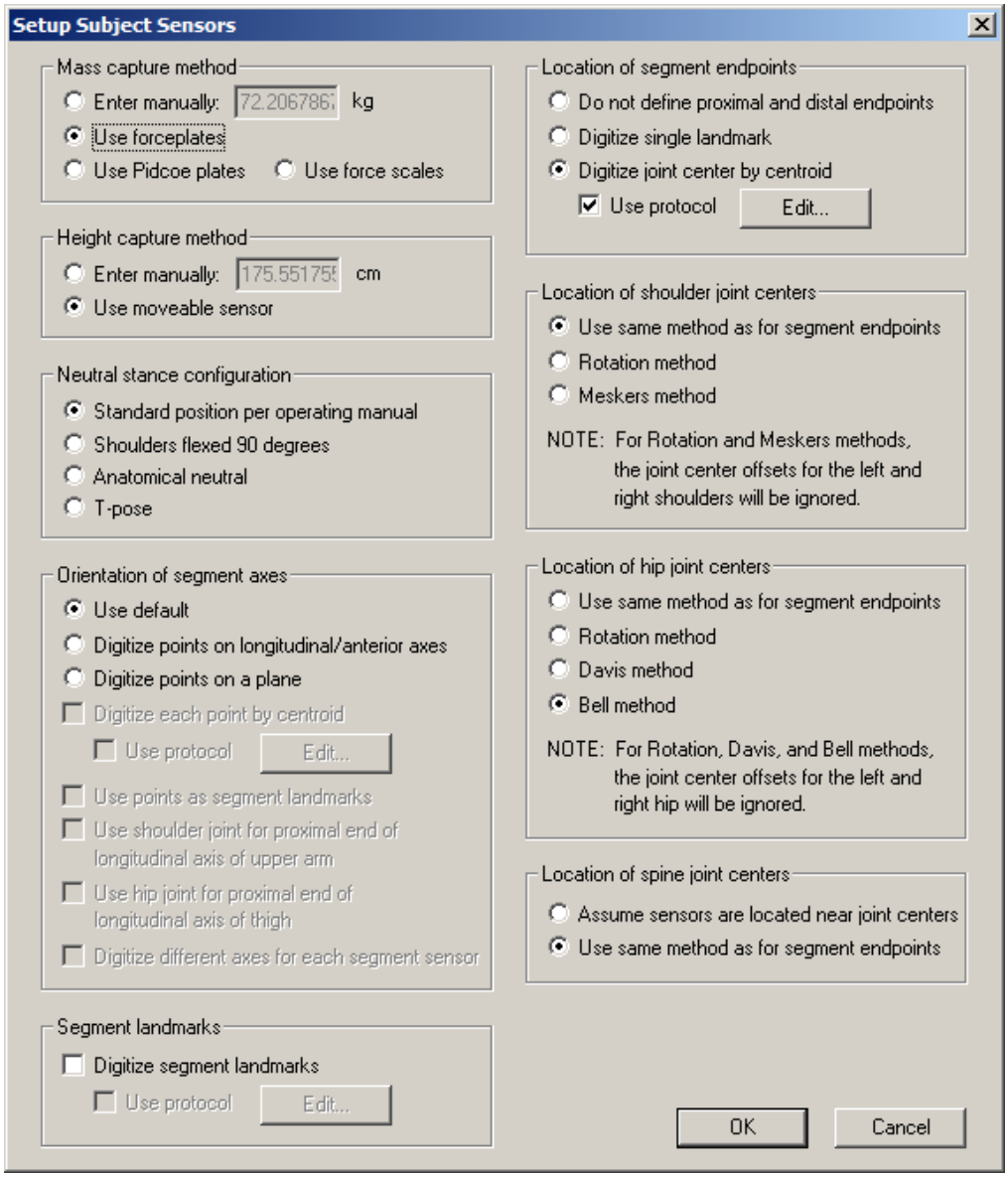


41. Error should be less than 1 cm. If it is greater than 1.0, repeat steps 32-38.

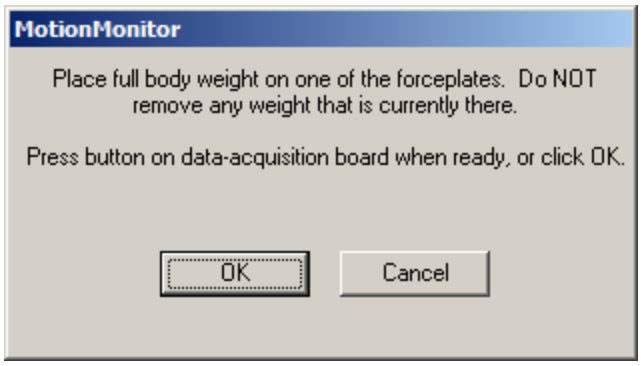


42. Go to the top menu and select Setup and Setup Subject Sensors. Select setup sensors using digitization.

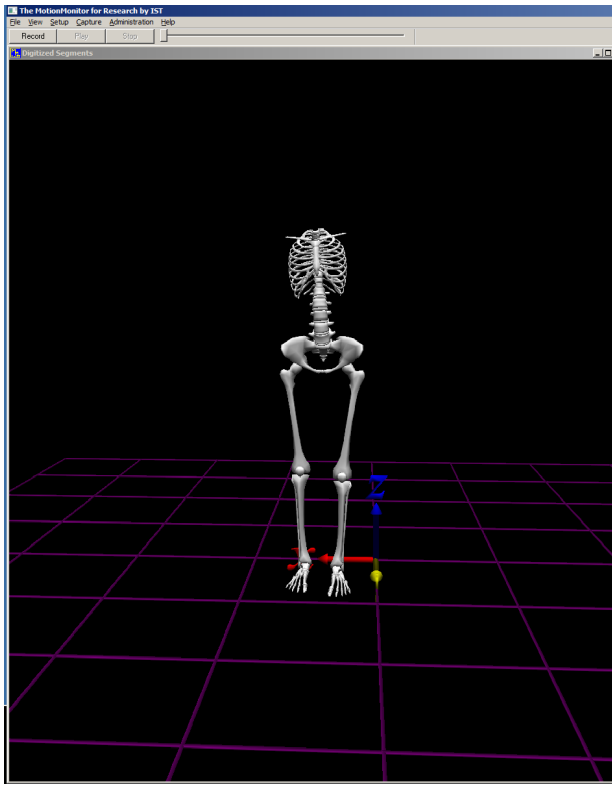


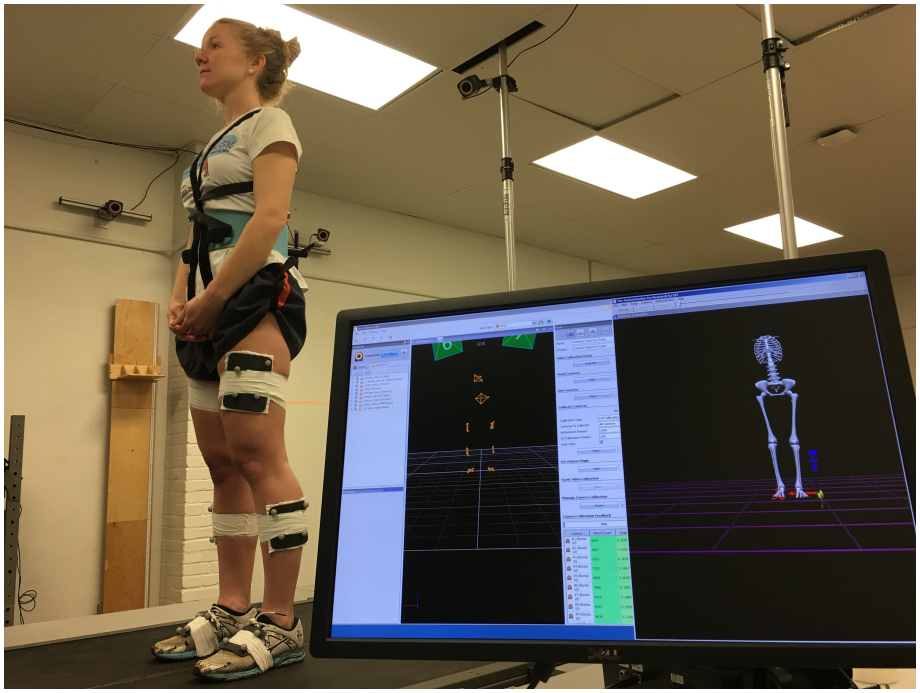


43. With below image on screen, ask subject to step onto ONE of the forceplates (one treadmill belt) with both feet. Once subject is in place, click "OK" to record body weight.



