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An Electromyographic Study of the Quadriceps and Hamstrings Recruitment during Two Closed Kinetic Chain Activities

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AN ELECTROMYOGRAPHIC STUDY OF THE QUADRICEPS AND HAMSTRINGS RECRUITMENT DURING TWO CLOSED KINETIC CHAIN ACTIVITIES

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A Scholarly Project

Submitted to the Graduate Faculty of the

Department of Physical Therapy

School of Medicine

University of North Dakota

in partial fulfillment of the requirements

for the degree of

Doctor of Physical Therapy

Grand Forks, North Dakota May 2005



This Scholarly Project, submitted by Linda Hanson, Shauna Salz, and Suzanne Steffes in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

(Graduate School Advisor)

(Chairperson, Physical Therapy)

PERMISSION

An Electromyographic Study of the Quadriceps and Hamstrings Recruitment During Two Closed Kinetic Chain Activities

Department

Physical Therapy

Degree

Title

Doctor of Physical Therapy

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Signatures

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(Shauna T. Salz)

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Date

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ABSTRACT

Knee pain and injury are a commonly seen diagnosis in physical therapy practice. Closed kinetic chain activities are frequently used to treat these diagnoses, because of their safety and functional properties. However isolation of specific muscles is difficult with closed kinetic chain exercises. The researchers chose to further study closed kinetic chain exercises in order to compare traditional closed kinetic chain exercises with a recently developed closed kinetic chain device. The purpose of this study is to assess EMG activity of the quadriceps and hamstrings during two different closed kinetic chain activities of the knee, one a traditional method and the other a new, untested device. The first is a traditional wall slide, consisting of the participant leaning with the back on the wall and squatting. The second is a squat using a closed kinetic chain device (CCD) that holds the leg below the knee stationary.

Seventeen healthy subjects between the ages of 22-26 years of age, mean age of 23.5, performed a maximal voluntary contraction (MVC) and 2 trials of each exercise. EMG activity of the quadriceps (vastus medialis and vastus lateralis) and hamstrings (semitendinosus and biceps femoris) was recorded through surface electrodes. This data was then normalized to percent MVC by comparing the muscle activity in the trial with the muscle activity in the reference MVC.

Results of this study showed a significant difference in % MVC between exercises in the vastus medialis, vastus lateralis, and semitendinosus. There was no significant difference in the % MVC for the biceps femoris.

In conclusion, the CCD resulted in a higher % MVC in the quadriceps than the wall slide. It also resulted in a decrease in the % MVC of the semitendinosus as compared to the wall slide.

CHAPTER I

INTRODUCTION

Knee pain and injury are a commonly seen diagnosis in physical therapy practice. Closed kinetic chain activities are frequently used to treat these diagnoses, because of their safety and functional properties. However isolation of specific muscles is difficult with closed kinetic chain exercises. The researchers chose to further study closed kinetic chain exercises in order to compare traditional closed kinetic chain exercises with a recently developed closed kinetic chain device.

Problem Statement

The problem to be answered in this study is whether the electromyographic (EMG) activity of the quadriceps and hamstrings while using the closed kinetic chain squat device is greater, equal to, or less than the EMG activity of the same muscles during the wall slide.

Purpose of Study

The purpose of this study is to assess EMG activity of the quadriceps and hamstrings during two different closed kinetic chain activities of the knee, one a traditional method and the other a new, untested device. The first is a traditional wall slide, consisting of the participant leaning with the back on the wall and squatting. The second is a squat using a device that holds the leg below the knee stationary.

Significance

The significance of this study is to determine if activation of the quadriceps and hamstrings in the closed kinetic chain squat device is equivalent to that of the wall slide.

Research Question

How does the EMG activity quadriceps and hamstrings during use of the closed kinetic chain squat device compare to that of wall slide?

Hypothesis

There will be a significant difference in EMG activity of the quadriceps and hamstrings between use of the new closed kinetic chain squat device and the wall slide.

CHAPTER II

LITERATURE REVIEW

There has been a considerable amount of research done comparing closed kinetic chain exercises to open kinetic chain activities in the lower extremities for rehabilitation. However, closed kinetic chain exercises are being advocated more in the rehabilitation process because they have been shown to closely simulate functional activities. Closed kinetic chain exercise was first described in 1955 by Steindler,¹ who observed that when the fixed foot or hand meets considerable resistance, muscular recruitment of the joint motion occurred differently from that seen when the foot or hand was free to move without restriction. He defined a closed chain condition occurring when the foot and hand meet enough resistance to prohibit or restrain their free motion, requiring the muscles to be activated consecutively from distal to proximal. Kisner and Colby² define closed kinetic chain exercise as an activity in which the body moves over a fixed distal segment, when in a weight-bearing position. Open kinetic chain exercise is defined as an activity in which the distal segment of the body moves freely during exercise when in a non-weightbearing position.²

Physical therapy lower extremity rehabilitation protocols until recently contained many open kinetic chain exercises. Such exercises in which the foot is "free" to move include seated knee extension and flexion exercises, hamstring curls, and multi-

directional hip. These exercises appear to be less functional in terms of many athletic movements and serve primarily as a supportive role in strength and conditioning programs.³ Research has shown that there are many limitations with open kinetic chain exercises such as putting more anteroposterior shear force at the knee joint, when there is increased quadriceps femoris muscle tension. As a result this may produce a potentially dangerous situation in which too much force can be directed through the knee joint.⁴ Other limitations that occur with open chain exercises include increased patellofemoral compression, increased tibial sheer forces, increased anterior cruciate ligament (ACL) strain, and nonfunctional muscle recruitment patterns.