44. Place the tip of the stylus on top of the subject's head when prompted by MotionMonitor. Make sure height and weight are accurate (around what you would expect). Hold still with stylus to don sensors.
45. Point out the following landmarks on the subject in the following order (hitting Control-R on Vicon Nexus screen as appropriate):
    a. Left ASIS
    b. Right ASIS (hold still to get final hip reading)
    c. C7/T1
    d. T12/L1
    e. L5/S1
    f. Left Lateral Knee Joint Line
    g. Left Medial Knee Joint Line
    h. Left Lateral Malleolus
    i. Left Medial Malleolus
    j. Left Tip of 2nd Phalanx
    k. Right Lateral Knee Joint Line
    l. Right Medial Knee Joint Line
    m. Right Lateral Malleolus
    n. Right Medial Malleolus
    o. Right Tip of 2nd Phalanx
46. If skeleton looks appropriate, continue with collection. If anything does not look right, redigitize the skeleton (redo steps 40-43).





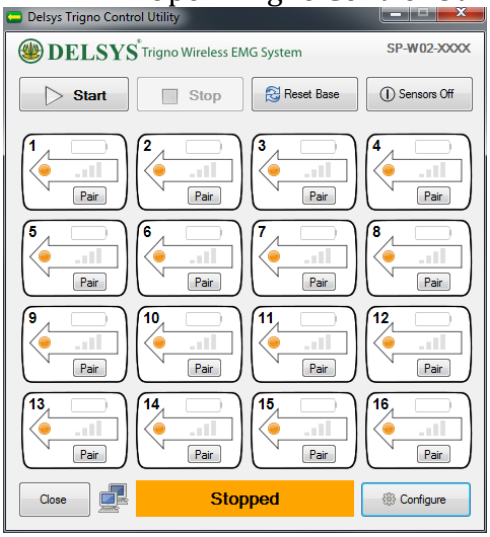
47. Go to the top menu and select Setup and Select Data to Collect. Recheck EMG Data.

Table C23: Range of Motion Measures

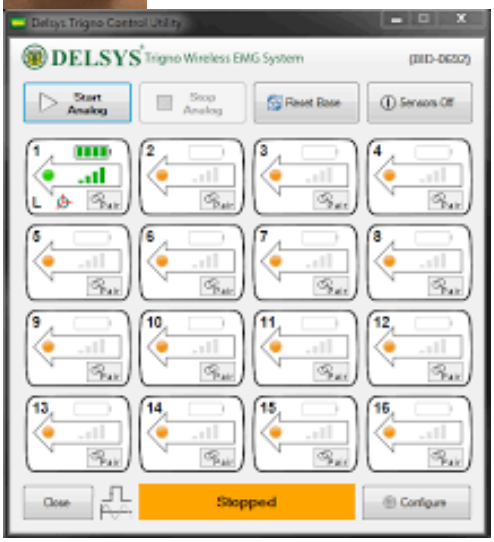
1) Ankle Range of Motion
    a) Dorsiflexion and plantarflexion
        i) Axis of rotation is aligned with lateral malleolus, stationary arm aligned with fibular head and moving arm aligned with fifth metatarsal
    b) Inversion and Eversion
        i) Axis of rotation is aligned in center of anterior ankle between lateral and medial malleoli, stationary arm aligned to tibial tuberosity and moveable arm aligned with 2nd phalanx
2) Knee Range of Motion
    a) Knee flexion
        i) Axis of rotation is aligned to lateral epicondyle, stationary arm aligned to greater trochanter and moveable arm aligned with lateral malleolus
3) Hip Range of Motion
    a) Internal and external rotation
        i) Axis of rotation is aligned to center of patella, stationary arm aligned vertically and moveable arm aligned with crest of tibia
    b) IT band
        i) Bubble inclinometer was zeroed in on treatment table and placed proximal to lateral knee joint
    c) Hamstring
        i) Bubble inclinometer was zeroed in on treatment table and placed on anterior distal tibia

Table C24: Electromyography (Set-up)

1. Open Trigno Control Utility window



2. Turn electrodes on (green light illuminates)



3. EMG Electrode Preparation
   a. Double sided Delsys Trigno Electrode Tape was applied to 12 sensors prior to subject arrival at the Exercise and Sport Injury Laboratory
4. EMG Electrode Placement (www.seniam.org)
   a. Prior to electrode placement skin was prepared
      i. This area was shaved using a disposable razor
      ii. This area was then lightly debrided using a brillo pad

iii. The area was cleansed using isopropyl alcohol

b. Electrode location in prone position
    i. Biceps femoris
        1. Electrode location was identified at 50% distance between ischial tuberosity and lateral epicondyle of the tibia
        2. Palpation of the muscle belly was confirmed with manual resistance during knee flexion
        3. Electrode was oriented in direction between ishial tuberosity and lateral epicondyle
    ii. Medial Gastrocnemius
        1. Patient performed ankle plantarflexion
        2. Electrode location was identified at most prominent bulge of the muscle
        3. Electrode was oriented in angle of the muscle
    iii. Gluteus Maximus
        1. Electrode location was identified at 50% between sacral vertebrae and greater trochanter
        2. Palpation of the muscle belly was confirmed with manual resistance during hip extension
        3. Electrode was oriented in direction of line between PSIS and posterior aspect of thigh
        4. Process was repeated on contralateral limb
c. Electrode location in side lying position
    i. Gluteus Medius
        1. Electrode location was identified at 50% between greater trochanter and superior aspect of the iliac crest
        2. Palpation of the muscle belly was confirmed with manual resistance during hip abduction with slight hip extension and external rotation
        3. Electrode was oriented in direction of line between greater trochanter and iliac crest
        4. Participant rotated 180 degrees and the process was repeated on contralateral limb
d. Electrode location in short seated position
    i. Vastus medialis oblique
        1. Manual resistance during knee extension was performed
        2. Most prominent muscle belly of the vastus medialis oblique was palpated approximately 5 cm superior and 3 cm medial to the patella
        3. Electrode was placed in 35 degrees of medial rotation
        4. Process was repeated on contralateral limb
    ii. Vastus lateralis
        1. Manual resistance during knee extension was performed

2. Most prominent muscle belly of the vastus lateralis was palpated approximately 2/3 the distance of the patella and anterior superior iliac spine
3. Electrode was oriented in direction of muscle fibers
4. Process was repeated on contralateral limb

iii. Adductor Longus
1. Manual resistance during hip adduction was performed
2. Palpation of the muscle approximately 1/3 the distance between the pubic symphysis and adductor tubercle
3. Electrode was oriented in direction of pubic symphysis

iv. Erector spinae (Longissimus)
1. Electrode was positioned 2 fingers superior from L1 spinous process
2. Orientation of electrode was in superior direction

e. EMG data collection
i. Maximal voluntary isometric contractions was collected during manual muscle testing(listed below)
ii. Following patient set-up
1. Standing position with feet shoulder width apart
2. Quiet standing was collected for 10 seconds

Table C25: Manual Muscle Testing (With or Without EMG)

1. Each direction was completed for three trials
2. Participant was instructed to push as hard as possible into the hand held dynamometer for 5 seconds
3. Researcher will not allow participant to push through the full range of motion
    a. Ankle range of motion (Kelln et al)
        i. Ankle dorsiflexion in neutral position
        ii. Ankle inversion in neutral position
        iii. Ankle eversion in neutral position
        iv. Ankle plantarflexion in prone position with knee flexed to 90 degrees
            1. Electromyography collection was conducted simultaneously
        v. All 4 assessments were conducted on contralateral limb
    b. Knee range of motion
        i. Knee flexion in prone position
        ii. Knee extension in short seated position
            1. Electromyography collection was conducted simultaneously
            2. Strength and EMG data was collected on contralateral limb
    c. Hip range of motion
        i. Hip flexion in short seated position bilaterally
        ii. Hip Extension
            1. Knee extension position
                a. Strength and electromyography data was collected simultaneously
                b. Strength was collected on contralateral limb
            2. Knee flexion to 90 degrees
                a. Strength and electromyography data was collected simultaneously
                b. Strength and EMG data was collected on contralateral limb
        iii. Hip abduction
            1. Patient positioned in side lying position in 20 degrees of hip abduction, slight extension and hip external rotation
                a. Strength and electromyography data was collected simultaneously
                b. Strength and EMG data was collected on contralateral limb
        iv. Hip adduction in short seated position
                a. Strength and electromyography data was collected simultaneously
        v. Hip internal rotation in prone position
        vi. Hip external rotation in prone position

Table C26: Functional Assessments

1. Single leg squat
    a. Participant received instructions for task
        i. Arms across shoulder
        ii. Single limb stance on painful limb
        iii. 2 second descend as far as possible
        iv. 2 second ascend to starting position
        v. Return to double limb stance
        vi. 3 practice trials were provided
    b. 5 single leg squats were collected
        i. 1-minute rest was provided between each trial
2. Stair ambulation
    a. Participant received instructions for task
        i. Participant stood in front of stairs
        ii. Participant stepped with left limb and then altered up and down stairs.
        iii. Following last step participant stood in double limb stance
        iv. Returned back to starting position
        v. Repeated stair navigation starting with right limb
        vi. Provided 3 practice trials
    b. Data collection
        i. Single trial was collected with initiation stair ambulation with left then right limb
        ii. 1-minute rest was provided
        iii. 4 more trials were collected
3. Step-down task
    a. Participant received instructions for task
        i. Arms across shoulder
        ii. Single limb stance on painful limb
        iii. Lowered body until contralateral limb touched ground
        iv. Returned to starting position
        v. 3 practice trials were provided
    b. Data collection of ten consecutive trials was conducted
4. Lunge
    a. Participant received instructions for task
        i. Arms on hips
        ii. Step forward until foot comes in contact with floor
        iii. Lower body by flexing knee
        iv. Return to starting position
        v. Perform same movement on contralateral limb
        vi. 3 practice trials were provided
    b. Data collection of 10 consecutive lunges (5 per limb) was recorded
5. Walking
    a. Walking on treadmill at a speed of 1.1 was conducted for 30 seconds
6. Jogging

Jogging on treadmill at a speed of 3.55 was conducted for 30 seconds

APPENDIX D
Additional Results

	N	Minimum	Maximum	Mean	Std. Deviation	Skewness		Kurtosis
	Statistic	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic
Duration	20	3.00	96.00	24.8000	27.11884	2.020	.512	3.497
AKPS_Pre	20	56.00	84.00	76.7500	7.49649	-1.239	.512	1.532
ADLS_Pre	20	62.80	98.00	79.7800	10.17316	.064	.512	-.710
Godin_Pre	20	60.00	602.00	192.9500	134.78032	1.701	.512	3.348
Tegner_Pre	20	2.00	8.00	5.6500	1.66307	-.445	.512	-.223
FABQ_Pre	20	3.00	22.00	13.4000	4.55839	.071	.512	.708
LEFS_Pre	20	56.20	95.00	81.5200	10.26343	-.821	.512	.748
C_VAS_Pre	20	.00	5.90	1.3100	1.61893	1.571	.512	2.200
W_VAS_Pre	20	1.40	7.70	4.3700	1.70945	-.099	.512	-.589
Hip_Ext_Pre	20	1.70	5.85	3.6378	1.33959	.120	.512	-1.116
Hip_Abd_Pre	20	1.58	5.05	2.9795	.84259	.437	.512	.845
Hip_Add_Pre	20	.97	4.03	2.6149	.86939	.066	.512	-.825
Hip_IR_Pre	20	.74	2.87	1.4643	.54047	.834	.512	.744
Hip_ER_Pre	20	.88	2.79	1.5919	.48125	.894	.512	.807
Knee_Flex_Pre	20	1.15	3.47	2.2102	.65618	.228	.512	-.416
Knee_Ext_Pre	20	1.57	7.36	4.0367	1.52991	.473	.512	.803
Quad_Flex_Pre	20	120.00	147.00	134.9750	8.01393	-.134	.512	-1.149
Ham_Flex_Pre	20	8.50	121.00	82.7750	22.92980	-1.629	.512	5.280
IT_Flex_pre	20	1.00	54.00	27.2000	13.34600	.031	.512	-.381
Gas_Flex_Pre	20	1.00	27.50	14.0750	6.81383	.277	.512	-.157

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Mass	0	10	69.8400	19.02852	6.01735	56.2278	83.4522	49.13	105.73
	1	11	68.2555	11.39427	3.43550	60.6007	75.9102	53.55	91.43
	Total	21	69.0100	15.11656	3.29870	62.1290	75.8910	49.13	105.73
Height	0	10	166.7650	7.82536	2.47460	161.1671	172.3629	151.77	181.91
	1	11	169.1618	7.34093	2.21337	164.2301	174.0935	160.15	183.94
	Total	21	168.0205	7.48368	1.63307	164.6139	171.4270	151.77	183.94
Age	0	10	23.0000	3.77124	1.19257	20.3022	25.6978	20.00	31.00
	1	11	23.8182	5.63592	1.69929	20.0319	27.6044	18.00	37.00
	Total	21	23.4286	4.73890	1.03411	21.2715	25.5857	18.00	37.00
Duration	0	10	23.0000	27.82884	8.80025	3.0924	42.9076	4.00	96.00
	1	11	26.3636	26.35251	7.94558	8.6598	44.0675	3.00	96.00
	Total	21	24.7619	26.43275	5.76810	12.7299	36.7940	3.00	96.00
AKPS_Pre	0	10	73.1000	7.97844	2.52301	67.3926	78.8074	56.00	83.00
	1	11	79.2727	6.06780	1.82951	75.1963	83.3491	68.00	84.00
	Total	21	76.3333	7.55204	1.64799	72.8957	79.7710	56.00	84.00
ADLS_Pre	0	10	79.6600	12.03026	3.80430	71.0541	88.2659	64.00	98.00
	1	11	79.1273	8.53945	2.57474	73.3904	84.8642	62.80	92.00
	Total	21	79.3810	10.08279	2.20024	74.7913	83.9706	62.80	98.00
Godin_Pre	0	10	189.4000	165.81529	52.43540	70.7829	308.0171	60.00	602.00
	1	11	192.5455	99.58149	30.02495	125.6457	259.4452	69.00	396.00
	Total	21	191.0476	131.65655	28.72981	131.1183	250.9770	60.00	602.00
Tegner_Pre	0	10	5.2000	1.98886	.62893	3.7773	6.6227	2.00	8.00
	1	11	6.0000	1.18322	.35675	5.2051	6.7949	4.00	8.00

	Total	21	5.6190	1.62715	.35507	4.8784	6.3597	2.00	8.00
	0	10	14.4000	3.68782	1.16619	11.7619	17.0381	10.00	22.00
FABQ_Pre	1	11	12.3636	5.02539	1.51521	8.9875	15.7397	3.00	22.00
	Total	21	13.3333	4.45346	.97183	11.3061	15.3605	3.00	22.00
	0	10	79.8900	13.11280	4.14663	70.5097	89.2703	56.20	95.00
LEFS_Pre	1	11	83.5455	6.46512	1.94931	79.2021	87.8888	73.75	95.00
	Total	21	81.8048	10.08831	2.20145	77.2126	86.3969	56.20	95.00
	0	10	1.8600	2.04679	.64725	.3958	3.3242	.00	5.90
C_VAS_Pre	1	11	.8909	.89045	.26848	.2927	1.4891	.00	2.20
	Total	21	1.3524	1.58985	.34693	.6287	2.0761	.00	5.90
	0	10	5.6000	1.20370	.38064	4.7389	6.4611	3.00	7.70
W_VAS_Pre	1	11	3.1636	1.10840	.33419	2.4190	3.9083	1.40	4.80
	Total	21	4.3238	1.67955	.36651	3.5593	5.0883	1.40	7.70
	0	10	3.7680	1.57489	.49802	2.6414	4.8946	1.70	5.85
Hip_Ext_Pre	1	11	3.4137	1.11376	.33581	2.6655	4.1619	1.77	5.51