Due to the limitations of open kinetic chain exercises, closed kinetic chain exercises have received increased attention over the last 15 years. One reason for the increased attention toward closed kinetic chain exercises is that they simulate many functional activities, such as squatting, stooping, and ascending and descending stairs.⁵ Research has shown that there is a tendency toward better results in terms of strength⁵ and functional performance enhancement⁶ from closed kinetic chain exercises as compared to open kinetic chain exercises. Kibler and Livingston⁷ stated "closed kinetic chain is preferable to other exercise programs in that they simulate normal physiologic and biomechanical functions, create little shear stress across injured or healing joints, and reproduce proprioceptive stimuli." Closed kinetic chain exercises reduce anteroposterior force by increasing the joint compressive forces that occur when the extremity is loaded by body weight. Body weight provides joint stability and allows for more strenuous strengthening workouts without the shearing forces that are produced with open kinetic chain exercises. Weightbearing exercises cause less elongation of the ACL than non-

weightbearing (open kinetic chain) exercises, ⁴ an observation, which has been shown to be beneficial in ACL rehabilitation programs. These exercises require graded, coordinated, and sequential muscle activation. They also promote cocontraction muscle activation and emphasize proprioceptive feedback to initiate and control the muscle activation sequences.⁸ Such exercise techniques have been shown to be effective in accelerating rehabilitation protocols and returning athletes to play more quickly after injury.

Two common closed kinetic chain exercise commonly used in rehabilitation programs are the wall slide and the squat. During a squat, the hip extensors and plantarflexors are active to control motion at the hip and ankle, but because it is a closed kinetic chain exercise, the hip extensors and ankle plantar flexors also contribute to the forces and torques that occur at the knee.⁹ Blanpied⁹ showed that a squat machine exercise showed greater activation of the gluteal and hamstring muscles when compared to the wall slide. The wall slide demonstrated greater activation of the quadriceps when compared to the squat machine exercise.

Understanding the biomechanics of the knee can help to determine whether open or closed chain exercises are appropriate rehabilitation exercises to use in physical therapy. Looking at the compressive joint load of the knee can be a way to understand the biomechanics of the knee. Compressive joint forces have been shown to force the articular surfaces of the tibia and femur together, resulting in less tibial anterior-posterior (AP) displacement when compared to the femur in an unweighted knee. A cadaver study by Markolf et al¹⁰ showed that compressive joint loading produced a decrease in resultant ACL force when compared with the unweighted knee.

Measuring EMG activity of the hamstring and quadriceps muscles to estimate the amount of cocontraction is also an approach to understand the biomechanics of the knee. The magnitude and direction of the hamstring and quadriceps muscle forces directly affect the force balance across the knee, especially the anterior-directed shear force that acts on the tibia. During a closed kinetic chain exercise such as squatting, the hamstrings are thought to produce a greater contraction because they are needed to stabilize the pelvis, trunk, and knee. This shows that weightbearing exercises require cocontraction of the quadriceps and hamstrings, therefore minimizing the anterior directed shear force that acts on the ACL and tibia.¹¹ Escamilla et al³ showed greater co contraction of the quadriceps and hamstrings during a closed kinetic chain exercise (squat), when compared to an open kinetic chain exercise, with the greatest difference in hamstring activity during knee extension.

Measuring AP displacement has been a way to describe the knee biomechanics. A study by Yack et al¹² showed that for an ACL deficient knee, there is greater anterior displacement of the tibia during active extension than during squatting. For normal knees, there was no difference in the anterior displacement of the tibia with the type of exercise performed. They concluded that there is less stress on the ACL with squatting than with an active open chain extension exercise. The flexion-extension motion of the knee produces three dimensional displacement of the tibia relative to the femur because of the complex geometry of the articular surfaces with resultant strain on the ACL.¹³ With active flexion-extension and squatting, there is distal displacement and internal-external rotation of the tibia relative to femur. This shows that the kinematic behavior of the knee is not isolated to an AP-directed axis. It instead involves a complex three-dimensional

action between the femur and tibia and is guided by the biomechanical behavior of the ligaments.¹¹ Open kinetic chain exercises increase anterior displacement of the tibia on the femur. When external resistance of seven pounds or less is applied to the distal tibia, the quadriceps are required to work twice as hard as when there is not resistance, greatly increasing the stress on the ACL. This stress can be reduced through cocontraction of the quadriceps and hamstrings. Cocontraction adds a posterior translatory force to counteract the anterior translation placed by the quadriceps. This cocontraction is thought to stabilize the knee during the strengthening process. "The hamstrings are the primary stabilizers of the knee, acting synergistically with the ACL, as well as protecting it from excessive stress."¹⁴ Establishing a strong quadriceps to hamstring ratio will produce better outcomes during rehabilitation.¹⁴

Closed kinetic chain (CKC) exercises have become a very prevalent exercise in physical therapy in the last 15 years. CKC exercise is commonly used post-operatively following anterior cruciate ligament (ACL) reconstruction and for patellofemoral syndrome management.

Following ACL reconstruction surgery, the graft is very fragile and exercises done in rehabilitation need to protect this graft. CKC exercises have been shown to decrease joint shear and minimize ACL strain while providing cocontraction of the agonist/antagonist muscles.⁷ Another study states that CKC exercise accelerate and improve functional restoration while decreasing loss of range of motion, loss of strength, and preventing anterior knee pain.¹⁵

In rehabilitation of patellofemoral syndrome, improving quadriceps strength and minimizing the shear force of the patellofemoral joint are the main goals. These goals

can be achieved through using CKC exercises as stated in the following studies. Steinkamp et al¹⁶ stated that CKC activities decrease stress on the patellofemoral joint, allowing increased pain free range of motion.¹⁶ An additional study showed CKC exercises from 0° to 60° knee flexion cause maximal vastus medialis activation.¹⁷

Both ACL surgical reconstruction and patellofemoral syndrome could benefit from the findings of this study of the CCD. This study will show EMG output of the quadriceps and hamstrings during the 0° to 90° knee flexion range of motion. The results will show if using the CCD will increase or decrease EMG output and these results can be applied to rehabilitation.

Electromyography (EMG) is the recording and study of muscle action potentials for the purpose of evaluating nerve and muscle function¹⁸. Electromyography is frequently used in order to assess muscle activation during closed kinetic chain exercises. The collected EMG data allows researchers to draw conclusions regarding specific muscle group activity, timing, and motor unit recruitment. Wilk et al¹⁹ compared the EMG data of open and closed kinetic chain exercises, concluding that there was greater cocontraction of the quadriceps and hamstrings during closed kinetic chain as compared to open kinetic chain, resulting in a smaller quadriceps and hamstring ratio. Quadriceps muscle activity was greatest in CKCE when the knee was near full flexion in a study by Escamilla et al³ in which they quantified the EMG activity of muscles during closed kinetic chain and open kinetic chain activity. In the same study, they found that the vasti muscles of the quadriceps were more active during closed kinetic chain activity than the rectus femoris, suggesting the importance of EMG measurement of the vastus medialis and vastus lateralis during analysis of closed kinetic chain activities.

The purpose of this study is to examine the muscle activation of the quadriceps and hamstring muscles during a wall slide compared to the muscle activation using a closed kinetic chain device similar to the wall slide. Hopefully the results can give direction as to the more efficient activity for the recruitment of lower extremity musculature in knee strengthening exercises.

CHAPTER III

METHODS

Subjects

Subjects selected for participation in this study were obtained on a voluntary basis. Seventeen subjects (5 male, 12 female) took part in the study. The mean age of the subjects was 23.5 years. Exclusion criteria for the study consisted of current or chronic knee, hip, or ankle pathology, history of anterior cruciate ligament reconstruction, and current low back pain. The testing was completed on the UND campus in the School of Medicine and Health Sciences in one session lasting between 30 minutes to 1 hour. All subjects signed an informed consent prior to testing and the University of North Dakota Institutional Review Board approved the study and is designated project number IRB-200406-388 (See Appendix). The subjects randomly selected a card to determine which exercise they would begin first.

Instrumentation

Electromyographic (EMG) signals were used to determine the muscle activity during the chosen exercises. These signals were collected using a handheld Noraxon Telemyo 8 telemetry unit (Noraxon USA, Scottsdale, AZ). The transmitted EMG signal was collected by a Noraxon Telemyo 8 receiver and then digitalized by an analog digital interface board in the Peak Analog Module (Peak Performance Technologies, Englewood CO).

Electrode Placement

Bipolar circular surface electrodes were placed onto the vastus medialis, vastus lateralis, biceps femoris and semitendinosus of the right leg. There was distance of 1.5 inches between the centers of electrodes. Prior to electrode placement the skin was shaved with an electric razor and cleaned with isopropyl alcohol and allowed to dry in order to reduce impedance²⁰. Electrode placements, shown in Figure 1, indicate the appropriate motor points for standard electrode placement. Placement for the vastus lateralis electrodes was ¹/₄ of the distance from the lateral knee joint to the ASIS. The vastus medialis electrodes were placed 1/4 of the distance between the medial knee joint and the ASIS, the biceps femoris electrodes $\frac{1}{2}$ the distance between the ischial tuberosity and the lateral femoral condyle. The semitendinosus electrodes were placed 1/2 the distance between the ischial tuberosity to the medial femoral condyle. For standardization the same standard tape measure was used for all subjects. Positive and negative electrodes were placed at each motor point, oriented in a parallel relation to the muscle fibers. A ground electrode was placed over the medial proximal tibia of the dominant leg. An electrogoniometer was also attached to the lateral border of the right knee running parallel with the long axes of the fibula and femur in order to determine knee angles during each trial.