Descriptives		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
Hip_Ext_Pre	Total	21	3.5824	1.33013	.29026	2.9770	4.1879	1.70	5.85
	0	10	2.9123	.87208	.27578	2.2884	3.5361	1.58	4.29
Hip_Abd_Pre	1	11	2.9638	.85511	.25782	2.3893	3.5383	2.04	5.05
	Total	21	2.9393	.84175	.18368	2.5561	3.3224	1.58	5.05
	0	10	2.5597	1.00130	.31664	1.8434	3.2760	.97	4.03
Hip_Add_Pre	1	11	2.6780	.72689	.21916	2.1897	3.1663	1.76	3.88
	Total	21	2.6217	.84795	.18504	2.2357	3.0077	.97	4.03
	0	10	1.2215	.40159	.12699	.9342	1.5088	.74	2.11
Hip_IR_Pre	1	11	1.6500	.57249	.17261	1.2654	2.0346	.87	2.87
	Total	21	1.4460	.53342	.11640	1.2031	1.6888	.74	2.87
	0	10	1.4606	.54118	.17114	1.0735	1.8477	.88	2.79
Hip_ER_Pre	1	11	1.6822	.40060	.12079	1.4131	1.9513	1.25	2.46
	Total	21	1.5767	.47423	.10349	1.3608	1.7925	.88	2.79
	0	10	1.9284	.60974	.19282	1.4922	2.3646	1.15	3.10
Knee_Flex_Pre	1	11	2.4285	.60751	.18317	2.0203	2.8366	1.58	3.47
	Total	21	2.1903	.64601	.14097	1.8963	2.4844	1.15	3.47
	0	10	3.7721	1.71866	.54349	2.5426	5.0015	1.57	7.36
Knee_Ext_Pre	1	11	4.1469	1.38240	.41681	3.2182	5.0757	2.18	7.28
	Total	21	3.9684	1.52365	.33249	3.2749	4.6620	1.57	7.36
	0	10	135.0000	7.82091	2.47319	129.4053	140.5947	126.00	147.00
Quad_Flex_Pre	1	11	134.7273	8.21694	2.47750	129.2071	140.2475	120.00	145.50
	Total	21	134.8571	7.82966	1.70857	131.2931	138.4212	120.00	147.00
Ham_Flex_Pre	0	10	83.9000	14.83390	4.69089	73.2885	94.5115	64.00	111.00

	1	11	74.2273	37.47623	11.29951	49.0504	99.4041	.00	121.00
	Total	21	78.8333	28.73601	6.27071	65.7529	91.9138	.00	121.00
	0	10	23.0000	15.24066	4.81952	12.0975	33.9025	1.00	54.00
IT_Flex_pre	1	11	32.5455	10.41742	3.14097	25.5469	39.5440	15.00	45.00
	Total	21	28.0000	13.51481	2.94917	21.8481	34.1519	1.00	54.00
	0	10	14.1500	7.96886	2.51998	8.4494	19.8506	1.00	25.50
Gas_Flex_Pre	1	11	14.6364	5.95857	1.79658	10.6333	18.6394	8.50	27.50
	Total	21	14.4048	6.81106	1.48629	11.3044	17.5051	1.00	27.50
	0	10	8970.7000	1968.77266	622.58058	7562.3249	10379.0751	6035.00	11961.00
Steps_pre	1	11	7963.7273	2949.02696	889.16508	5982.5440	9944.9105	999.00	13326.00
	Total	21	8443.2381	2521.54308	550.24581	7295.4454	9591.0307	999.00	13326.00

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
	Between Groups	13.152	1	13.152	.055	.817
Mass	Within Groups	4557.056	19	239.845		
	Total	4570.208	20			
	Between Groups	30.091	1	30.091	.525	.478
Height	Within Groups	1090.019	19	57.369		
	Total	1120.110	20			
	Between Groups	3.506	1	3.506	.150	.703
Age	Within Groups	445.636	19	23.455		
	Total	449.143	20			
	Between Groups	59.264	1	59.264	.081	.779
Duration	Within Groups	13914.545	19	732.344		
	Total	13973.810	20			
	Between Groups	199.585	1	199.585	4.030	.059
AKPS_Pre	Within Groups	941.082	19	49.531		
	Total	1140.667	20			
	Between Groups	1.487	1	1.487	.014	.907
ADLS_Pre	Within Groups	2031.766	19	106.935		
	Total	2033.252	20			
	Between Groups	51.825	1	51.825	.003	.958
Godin_Pre	Within Groups	346617.127	19	18243.007		
	Total	346668.952	20			
	Between Groups	3.352	1	3.352	1.284	.271
Tegner_Pre	Within Groups	49.600	19	2.611		
	Total	52.952	20			

	Between Groups	21.721	1	21.721	1.101	.307
FABQ_Pre	Within Groups	374.945	19	19.734		
	Total	396.667	20			
	Between Groups	69.993	1	69.993	.677	.421
LEFS_Pre	Within Groups	1965.486	19	103.447		
	Total	2035.480	20			
	Between Groups	4.919	1	4.919	2.048	.169
C_VAS_Pre	Within Groups	45.633	19	2.402		
	Total	50.552	20			
	Between Groups	31.093	1	31.093	23.327	.000
W_VAS_Pre	Within Groups	25.325	19	1.333		
	Total	56.418	20			
	Between Groups	.658	1	.658	.360	.556
Hip_Ext_Pre	Within Groups	34.727	19	1.828		
	Total	35.385	20			

ANOVA		Sum of Squares	df	Mean Square	F	Sig.
	Between Groups	.014	1	.014	.019	.893
Hip_Abd_Pre	Within Groups	14.157	19	.745		
	Total	14.171	20			
	Between Groups	.073	1	.073	.097	.758
Hip_Add_Pre	Within Groups	14.307	19	.753		
	Total	14.380	20			
	Between Groups	.962	1	.962	3.864	.064
Hip_IR_Pre	Within Groups	4.729	19	.249		
	Total	5.691	20			
	Between Groups	.257	1	.257	1.152	.297
Hip_ER_Pre	Within Groups	4.241	19	.223		
	Total	4.498	20			
	Between Groups	1.310	1	1.310	3.537	.075
Knee_Flex_Pre	Within Groups	7.037	19	.370		
	Total	8.347	20			
	Between Groups	.736	1	.736	.306	.587
Knee_Ext_Pre	Within Groups	45.694	19	2.405		
	Total	46.430	20			
	Between Groups	.390	1	.390	.006	.939
Quad_Flex_Pre	Within Groups	1225.682	19	64.510		
	Total	1226.071	20			
	Between Groups	490.085	1	490.085	.581	.455
Ham_Flex_Pre	Within Groups	16025.082	19	843.425		
	Total	16515.167	20			
IT_Flex_pre	Between Groups	477.273	1	477.273	2.855	.107

	Within Groups	3175.727	19	167.144		
	Total	3653.000	20			
	Between Groups	1.239	1	1.239	.025	.875
Gas_Flex_Pre	Within Groups	926.570	19	48.767		
	Total	927.810	20			
	Between Groups	5311397.528	1	5311397.528	.828	.374
Steps_pre	Within Groups	121852192.282	19	6413273.278		
	Total	127163589.810	20			

Descriptive Statistics

	Intervention	Mean	Std. Deviation	N
AKPS_Pre	1	80.4000	5.03764	10
	2	73.1000	7.97844	10
	Total	76.7500	7.49649	20
AKPS_Post	1	87.2000	9.71597	10
	2	87.0000	5.63718	10
	Total	87.1000	7.73168	20
ADLS_Pre	1	79.9000	8.58642	10
	2	79.6600	12.03026	10
	Total	79.7800	10.17316	20
ADLS_Post	1	88.6600	5.94628	10
	2	87.3600	5.23836	10
	Total	88.0100	5.49468	20
FABQ_Pre	1	12.4000	5.29570	10
	2	14.4000	3.68782	10
	Total	13.4000	4.55839	20
FABQ_Post	1	8.6000	5.25357	10
	2	11.4000	3.83551	10
	Total	10.0000	4.70162	20
LEFS_Pre	1	83.1500	6.67312	10
	2	79.8900	13.11280	10
	Total	81.5200	10.26343	20
LEFS_Post	1	90.8240	6.08480	10
	2	91.8500	5.78456	10
	Total	91.3370	5.80216	20