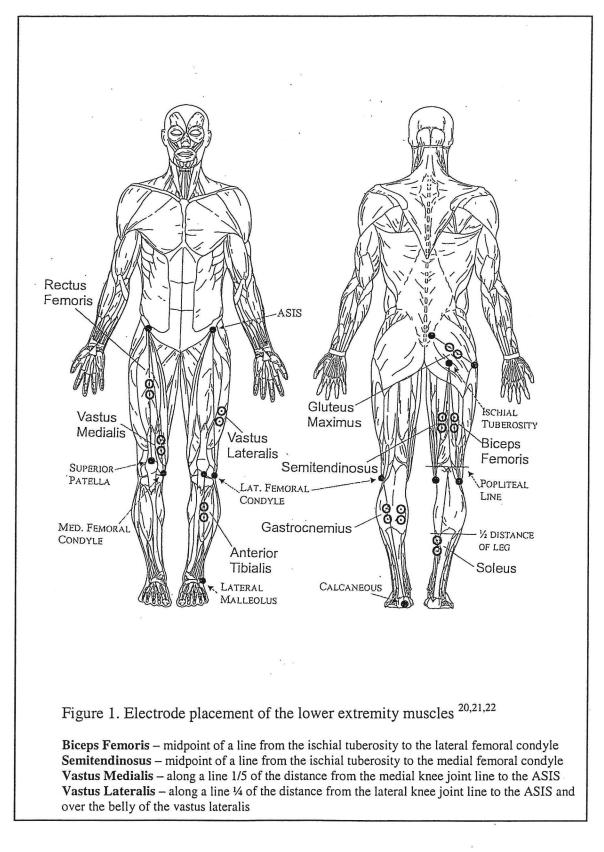
Procedure

The subjects completed a 3-minute, low intensity warm up on a stationary bike. Surface electrodes recorded their EMG activity during the testing. EMG activity was recorded for the vastus medialis, vastus lateralis, biceps femoris, and semitendinosus of

the right leg. Their maximal voluntary isometric contraction was recorded for both the right hamstrings and quadriceps. The subjects chose a card in order to determine the order of the exercises performed. The closed kinetic chain (CKC) device (Figure 2) was adjusted according to their height. When the subjects were seated on the CKC device, their knee angle was measured to be 90 degrees. The shin pads were adjusted in order to keep the lower leg secure and stabilized throughout the exercise. The subjects were instructed to try to keep their back straight and their arms crossed over their chests. The subjects were also told not to rebound off the seat of the device and to match their pace with the metronome. The subjects were allowed 3 practice repetitions. They performed two sets of 5 repetitions of the exercise as their EMG and electrogoniometer data were recorded. The wall slide exercises consisted of the subject performing a squat with the back flat against a wall, lower their buttocks to a box. The box was adjusted so the subjects were seated on the wall slide box with the knee angle was measured at 90 degrees. . Tape was placed on the floor to insure proper foot placement. They were instructed not to sit on the box during the exercise testing, not to "rebound" off the box, and to keep their arms crossed over their chests. They were given 3 practice repetitions to practice the exercise, matching the pace set by the metronome. The subjects performed two sets of 5 repetitions of the wall slides, as EMG and electrogoniometer data were collected. They were given a 2-minute rest between sets. All repetitions of the CKC and wall slide were synchronized with a metronome set at 40 beats per minute.

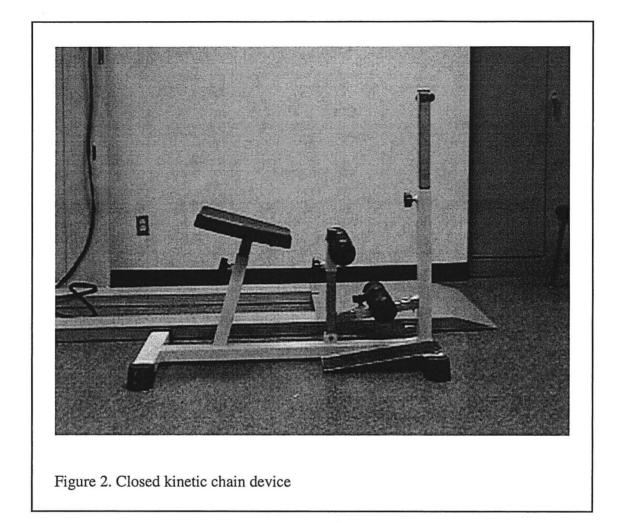
Statistical Analysis

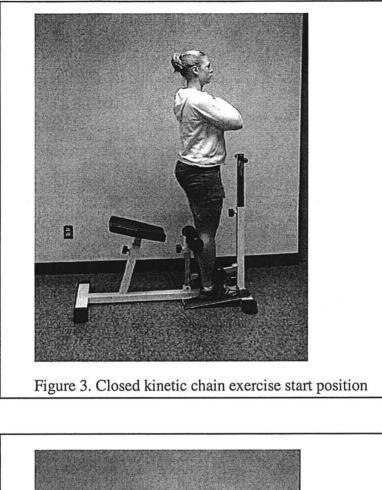
The EMG data were exported to the Noraxon Myoresearch XP software package and analyzed. The raw EMG data were divided into repetitions in reference to the electrogoniometer data (one repetition is from standing position to squatting and back to standing). The EMG signals recorded were rectified, normalized, and smoothed. The 3^{rd} and 4^{th} repetitions were selected for data analysis. The EMG data of the two repetitions for each muscle group recorded were averaged. Data were then recorded as a percentage of the maximum voluntary contraction. The data were then entered into SPSS statistic software package (SPSS Inc., Chicago, IL) for statistical analysis. A repeated measures two way analysis of variance (ANOVA) was performed to compare the EMG values for each of the four muscles during the closed kinetic chain exercise and the wall slide. All tests of significance were carried out at an alpha level of P < 0.05.