	1	.7600	.81948	10
C_VAS_Pre	2	1.8600	2.04679	10
	Total	1.3100	1.61893	20
	1	.5300	.66341	10
C_VAS_Post	2	.7200	.64083	10
	Total	.6250	.64226	20
	1	3.5076	1.12713	10
Hip_Ext_Pre	2	3.7680	1.57489	10
	Total	3.6378	1.33959	20
	1	4.2199	1.11858	10
Hip_Ext_Post	2	4.8120	1.47748	10
	Total	4.5160	1.31110	20
	1	3.0468	.85336	10
Hip_Abd_Pre	2	2.9123	.87208	10
	Total	2.9795	.84259	20
	1	4.6719	2.92673	10
Hip_Abd_Post	2	4.3247	2.29842	10
	Total	4.4983	2.56740	20
	1	1.7232	.39718	10
Hip_ER_Pre	2	1.4606	.54118	10
	Total	1.5919	.48125	20
	1	3.7452	4.44976	10
Hip_ER_Post	2	2.8229	2.49011	10
	Total	3.2841	3.54120	20
Hip_IR_Pre	1	1.7070	.56960	10

	2	1.2215	.40159	10
	Total	1.4643	.54047	20
	1	1.7528	.39560	10
Hip_IR_Post	2	1.7652	.45166	10
	Total	1.7590	.41328	20
	1	2.4920	.60060	10
Knee_Flex_Pre	2	1.9284	.60974	10
	Total	2.2102	.65618	20
	1	2.5000	.75122	10
Knee_Flex_Post	2	2.4396	.66920	10
	Total	2.4698	.69311	20
	1	4.3014	1.35349	10
Knee_Ext_Pre	2	3.7721	1.71866	10
	Total	4.0367	1.52991	20
	1	5.5745	3.61323	10
Knee_Ext_Post	2	4.3606	1.94439	10
	Total	4.9675	2.89185	20
	1	8660.2000	1932.45473	10
Steps_pre	2	8970.7000	1968.77266	10
	Total	8815.4500	1905.33979	20
	1	9593.6000	2350.50766	10
Steps_Post	2	10128.6000	3627.86620	10
	Total	9861.1000	2987.76294	20

Multivariate Tests[a]

Effect			Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power
Between Subjects	Intercept	Pillai's Trace	1.000	1501.497[b]	12.000	7.000	.000	1.000	18017.967[b]	1.000
		Wilks' Lambda	.000	1501.497[b]	12.000	7.000	.000	1.000	18017.967[b]	1.000
		Hotelling's Trace	2573.995	1501.497[b]	12.000	7.000	.000	1.000	18017.967[b]	1.000
		Roy's Largest Root	2573.995	1501.497[b]	12.000	7.000	.000	1.000	18017.967[b]	1.000
	Intervention	Pillai's Trace	.760	1.845[b]	12.000	7.000	.212	.760	22.142[b]	.401
		Wilks' Lambda	.240	1.845[b]	12.000	7.000	.212	.760	22.142[b]	.401
		Hotelling's Trace	3.163	1.845[b]	12.000	7.000	.212	.760	22.142[b]	.401
		Roy's Largest Root	3.163	1.845[b]	12.000	7.000	.212	.760	22.142[b]	.401
Within Subjects	Time	Pillai's Trace	.824	2.735[b]	12.000	7.000	.095	.824	32.820[b]	.575
		Wilks' Lambda	.176	2.735[b]	12.000	7.000	.095	.824	32.820[b]	.575
		Hotelling's Trace	4.689	2.735[b]	12.000	7.000	.095	.824	32.820[b]	.575
		Roy's Largest Root	4.689	2.735[b]	12.000	7.000	.095	.824	32.820[b]	.575
	Time * Intervention	Pillai's Trace	.717	1.478[b]	12.000	7.000	.310	.717	17.735[b]	.323
		Wilks' Lambda	.283	1.478[b]	12.000	7.000	.310	.717	17.735[b]	.323
		Hotelling's Trace	2.534	1.478[b]	12.000	7.000	.310	.717	17.735[b]	.323
		Roy's Largest Root	2.534	1.478[b]	12.000	7.000	.310	.717	17.735[b]	.323

a. Design: Intercept + Intervention
Within Subjects Design: Time

b. Exact statistic c. Computed using alpha =

Multivariate[a,b]

Within Subjects Effect		Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power
Time	Pillai's Trace	.824	2.735[c]	12.000	7.000	.095	.824	32.820	.575[c]
	Wilks' Lambda	.176	2.735[c]	12.000	7.000	.095	.824	32.820	.575[c]
	Hotelling's Trace	4.689	2.735[c]	12.000	7.000	.095	.824	32.820	.575[c]
	Roy's Largest Root	4.689	2.735[c]	12.000	7.000	.095	.824	32.820	.575[c]
Time * Intervention	Pillai's Trace	.717	1.478[c]	12.000	7.000	.310	.717	17.735	.323[c]
	Wilks' Lambda	.283	1.478[c]	12.000	7.000	.310	.717	17.735	.323[c]
	Hotelling's Trace	2.534	1.478[c]	12.000	7.000	.310	.717	17.735	.323[c]
	Roy's Largest Root	2.534	1.478[c]	12.000	7.000	.310	.717	17.735	.323[c]

a. Design: Intercept + Intervention Within Subjects Design: Time b. Tests are based on averaged variables. c. Exact statistic d. Computed using alpha =

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power
Time	AKPS	Sphericity Assumed	1071.225	1	1071.225	36.092	.000	.667	36.092	1.000
		Greenhouse-Geisser	1071.225	1.000	1071.225	36.092	.000	.667	36.092	1.000
		Huynh-Feldt	1071.225	1.000	1071.225	36.092	.000	.667	36.092	1.000
		Lower-bound	1071.225	1.000	1071.225	36.092	.000	.667	36.092	1.000
	ADLS	Sphericity Assumed	677.329	1	677.329	13.722	.002	.433	13.722	.938
		Greenhouse-Geisser	677.329	1.000	677.329	13.722	.002	.433	13.722	.938
		Huynh-Feldt	677.329	1.000	677.329	13.722	.002	.433	13.722	.938
		Lower-bound	677.329	1.000	677.329	13.722	.002	.433	13.722	.938
	FABQ	Sphericity Assumed	115.600	1	115.600	10.062	.005	.359	10.062	.851
		Greenhouse-Geisser	115.600	1.000	115.600	10.062	.005	.359	10.062	.851
		Huynh-Feldt	115.600	1.000	115.600	10.062	.005	.359	10.062	.851
		Lower-bound	115.600	1.000	115.600	10.062	.005	.359	10.062	.851
	LEFS	Sphericity Assumed	963.735	1	963.735	25.029	.000	.582	25.029	.997
		Greenhouse-Geisser	963.735	1.000	963.735	25.029	.000	.582	25.029	.997
		Huynh-Feldt	963.735	1.000	963.735	25.029	.000	.582	25.029	.997
		Lower-bound	963.735	1.000	963.735	25.029	.000	.582	25.029	.997
	C_Vas	Sphericity Assumed	4.692	1	4.692	5.308	.033	.228	5.308	.587
		Greenhouse-Geisser	4.692	1.000	4.692	5.308	.033	.228	5.308	.587

	Huynh-Feldt	4.692	1.000	4.692	5.308	.033	.228	5.308	.587
	Lower-bound	4.692	1.000	4.692	5.308	.033	.228	5.308	.587
Hip_Ext	Sphericity Assumed	7.711	1	7.711	15.460	.001	.462	15.460	.960
	Greenhouse-Geisser	7.711	1.000	7.711	15.460	.001	.462	15.460	.960
	Huynh-Feldt	7.711	1.000	7.711	15.460	.001	.462	15.460	.960
	Lower-bound	7.711	1.000	7.711	15.460	.001	.462	15.460	.960
Hip_Abd	Sphericity Assumed	23.066	1	23.066	9.112	.007	.336	9.112	.814
	Greenhouse-Geisser	23.066	1.000	23.066	9.112	.007	.336	9.112	.814
	Huynh-Feldt	23.066	1.000	23.066	9.112	.007	.336	9.112	.814
	Lower-bound	23.066	1.000	23.066	9.112	.007	.336	9.112	.814
Hip_ER	Sphericity Assumed	28.634	1	28.634	5.035	.038	.219	5.035	.565
	Greenhouse-Geisser	28.634	1.000	28.634	5.035	.038	.219	5.035	.565
	Huynh-Feldt	28.634	1.000	28.634	5.035	.038	.219	5.035	.565
	Lower-bound	28.634	1.000	28.634	5.035	.038	.219	5.035	.565
Hip_IR	Sphericity Assumed	.869	1	.869	13.515	.002	.429	13.515	.935
	Greenhouse-Geisser	.869	1.000	.869	13.515	.002	.429	13.515	.935
	Huynh-Feldt	.869	1.000	.869	13.515	.002	.429	13.515	.935
	Lower-bound	.869	1.000	.869	13.515	.002	.429	13.515	.935
Knee_Flex	Sphericity Assumed	.674	1	.674	4.663	.045	.206	4.663	.533
	Greenhouse-Geisser	.674	1.000	.674	4.663	.045	.206	4.663	.533
	Huynh-Feldt	.674	1.000	.674	4.663	.045	.206	4.663	.533

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power
Time	Knee_Flex	Lower-bound	.674	1.000	.674	4.663	.045	.206	4.663	.533
	Knee_Ext	Sphericity Assumed	8.664	1	8.664	3.847	.065	.176	3.847	.459
		Greenhouse-Geisser	8.664	1.000	8.664	3.847	.065	.176	3.847	.459
		Huynh-Feldt	8.664	1.000	8.664	3.847	.065	.176	3.847	.459
		Lower-bound	8.664	1.000	8.664	3.847	.065	.176	3.847	.459
	Steps	Sphericity Assumed	10933839.225	1	10933839.225	4.875	.040	.213	4.875	.552
		Greenhouse-Geisser	10933839.225	1.000	10933839.225	4.875	.040	.213	4.875	.552
		Huynh-Feldt	10933839.225	1.000	10933839.225	4.875	.040	.213	4.875	.552
		Lower-bound	10933839.225	1.000	10933839.225	4.875	.040	.213	4.875	.552
	AKPS	Sphericity Assumed	126.025	1	126.025	4.246	.054	.191	4.246	.496
		Greenhouse-Geisser	126.025	1.000	126.025	4.246	.054	.191	4.246	.496
		Huynh-Feldt	126.025	1.000	126.025	4.246	.054	.191	4.246	.496
		Lower-bound	126.025	1.000	126.025	4.246	.054	.191	4.246	.496
Time * Intervention	ADLS	Sphericity Assumed	2.809	1	2.809	.057	.814	.003	.057	.056
		Greenhouse-Geisser	2.809	1.000	2.809	.057	.814	.003	.057	.056
		Huynh-Feldt	2.809	1.000	2.809	.057	.814	.003	.057	.056
		Lower-bound	2.809	1.000	2.809	.057	.814	.003	.057	.056
	FABQ	Sphericity Assumed	1.600	1	1.600	.139	.713	.008	.139	.064
		Greenhouse-Geisser	1.600	1.000	1.600	.139	.713	.008	.139	.064
		Huynh-Feldt	1.600	1.000	1.600	.139	.713	.008	.139	.064
		Lower-bound	1.600	1.000	1.600	.139	.713	.008	.139	.064

LEFS	Sphericity Assumed	45.924	1	45.924	1.193	.289	.062	1.193	.179
	Greenhouse-Geisser	45.924	1.000	45.924	1.193	.289	.062	1.193	.179
	Huynh-Feldt	45.924	1.000	45.924	1.193	.289	.062	1.193	.179
	Lower-bound	45.924	1.000	45.924	1.193	.289	.062	1.193	.179
C_Vas	Sphericity Assumed	2.070	1	2.070	2.342	.143	.115	2.342	.305
	Greenhouse-Geisser	2.070	1.000	2.070	2.342	.143	.115	2.342	.305
	Huynh-Feldt	2.070	1.000	2.070	2.342	.143	.115	2.342	.305
	Lower-bound	2.070	1.000	2.070	2.342	.143	.115	2.342	.305
Hip_Ext	Sphericity Assumed	.275	1	.275	.552	.467	.030	.552	.108
	Greenhouse-Geisser	.275	1.000	.275	.552	.467	.030	.552	.108
	Huynh-Feldt	.275	1.000	.275	.552	.467	.030	.552	.108
	Lower-bound	.275	1.000	.275	.552	.467	.030	.552	.108
Hip_Abd	Sphericity Assumed	.113	1	.113	.045	.835	.002	.045	.055
	Greenhouse-Geisser	.113	1.000	.113	.045	.835	.002	.045	.055
	Huynh-Feldt	.113	1.000	.113	.045	.835	.002	.045	.055
	Lower-bound	.113	1.000	.113	.045	.835	.002	.045	.055
Hip_ER	Sphericity Assumed	1.088	1	1.088	.191	.667	.011	.191	.070
	Greenhouse-Geisser	1.088	1.000	1.088	.191	.667	.011	.191	.070

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power
Time * Intervention	Hip_ER	Huynh-Feldt	1.088	1.000	1.088	.191	.667	.011	.191	.070
		Lower-bound	1.088	1.000	1.088	.191	.667	.011	.191	.070
	Hip_IR	Sphericity Assumed	.620	1	.620	9.644	.006	.349	9.644	.836
		Greenhouse-Geisser	.620	1.000	.620	9.644	.006	.349	9.644	.836
		Huynh-Feldt	.620	1.000	.620	9.644	.006	.349	9.644	.836
		Lower-bound	.620	1.000	.620	9.644	.006	.349	9.644	.836
	Knee_Flex	Sphericity Assumed	.633	1	.633	4.380	.051	.196	4.380	.508
		Greenhouse-Geisser	.633	1.000	.633	4.380	.051	.196	4.380	.508
		Huynh-Feldt	.633	1.000	.633	4.380	.051	.196	4.380	.508
		Lower-bound	.633	1.000	.633	4.380	.051	.196	4.380	.508
	Knee_Ext	Sphericity Assumed	1.172	1	1.172	.520	.480	.028	.520	.105
		Greenhouse-Geisser	1.172	1.000	1.172	.520	.480	.028	.520	.105
		Huynh-Feldt	1.172	1.000	1.172	.520	.480	.028	.520	.105
		Lower-bound	1.172	1.000	1.172	.520	.480	.028	.520	.105
	Steps	Sphericity Assumed	126000.625	1	126000.625	.056	.815	.003	.056	.056
		Greenhouse-Geisser	126000.625	1.000	126000.625	.056	.815	.003	.056	.056
		Huynh-Feldt	126000.625	1.000	126000.625	.056	.815	.003	.056	.056
		Lower-bound	126000.625	1.000	126000.625	.056	.815	.003	.056	.056
Error(Time)	AKPS	Sphericity Assumed	534.250	18	29.681					
		Greenhouse-Geisser	534.250	18.000	29.681					
		Huynh-Feldt	534.250	18.000	29.681					

	Lower-bound	534.250	18.000	29.681
ADLS	Sphericity Assumed	888.522	18	49.362
	Greenhouse-Geisser	888.522	18.000	49.362
	Huynh-Feldt	888.522	18.000	49.362
	Lower-bound	888.522	18.000	49.362
FABQ	Sphericity Assumed	206.800	18	11.489
	Greenhouse-Geisser	206.800	18.000	11.489
	Huynh-Feldt	206.800	18.000	11.489
	Lower-bound	206.800	18.000	11.489
LEFS	Sphericity Assumed	693.074	18	38.504
	Greenhouse-Geisser	693.074	18.000	38.504
	Huynh-Feldt	693.074	18.000	38.504
	Lower-bound	693.074	18.000	38.504
C_Vas	Sphericity Assumed	15.913	18	.884
	Greenhouse-Geisser	15.913	18.000	.884
	Huynh-Feldt	15.913	18.000	.884
	Lower-bound	15.913	18.000	.884
Hip_Ext	Sphericity Assumed	8.977	18	.499