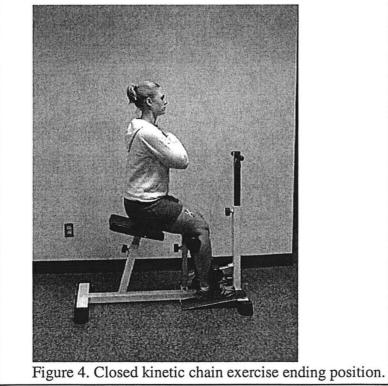


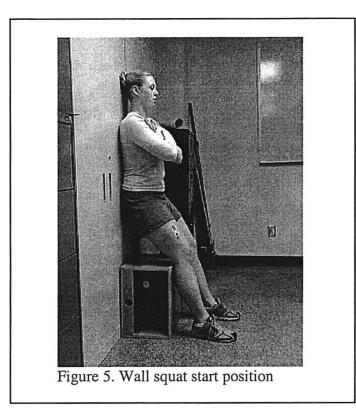
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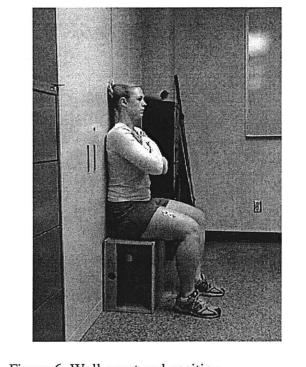


Figure 6. Wall squat end position

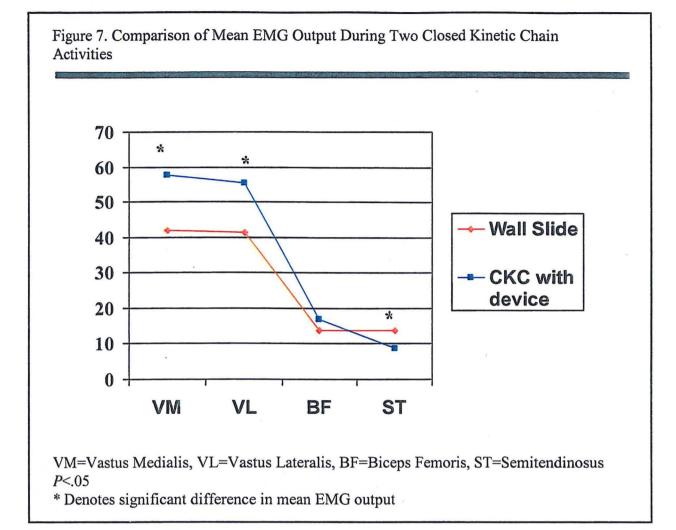
CHAPTER IV

RESULTS

The mean EMG output (Table 1 and Figure 7) reported as a percent of maximal voluntary contraction was significantly different in three of the four muscles during the closed kinetic chain activity with the device (CCD) than in the wall slide, with two of them being greater in the CCD. As stated in Table 2, eta squared is \geq .81, *P* is <.001, and the power is 1.00 in all muscle comparisons. Pairwise comparison was done on each muscle group to determine significant differences. Significant differences were found in the comparison of EMG data of the two closed kinetic chain exercises in the semitendinosus, vastus lateralis, and vastus medialis muscles. EMG output of the vastus lateralis and vastus medialis in the CCD was increased by 25-30% as compared to the wall slide. However, a decrease in EMG output of approximately 40% was reported in the semitendinosus during the CCD. The biceps femoris showed no significant difference in EMG output while comparing the two exercises.

Table 1. Means and Standard Deviations of EMG output during tested exercises reported as a percent of maximal voluntary contraction.

Muscle	Condition	Mean	Standard
		(%)	Deviation
Vastus Medialis	MVC	100	0
	Wall Slide	41.93	13.14
	CKC	57.57	20.50
Vastus Lateralis	MVC	100	0
	Wall Slide	41.37	22.11
	CKC	55.28	28.51
Biceps Femoris	MVC	100	0
	Wall Slide	13.87	10.04
	CKC	16.97	16.52
Semitendinosus	MVC	100	0
	Wall Slide	13.84	14.26
	CKC	8.67	7.45



Muscle	F	Degrees of Freedom	Р	Eta Squared	Power
Vastus Medialis	110.18	2,30	<.001		1.00
Vastus Lateralis	64.74	2,30	<.001	.81	1.00
Biceps Femoris	372.42	2,30	<.001	.96	1.00
Semitendinosus	788.26	2,30	<.001	.98	1.00

Table 2. Repeated Measures Two Way ANOVA results summary table.

CHAPTER V

DISCUSSION

The hypothesis that there will be a significant difference in EMG activity of the quadriceps and hamstrings when comparing activities between the new closed kinetic chain squat device and the wall slide was found to be true except for the biceps femoris. A significant difference was found for the VM and VL by showing an increase in EMG activity with the closed kinetic chain device. A significant difference was found in the semitendinosus by demonstrating a decrease in EMG activity. The only muscle group that did not show a significant difference between exercise types was the biceps femoris. The researchers anticipated an increase in quadriceps EMG activity resulting from the positioning in the CCD. While the subjects lowered themselves to the seat of the CCD there was no friction to decrease the gravitational forces assisting the quadriceps as during the wall slide. The subjects would then require less muscle activity to complete the wall slide as compared to the CCD activity. As previously discussed, during a closed kinetic chain exercise such as squatting, the hamstrings are thought to produce a greater contraction because they are needed to stabilize the pelvis, trunk and knee.¹¹ The researchers then expected the EMG activity of hamstrings to be significantly less during the CCD activity due to the external stabilization of the lower leg.