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.
Error(Time)	Hip_Ext	Greenhouse-Geisser	8.977	18.000	.499		
		Huynh-Feldt	8.977	18.000	.499		
		Lower-bound	8.977	18.000	.499		
	Hip_Abd	Sphericity Assumed	45.563	18	2.531		
		Greenhouse-Geisser	45.563	18.000	2.531		
		Huynh-Feldt	45.563	18.000	2.531		
		Lower-bound	45.563	18.000	2.531		
	Hip_ER	Sphericity Assumed	102.374	18	5.687		
		Greenhouse-Geisser	102.374	18.000	5.687		
		Huynh-Feldt	102.374	18.000	5.687		
		Lower-bound	102.374	18.000	5.687		
	Hip_IR	Sphericity Assumed	1.157	18	.064		
		Greenhouse-Geisser	1.157	18.000	.064		
		Huynh-Feldt	1.157	18.000	.064		
		Lower-bound	1.157	18.000	.064		
	Knee_Flex	Sphericity Assumed	2.601	18	.144		
		Greenhouse-Geisser	2.601	18.000	.144		
		Huynh-Feldt	2.601	18.000	.144		
		Lower-bound	2.601	18.000	.144		
	Knee_Ext	Sphericity Assumed	40.537	18	2.252		

Steps	Greenhouse-Geisser	40.537	18.000	2.252	
	Huynh-Feldt	40.537	18.000	2.252	
	Lower-bound	40.537	18.000	2.252	
	Sphericity Assumed	40371866.650	18	2242881.481	
	Greenhouse-Geisser	40371866.650	18.000	2242881.481	
	Huynh-Feldt	40371866.650	18.000	2242881.481	
	Lower-bound	40371866.650	18.000	2242881.481	

a. Computed using alpha =

Tests of Within-Subjects Contrasts

Source	Measure	Time	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power
Time	AKPS	Linear	1071.225	1	1071.225	36.092	.000	.667	36.092	1.000
	ADLS	Linear	677.329	1	677.329	13.722	.002	.433	13.722	.938
	FABQ	Linear	115.600	1	115.600	10.062	.005	.359	10.062	.851
	LEFS	Linear	963.735	1	963.735	25.029	.000	.582	25.029	.997
	C_Vas	Linear	4.692	1	4.692	5.308	.033	.228	5.308	.587
	Hip_Ext	Linear	7.711	1	7.711	15.460	.001	.462	15.460	.960
	Hip_Abd	Linear	23.066	1	23.066	9.112	.007	.336	9.112	.814
	Hip_ER	Linear	28.634	1	28.634	5.035	.038	.219	5.035	.565
	Hip_IR	Linear	.869	1	.869	13.515	.002	.429	13.515	.935
	Knee_Flex	Linear	.674	1	.674	4.663	.045	.206	4.663	.533
	Knee_Ext	Linear	8.664	1	8.664	3.847	.065	.176	3.847	.459
	Steps	Linear	10933839.225	1	10933839.225	4.875	.040	.213	4.875	.552
Time * Intervention	AKPS	Linear	126.025	1	126.025	4.246	.054	.191	4.246	.496
	ADLS	Linear	2.809	1	2.809	.057	.814	.003	.057	.056
	FABQ	Linear	1.600	1	1.600	.139	.713	.008	.139	.064
	LEFS	Linear	45.924	1	45.924	1.193	.289	.062	1.193	.179
	C_Vas	Linear	2.070	1	2.070	2.342	.143	.115	2.342	.305
	Hip_Ext	Linear	.275	1	.275	.552	.467	.030	.552	.108
	Hip_Abd	Linear	.113	1	.113	.045	.835	.002	.045	.055
	Hip_ER	Linear	1.088	1	1.088	.191	.667	.011	.191	.070
	Hip_IR	Linear	.620	1	.620	9.644	.006	.349	9.644	.836

	Knee_Flex	Linear	.633	1	.633	4.380	.051	.196	4.380	.508
	Knee_Ext	Linear	1.172	1	1.172	.520	.480	.028	.520	.105
	Steps	Linear	126000.625	1	126000.625	.056	.815	.003	.056	.056
	AKPS	Linear	534.250	18	29.681					
	ADLS	Linear	888.522	18	49.362					
	FABQ	Linear	206.800	18	11.489					
	LEFS	Linear	693.074	18	38.504					
	C_Vas	Linear	15.912	18	.884					
Error(Time	Hip_Ext	Linear	8.977	18	.499					
)	Hip_Abd	Linear	45.563	18	2.531					
	Hip_ER	Linear	102.374	18	5.687					
	Hip_IR	Linear	1.157	18	.064					
	Knee_Flex	Linear	2.601	18	.144					
	Knee_Ext	Linear	40.537	18	2.252					
	Steps	Linear	40371866.650	18	2242881.481					

Levene's Test of Equality of Error Variances[a]

	F	df1	df2	Sig.
AKPS_Pre	1.111	1	18	.306
AKPS_Post	1.504	1	18	.236
ADLS_Pre	2.410	1	18	.138
ADLS_Post	.148	1	18	.705
FABQ_Pre	.927	1	18	.348
FABQ_Post	1.261	1	18	.276
LEFS_Pre	3.592	1	18	.074
LEFS_Post	.281	1	18	.602
Hip_Ext_Pre	2.000	1	18	.174
Hip_Ext_Post	1.220	1	18	.284
Hip_Abd_Pre	.202	1	18	.658
Hip_Abd_Post	.312	1	18	.584
Hip_ER_Pre	.086	1	18	.773
Hip_ER_Post	2.457	1	18	.134
Hip_IR_Pre	.520	1	18	.480
Hip_IR_Post	.031	1	18	.863
Knee_Flex_Pre	.107	1	18	.748
Knee_Flex_Post	.040	1	18	.844
Knee_Ext_Pre	.676	1	18	.422
Knee_Ext_Post	2.281	1	18	.148
Steps_pre	.274	1	18	.607
Steps_Post	3.500	1	18	.078

Tests of Between-Subjects Effects

Transformed Variable: Average

Source	Measure	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power
Intercept	AKPS	268468.225	1	268468.225	3445.213	.000	.995	3445.213	1.000
	ADLS	281534.841	1	281534.841	3084.844	.000	.994	3084.844	1.000
	FABQ	5475.600	1	5475.600	179.593	.000	.909	179.593	1.000
	LEFS	298795.424	1	298795.424	2846.300	.000	.994	2846.300	1.000
	C_Vas	37.442	1	37.442	18.989	.000	.513	18.989	.984
	Hip_Ext	664.843	1	664.843	214.903	.000	.923	214.903	1.000
	Hip_Abd	559.182	1	559.182	108.847	.000	.858	108.847	1.000
	Hip_ER	237.750	1	237.750	31.539	.000	.637	31.539	1.000
	Hip_IR	103.891	1	103.891	289.520	.000	.941	289.520	1.000
	Knee_Flex	219.021	1	219.021	300.920	.000	.944	300.920	1.000
	Knee_Ext	810.770	1	810.770	94.729	.000	.840	94.729	1.000
	Steps	3488135199.025	1	3488135199.025	319.851	.000	.947	319.851	1.000
Intervention	AKPS	140.625	1	140.625	1.805	.196	.091	1.805	.246
	ADLS	5.929	1	5.929	.065	.802	.004	.065	.057
	FABQ	57.600	1	57.600	1.889	.186	.095	1.889	.256
	LEFS	12.477	1	12.477	.119	.734	.007	.119	.062
	C_Vas	4.160	1	4.160	2.110	.164	.105	2.110	.280
	Hip_Ext	1.817	1	1.817	.587	.453	.032	.587	.112
	Hip_Abd	.580	1	.580	.113	.741	.006	.113	.062
	Hip_ER	3.510	1	3.510	.466	.504	.025	.466	.099

	Hip_IR	.560	1	.560	1.559	.228	.080	1.559	.219
	Knee_Flex	.974	1	.974	1.338	.263	.069	1.338	.195
	Knee_Ext	7.597	1	7.597	.888	.359	.047	.888	.145
	Steps	1787175.625	1	1787175.625	.164	.690	.009	.164	.067
Error	AKPS	1402.650	18	77.925					
	ADLS	1642.750	18	91.264					
	FABQ	548.800	18	30.489					
	LEFS	1889.582	18	104.977					
	C_Vas	35.492	18	1.972					
	Hip_Ext	55.687	18	3.094					
	Hip_Abd	92.472	18	5.137					
	Hip_ER	135.691	18	7.538					
	Hip_IR	6.459	18	.359					
	Knee_Flex	13.101	18	.728					
	Knee_Ext	154.060	18	8.559					
	Steps	196298851.850	18	10905491.769					