Limitations and Future Recommendations

There were several limitations to our study. First, the subjects were gathered through convenient sampling rather than random sampling of the population. The majority of the subjects were young and healthy. However, a random sampling of the population may have produced a more accurate statistical analysis. In addition, a larger number of subjects (> 30 subjects) may also have yielded a better statistical representation. Skin and fat increase the impedance and reduce the recorded EMG signal levels.²³ Taking skin fold measurements prior to testing may help eliminate subjects with excessive subcutaneous tissue. During the testing of the final subjects the electrogoniometer was unable to transmit data, preventing us from testing further subjects. Analysis of more muscle groups including gluteus maximus, rectus femoris, gastrocnemius and gracilis would result in a more complete analysis of EMG activity in the lower extremity. We suspect there would be less tibiofemoral stresses during the use of the CCD, so force analysis would be appropriate for future studies. Further studies in patellofemoral pain and the use of the CCD will help to assess available pain free range of motion and the ability to strengthen the VM while using the CCD. We also suspect that a reason for the significant increase in the EMG of quadriceps muscles with the CCD was due to the amount of friction and the support of the door on the subject's back during the wall slide activity. We suggest that in future studies of the CCD a comparison is made with other closed kinetic chain activities in which friction is not a factor such as unweighted squats.

Clinical Implications

In a rehabilitation setting it may be desired to target the quadriceps muscles and limit the effect of the hamstring muscles the CCD may be an appropriate device. Given the greater activity of the VM during the CCD it may be used following knee surgeries and knee injuries when the emphasis of rehabilitation is on quadriceps (VM) return such as ACL reconstruction, ligament tears, and meniscus repairs. The researchers suspect that by stabilizing the lower leg there will be less anterior shear force on the ACL, because the femur is not allowed to translate forward over the tibia. This may also result in less stress to the surgical graft site in an ACL reconstruction using a hamstring graft (semitendinosus and gracilis), while still allowing emphasis on the quadriceps muscles. On the other hand, if less hamstring cocontraction is present, more tibiofemoral AP shear may result from the increased quadriceps activity. If the latter is the case, the CCD may be more appropriate as a later stage exercise in ACL rehabilitation when increased anterior shear is better tolerated by the healing ACL.

CHAPTER VI

CONCLUSION

Significant differences were found in the VM, VL, and ST. These differences show that the CCD allows for a greater amount of quadriceps EMG activity between the exercises. This exercise with the CCD would be useful during rehabilitation when increased recruitment of the quadriceps is desired. These results show that this device may have a legitimate place in current physical therapy along with other established exercises and treatment techniques. The CCD may also be incorporated into a fitness or wellness program as a method to help isolate the quadriceps while maintaining the safety of a closed kinetic chain activity. This study creates a foundation for future studies to further establish the CCD in rehabilitation.

APPENDIX

University of North Dakota Human Subjects Review Form

All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University's policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and the Office of Research and Program Development (ORPD), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the "IRB Checklist" for additional guidance.

Please provide the information requested below:

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School/College: UND School of Medicine Department: Physical Therapy					
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Address or Box #: 501 N Columbia Rd, Grand Forks, ND 58202					
School/College: UND School of Medicine Department: Physical Therapy					
Project Title: An Electromyography Study of the Quadriceps and Hamstrings Recruitment During Two Closed Kinetic Chai					
Activities					
Proposed Project Dates: Beginning Date: 05/05/04 Completion Date: 05/15/05					
(Including data analysis)					
Funding agencies supporting this research: N/A					
A copy of the funding proposal for each agency identified above MUST be attached to this proposal when submitted.)					
Does the Principal Investigator or any researcher associated with this project have a financial interes in the results of this project? If yes, please submit, on a separate piece of paper, an additional YES or X NO explanation of the financial interest (other than receipt of a grant)					
f your project has been or will be submitted to other IRB's, list those Boards below, along with the status of each proposal.					
Date submitted: Status: Approved Pending					
Date submitted: Status: Approved Pending					
Type of Project: Check "Yes" or "No" for each of the following.					
X YES or NO New Project YES or X NO Dissertation/Thesis					
YES or X NO Continuation/Renewal X YES or NO Student Research Project					
$\begin{array}{c} \text{Does your project involve medical record information? If yes, complete the HIPAA Compliance} \\ \text{YES or } X \text{ NO} \text{Application and submit it with this form.} \end{array}$					
YES or X NO for additional guidelines regarding your topic.					
YES or X NO Does your project include Internet Research? If yes, refer to Chapter 3 of the Researcher Handbook for additional guidelines regarding your topic.					
Will subjects or data be provided by Altru Health Systems? If yes, submit two copies of the proposal. A copy of the proposal will be provided to Altru.					
$\begin{array}{c} \text{Will research subjects be recruited at another organization (e.g., hospitals, schools, YMCA) or will} \\ \text{YES or } X \\ \text{NO} \\ \end{array} \text{NO}$					

If yes, list all institutions:

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands their involvement in that study, and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and, if possible, should be printed on letterhead.