Estimates

Measure	Intervention	Mean	Std. Error	95% Confidence Interval	
				Lower Bound	Upper Bound
AKPS	1	83.800	1.974	79.653	87.947
	2	80.050	1.974	75.903	84.197
ADLS	1	84.280	2.136	79.792	88.768
	2	83.510	2.136	79.022	87.998
FABQ	1	10.500	1.235	7.906	13.094
	2	12.900	1.235	10.306	15.494
LEFS	1	86.987	2.291	82.174	91.800
	2	85.870	2.291	81.057	90.683
Hip_Ext	1	3.864	.393	3.037	4.690
	2	4.290	.393	3.464	5.116
Hip_Abd	1	3.859	.507	2.795	4.924
	2	3.618	.507	2.554	4.683
Hip_ER	1	2.734	.614	1.444	4.024
	2	2.142	.614	.852	3.432
Hip_IR	1	1.730	.134	1.448	2.011
	2	1.493	.134	1.212	1.775
Knee_Flex	1	2.496	.191	2.095	2.897
	2	2.184	.191	1.783	2.585
Knee_Ext	1	4.938	.654	3.564	6.312
	2	4.066	.654	2.692	5.441
Steps	1	9126.900	738.427	7575.522	10678.278
	2	9549.650	738.427	7998.272	11101.028

Pairwise Comparisons

Measure	(I) Intervention	(J) Intervention	Mean Difference	Std. Error	Sig.[a]	95% CI for Difference[a]	
AKPS	1	2	3.750	2.792	.196	-2.115	9.615
	2	1	-3.750	2.792	.196	-9.615	2.115
ADLS	1	2	.770	3.021	.802	-5.577	7.117
	2	1	-.770	3.021	.802	-7.117	5.577
FABQ	1	2	-2.400	1.746	.186	-6.068	1.268
	2	1	2.400	1.746	.186	-1.268	6.068
LEFS	1	2	1.117	3.240	.734	-5.690	7.924
	2	1	-1.117	3.240	.734	-7.924	5.690
Hip_Ext	1	2	-.426	.556	.453	-1.595	.742
	2	1	.426	.556	.453	-.742	1.595
Hip_Abd	1	2	.241	.717	.741	-1.265	1.747
	2	1	-.241	.717	.741	-1.747	1.265
Hip_ER	1	2	.592	.868	.504	-1.232	2.417
	2	1	-.592	.868	.504	-2.417	1.232
Hip_IR	1	2	.237	.189	.228	-.161	.635
	2	1	-.237	.189	.228	-.635	.161
Knee_Flex	1	2	.312	.270	.263	-.255	.879
	2	1	-.312	.270	.263	-.879	.255
Knee_Ext	1	2	.872	.925	.359	-1.072	2.815
	2	1	-.872	.925	.359	-2.815	1.072
Steps	1	2	-422.750	1044.294	.690	-2616.729	1771.229
	2	1	422.750	1044.294	.690	-1771.229	2616.729

Multivariate Tests

	Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power
Pillai's trace	.760	1.845[a]	12.000	7.000	.212	.760	22.142	.401
Wilks' lambda	.240	1.845[a]	12.000	7.000	.212	.760	22.142	.401
Hotelling's trace	3.163	1.845[a]	12.000	7.000	.212	.760	22.142	.401
Roy's largest root	3.163	1.845[a]	12.000	7.000	.212	.760	22.142	.401

Each F tests the multivariate effect of Intervention. These tests are based on the linearly independent pairwise comparisons among the estimated marginal means.

a. Exact statistic

b. Computed using alpha =

Measure		Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power
AKPS	Contrast	70.313	1	70.313	1.805	.196	.091	1.805	.246
	Error	701.325	18	38.963					
ADLS	Contrast	2.964	1	2.964	.065	.802	.004	.065	.057
	Error	821.375	18	45.632					
FABQ	Contrast	28.800	1	28.800	1.889	.186	.095	1.889	.256
	Error	274.400	18	15.244					
LEFS	Contrast	6.238	1	6.238	.119	.734	.007	.119	.062
	Error	944.791	18	52.488					
Hip_Ext	Contrast	.908	1	.908	.587	.453	.032	.587	.112
	Error	27.843	18	1.547					
Hip_Abd	Contrast	.290	1	.290	.113	.741	.006	.113	.062
	Error	46.236	18	2.569					
Hip_ER	Contrast	1.755	1	1.755	.466	.504	.025	.466	.099
	Error	67.845	18	3.769					
Hip_IR	Contrast	.280	1	.280	1.559	.228	.080	1.559	.219
	Error	3.230	18	.179					
Knee_Flex	Contrast	.487	1	.487	1.338	.263	.069	1.338	.195
	Error	6.551	18	.364					
Knee_Ext	Contrast	3.798	1	3.798	.888	.359	.047	.888	.145
	Error	77.030	18	4.279					
Steps	Contrast	893587.813	1	893587.813	.164	.690	.009	.164	.067
	Error	98149425.925	18	5452745.885					

Descriptives

GROC

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
1	10	4.2000	1.81353	.57349	2.9027	5.4973	.00	6.00
2	10	4.6000	1.83787	.58119	3.2853	5.9147	1.00	7.00
Total	20	4.4000	1.78885	.40000	3.5628	5.2372	.00	7.00

Test of Homogeneity of Variances

GROC

Levene Statistic	df1	df2	Sig.
.066	1	18	.800

ANOVA

GROC

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.800	1	.800	.240	.630
Within Groups	60.000	18	3.333		
Total	60.800	19			

Correlations

		changekneeext	changekneeflex	changehipext	changehipir	changehiper
changekneeext	Pearson Correlation	1	.306	.246	.202	.863**
	Sig. (2-tailed)		.190	.296	.393	.000
	N	20	20	20	20	20
changekneeflex	Pearson Correlation	.306	1	.366	.530*	.166
	Sig. (2-tailed)	.190		.112	.016	.485
	N	20	20	20	20	20
changehipext	Pearson Correlation	.246	.366	1	.357	.174
	Sig. (2-tailed)	.296	.112		.123	.464
	N	20	20	20	20	20
changehipir	Pearson Correlation	.202	.530*	.357	1	.013
	Sig. (2-tailed)	.393	.016	.123		.956
	N	20	20	20	20	20
changehiper	Pearson Correlation	.863**	.166	.174	.013	1
	Sig. (2-tailed)	.000	.485	.464	.956	
	N	20	20	20	20	20
changehipabd	Pearson Correlation	.741**	.239	.400	.059	.816**
	Sig. (2-tailed)	.000	.311	.081	.806	.000
	N	20	20	20	20	20
changeakps	Pearson Correlation	.126	.621**	.277	.479*	.044
	Sig. (2-tailed)	.597	.004	.236	.033	.852
	N	20	20	20	20	20
changeadls	Pearson Correlation	.226	.267	.084	.167	-.039
	Sig. (2-tailed)	.339	.254	.725	.482	.871

	N	20	20	20	20	20
	Pearson Correlation	.244	.521*	.166	.360	.006
changelefs	Sig. (2-tailed)	.299	.018	.485	.119	.979
	N	20	20	20	20	20
	Pearson Correlation	-.191	-.186	.061	-.219	-.233
changefabq	Sig. (2-tailed)	.420	.432	.798	.354	.322
	N	20	20	20	20	20
	Pearson Correlation	.046	-.127	.061	-.132	.146
changecvas	Sig. (2-tailed)	.849	.594	.797	.580	.539
	N	20	20	20	20	20
	Pearson Correlation	-.164	-.314	-.064	.006	-.294
changewvas	Sig. (2-tailed)	.490	.177	.789	.980	.208
	N	20	20	20	20	20
	Pearson Correlation	.061	.187	-.152	.107	.193
changesteps	Sig. (2-tailed)	.797	.429	.521	.655	.416
	N	20	20	20	20	20

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

APPENDIX E
Recommendations for Future Research

- Additional research evaluating differences in strength, muscle activity, balance, kinematics, and core function should be conducted between males and females with patellofemoral pain to modify impairment rehabilitation programs
- Differences between adolescent and adults with patellofemoral pain should be examined
- Duration of rehabilitation length may play a role in functional improvement
- Long-term studies should evaluate benefit of rehabilitation on strength, functional movement, and muscle activity.

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