Subject Classification: This study will involve subjects who are in the following special populations: Check all that apply.

 Minors (< 18 years)	_X	UND Students
 Prisoners		Pregnant Women/Fetuses
 Persons with impaired ability to understand their involvement and/or const	sequences	of participation in this research
Other		

For information about protections for each of the special populations, refer to Chapter 5 of the Researcher Handbook.

This study will involve: Check all that apply.

Deception	Stem Cells
Radiation	Discarded Tissue
New Drugs (IND)	Fetal Tissue
Non-approved Use of Drug(s)	Human Blood or Fluids
Recombinant DNA	Other
X None of the above will be involved in this study	

I. Project Overview

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as minors, prisoners, pregnant women/fetuses).

II. Protocol Description

Please provide a succinct description of the procedures to be used by addressing the instructions under each of the following categories. Individuals conducting clinical research please refer to the "Guidelines for Clinical-Research Protocols" on the Office of Research and Program Development website.

1. Subject Selection.

a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects.

- b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the "Subject Classification" section above.
- c) Describe your exclusionary criteria and provide a rationale for excluding subject categories.
- d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects.
- e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method.
- 2. Description of Methodology.
 - a) Describe the procedures used to obtain informed consent.
 - b) Describe where the research will be conducted.
 - c) Indicate who will carry out the research procedures.
 - d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them.
 - e) Describe audio/visual procedures and proper disposal of tapes.
 - f) Describe the qualifications of the individuals conducting all procedures used in the study.

g) Describe compensation procedures (payment or class credit, etc.).

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.

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3. Risk Identification.

- a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.
- b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.
- 4. Subject Protection.
 - a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).
 - b) Describe procedures you will implement to protect confidentiality (such as coding subject data, removing identifying information, reporting data in aggregate form, etc.).
 - c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.
 - d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study.

Describe: 1) the storage location of the research data (separate from consent forms and subject personal data)

- 2) who will have access to the data
- 3) how the data will be destroyed
- 4) the storage location of consent forms and personal data (separate from research data)
- 5) how the consent forms will be destroyed
- e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.).
- Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.

III. Benefits of the Study

Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). Please note: payment is not a benefit and should be listed in the Protocol Description section under Methodology.

IV. Consent Form

A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects. Refer to the ORPD website for further information regarding consent form regulations. Please note: Regulations require that all consent forms, and all pages of the consent forms, be kept for a minimum of 3 years after the completion of the study, even if subject does not continue participation. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. It is recommended that the consent form be written in the third person (please see the examples on the ORPD website). A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp. The consent form must include the following elements:

a) An introduction of the principal investigator

b) An explanation of the purposes of the research

- c) The expected duration of subject participation
- d) A brief summary of the project procedures
- e) A description of the benefits to the subject/others anticipated from this study
- f) A paragraph describing any reasonably foreseeable risks or discomforts to the subject
- g) Disclosure of any alternative procedures/treatments that are advantageous to the subject
- h) An explanation of compensation/medical treatment available if injury occurs.
- i) A description of how confidentiality of subjects and data will be maintained. Indicate that the data and consent forms will be stored separately for at least three years following the completion of the study. Indicate where, in general, the data and consent documents will be stored and who will have access. The following statement must be included in all consent forms and informational letters: "Only the researcher, the adviser, [if applicable] and people who audit IRB procedures will have access to the data." Please make appropriate additions to the persons that may have access to

your research data. Indicate how the data will be disposed of. Be sure to list any mandatory reporting requirements that may require breaking confidentiality.

j) The names, telephone numbers and addresses of two individuals to contact for information (generally the student and student adviser). This information should be included in the following statement: "If you have questions about the research, please call (insert Principal Investigator's name) at (insert phone number of Principal Investigator) or (insert Adviser's name) at (insert Adviser's phone number). If you have any other questions or concerns, please call the Office of Research and Program Development at 777-4279."

k) If applicable: an explanation of who to contact in the event of a research-related injury to the subject.

1) If applicable: an explanation of financial interest must be included.

m) Regarding participation in the study:

1) An indication that participation is voluntary and that no penalties or loss of benefits will result from refusal to participate.

2) An indication that the subject may discontinue participation at any time without penalty, with an explanation of how they can discontinue participation.

3) An explanation of circumstances which may result in the termination of a subject's participation in the study.

4) A description of any anticipated costs to the subject.

5) A statement indicating whether the subject will be informed of the findings of the study.

6) A statement indicating that the subject will receive a copy of the consent form.

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

Signatures:

(Principal Investigator)	Date:

Date:

(Student Adviser)

Requirements for submitting proposals:

Additional information can be found at the ORPD website at www.und.nodak.edu/dept/orpd

Original Proposals and all attachments should be submitted to the Office of Research and Program Development, P.O. Box 7134, Grand Forks, ND 58202-7134, or brought to Room 105, Twamley Hall.

Prior to receiving IRB approval, researchers must complete the required IRB human subjects' education. Please go to http://www.und.nodak.edu/dept/orpd/regucomm/irb/Default.htm for more information.

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require full Board review, you will need to provide additional copies. Further information can be found on the ORPD website regarding required copies and IRB review categories, or you may call the ORPD office at 701 777-4279.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 7 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 7 copies of the company's protocol must be provided.

Please Note: Student Researchers must complete the "Student Consent to Release of Educational Record".

Revised 5/30/03

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19. A. May ...

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Informed Consent

You are being invited to participate in a research project conducted by Dr. Mark Romanick, an associate professor in the Physical Therapy Department at the University of North Dakota, and Linda Hanson, Shauna Salz, and Suzanne Steffes, Graduate Physical Therapy students at the University of North Dakota. The purpose of this study is to assess quadriceps and hamstrings electromyography (EMG) activity during the use of a closed kinetic chain device (CCD) as compared with another closed kinetic chain (CKC) knee exercise of similar movement, called a wall slide. CKC activity is an exercise in which the limb is fixed in place. The CCD is a piece of equipment designed to be used with a CKC squat. The lower leg is stabilized with padded bars on the anterior side of the mid shin and behind the calf. This stabilization eliminates ankle motion during the squat. There is a seat, which is adjustable to a desired height indicated by the height of the subject and the desired angle of knee motion. Located in the front of the CCD are handlebars for a safety measure if the subject was to lose their balance. The conclusions drawn from this study will allow practicing physical therapists to understand the more effective CKC activity, which will provide more efficient and complete care. Only healthy subjects over eighteen years of age with no history of chronic hip, knee, and ankle injury or residual symptoms of these injuries, no previous anterior cruciate ligament reconstruction, and no current low back pain will be allowed to participate.

During this study, EMG muscle activity will be measured by using pre-gelled, self-adhesive electrodes placed on the skin over the vastus lateralis, vastus medialis, semitendinosus, and biceps femoris muscles of your right leg. Also, there will be a small joint angle measuring device attached to your knee with adhesive material. Initially, you will perform a 3-minute warm-up on a stationary bicycle. You will then be asked to perform 5 repetitions of one of the two exercises followed by a one-minute rest period and then 5 more repetitions on the other of the two exercises followed by a one-minute rest period and then 5 more repetitions of the same exercise followed by a rest period. Next you will be asked to perform 5 repetitions on the other of the two exercises followed by a one-minute rest period and then 5 more repetitions of the same exercise. Repetition speed will be paced by a metronome to ensure consistent rate of exercise between participants. You will draw a card before participating, that card will identify which exercise you will do first. Each wall slide and squat on the CCD will be perform a fully straightened knee to a nearly fully bent knee position.

This study will take approximately one hour of your time. You will be asked to report to the Physical Therapy research lab in the University of North Dakota Medical School at an assigned time. In addition to that you will need to be present for a short (15-30 minutes) introduction at least one day prior to the testing to familiarize yourself with the CCD you will be using.

Although physical performance testing always involves some degree of risk, the risk of injury or discomfort is minimal; however minor muscle soreness or strain may occur with this activity. The low intensity of the exercise along with the pre-exercise warm-up will minimize injury risk. In order to get an accurate recording of your muscle activity, we will be removing any hair (with electric clippers) and cleaning (with isopropyl alcohol) the area where the electrodes will be placed. Reddening of the skin in

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the areas where the electrodes are place is possible due to the adhesive material on the electrodes. The EMG device, to which the electrodes are connected, only records information from your muscles. It will not stimulate your skin so no adverse sensation should be felt. As a participant, if at any time you experience discomfort, pain, fatigue, or any other symptoms that may be detrimental to your health you may stop the experiment.

Benefits to you as a participant in this study include but are not limited to: 1) gaining a better understanding of muscle activity used during CKC activities of the lower extremity and 2) assisting the researchers to increase current knowledge concerning the levels of muscle activity during CKC with and without the CCD. There will be no compensation given for participation in this study nor is there any cost associated with your participation.

Your name will not be used in any reports of the results of this study. Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission. A number known only to the investigators will identify the data. The data and records collected in this study will be kept in separate locked file cabinets in the UND PT Research Lab and Dr. Romanick's office for three years following the completion of this study and will be shredded after that time. Only the researcher, the adviser, and people who audit the IRB procedures will have access to your data. Your decision whether or not to participate will not prejudice your future relationship with UND PT Department. If you decide to participate you are free to discontinue participation at any time with out prejudice by notifying the researchers of your decision to discontinue. The researchers reserve the right to terminate your participation in the study if you are unable to perform the testing procedures or if it is felt that continuation might lead to increased risk of injury.

The investigators are available to answer any questions you have concerning this study. In addition, you are encouraged to ask any questions concerning this study that you may have in the future. Questions may be asked by calling Dr. Mark Romanick at 777-3668 or Suzanne Steffes at 772-2417. Questions or concerns about this study may also be directed to the Office of Research and Program Development at 777-4279. A copy of the results of this study may be obtained by contacting Dr. Mark Romanick.

In the event that this research activity results in physical injury, medical treatment will be as available as it is to a member of the general public in similar circumstances. You and/or your third party payer must provide payment for any such treatment.

All of my questions have been answered and I am encouraged to ask any questions that I may have concerning this study in the future. I have read all of the above and willingly agree to participate in this study.

Subject's signature

Date

University of Nor	th Dak	ota		
Institutional Revie				
Approved on	JUN		2004	
Expires on	JUN	8	2005	

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