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ELECTROMYOGRAPHIC ANALYSIS OF AN ISOMETRIC VASTUS MEDIALIS OBLIQUE CONTRACTION WITH INCORPORATED ADDUCTOR COMPONENT

by

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A Scholarly Project

Submitted to the Graduate Faculty of the

Department of Physical Therapy

School of Medicine and Health Sciences

University of North Dakota

in partial fulfillment of the requirements

for the degree of

Master of Physical Therapy



Grand Forks, North Dakota May 2004 This Scholarly Project, submitted by Dan Thielen and Jimmy Turner in partial fulfillment of the requirements for the degree of Master of Physical Therapy from the University of North Dakota, has been read by the Graduate School Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

Graduate School Advisory

(Chairperson, Physical Therapy)

PERMISSION

TitleElectromyographic Analysis of an Isometric Vastus MedialisOblique Contraction with Incorporated Adductor Component

Department Physical Therapy

Degree Master of Physical Therapy

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ABSTRACT

Knee pathology is a common clinical complaint that may result in diminished function of the affected lower extremity, ultimately leading to atrophy of the vastus medialis oblique (VMO) muscle. The VMO contributes a great deal to the medial tracking mechanism of the patella which is crucial for normal biomechanical function of the knee joint. Effective strengthening of the VMO is a challenging task in physical therapy clinics. The purpose of this study was to determine if it is possible to enhance the muscle activity of the VMO with the addition of an adductor contraction.

Thirty-one subjects between the ages of 18 and 50 years with no history of debilitating trauma to the right knee were recruited to participate in this study. All subjects were recruited from the University of North Dakota and Center Court Fitness Club. Electromyography (EMG) was used to record muscle activity during each exercise trial. Pre-gelled, self-adhesive EMG electrodes were placed on the subject's right leg over the motor points of the following muscles: 1) Rectus Femoris, 2) Vastus Lateralis, 3) Vastus Medialis, and 4) Adductor Longus. After attachment of electrodes, each subject warmed-up on a cycle ergometer prior to performing 3 exercise trials. The trials included an isometric contraction of knee extension, an isometric contraction of hip adduction, and then a combined isometric contraction of knee extension with hip adduction. All trials were performed on the Kin-Kom isokinetic equipment at a preset angle of 50° of knee flexion.

The rectified EMG data were analyzed utilizing a Noraxon Telemyo 8 telemetry unit. The data were digitized and then analyzed using a simple T-test with a .05 confidence interval. The results of this study have demonstrated there is an increase in overall muscle activity of the VMO. This would suggest that utilizing hip adduction in conjunction with knee extension does facilitate an increased contraction of the VMO.

The results of this study have very important clinical applications. Being able to better elicit a muscle contraction of the VMO can be very valuable in early rehabilitation of the knee. When aiming to gain back stabilizing muscle forces following pathology, focus is on the VMO due to the large part it plays in knee function. If the VMO can be elicited earlier, this will allow for an accelerated rehabilitation pace, which ultimately will save the patient time and money.

CHAPTER I

INTRODUCTION

Patellofemoral knee pain is a commonplace injury seen in physical therapy. The focus of rehabilitation for this condition is on strengthening the quadriceps muscles. Primarily, selective strengthening of the vastus medialis oblique (VMO) is the goal of most rehabilitation programs. Numerous research studies have been performed to isolate activity in the vastus medialis oblique (VMO). One such study measured the activity of the VMO when an isometric contraction of the hip adductors was performed in conjunction with isometric knee extension. The emphasis of this activity is on the contraction of the adductor magnus (AM) prior to knee extension. Since the VMO has an origin on the AM tendon and myofacial structure, it is theorized that activation of the AM prior to knee extension may provide a better anchoring point from which the VMO can function.¹

Problem Statement

There remains a great deal of controversy as to the preferential recruitment of the VMO and whether the addition of an adductor contraction might enhance the activity of the VMO.

Purpose

The purpose of this study was to determine whether the electromyographic (EMG) activity of the VMO is influenced by the addition of a sub-maximal adduction contraction prior to an isometric knee extension contraction.

Significance

The significance of this study to the field of physical therapy is to discover whether adding hip adduction prior to performing extension of the knee would enhance the activity level of the VMO. This knowledge would assist physical therapists in combating diminished muscle activity of the VMO postoperatively as well as following knee trauma.

Research Question

Is there an increase in muscle activity of the VMO when utilizing a submaximal hip adduction contraction in conjunction with isometric knee extension at 50°?

Null Hypothesis

There is no significant difference in EMG activity of the VMO when utilizing a hip adduction contraction prior to an isometric knee extension at 50°.

Alternate Hypothesis

There is a significant difference in EMG activity at the VMO when utilizing a hip adduction component prior to an isometric knee extension at 50°.

CHAPTER II

LITERATURE REVIEW

One of the major areas of concern for professionals practicing in the field of physical therapy is implementing the proper rehabilitative plan for patients dealing with knee pathology. Patellofemoral pain syndrome is a pathological condition that is commonly encountered in the practice of physical therapy. It affects athletic and nonathletic persons and presents with symptoms of crepitus, peripatellar swelling, and buckling or locking of the knee joint.¹⁻⁵ Exacerbation of these symptoms can be caused by knee trauma, ascending and descending stairs, prolonged sitting with flexed knees, rising from a seated position, and kneeling.^{2,4,6,7}

The cause of patellofemoral pain is multifactorial and varies in severity with contributing factors consisting of knee joint misalignment, muscle imbalances, and lower limb abnormalities. Whether patients are treated surgically or non-surgically for their knee pathologies, the most common contributing evidence for dysfunction is weakness of the vastus medialis oblique (VMO).⁸⁻¹⁶ The VMO is the oblique continuance of the vastus medialis. It is noted in some articles that the VMO fibers have an attachment on the tendons of the adductor magnus and adductor longus muscles.^{2,7,9,17} The vastus medialis

and VMO seem to give physical therapists the most trouble when dealing with initiating strength gains in patients with knee pathology.

One controversial technique used in the clinic to address VMO weakness and its delayed recovery time is the addition of a hip adduction contraction prior to the initiation of knee extension activities. The use of a light medicine ball is an example of how adduction can be added to an exercise program to strengthen the knee extensors. The ball is placed between the knees and squeezed by both legs prior to knee extension strengthening activities.

Several studies have evaluated the use of this adduction technique to establish whether or not VMO strengthening can be enhanced to aid in the rehabilitation of knee pathology.^{2,7,9,10,16,17} The literature is back and forth on the issue, providing interesting results both for and against the validity of this technique. The central idea for strengthening the VMO stems from research showing this portion of the vastus medialis is attached to the muscle fascia of the adductor magnus and adductor longus.^{2,7,9,17} It is theorized that initiating an adduction contraction in conjunction with knee extension provides a more stable anchoring point from which the VMO can pull, which in turn allows medial tracking of the patella.^{2,10} A description of the anatomy will provide a better understanding of the structures involved as well as the effects of the VMO on knee mechanics.

Knee Anatomy

The knee joint structure involves 2 separate bony articulations which includes the femur on the tibia and the patella on the femur. The tibiofemoral

joint allows 3° of freedom and is classified as modified ginglymus which affords the motions of flexion, extension, and medial/lateral rotation.¹⁸ Normal range of motion of the tibifemoral joint is 5° of hyperextension to 140° of flexion. This is the largest joint in the human body and has static stabilizers (bony structures and fascial components) as well as dynamic stabilizers (ligaments and muscles).¹⁹

The femur is the longest and largest bone in the human body and provides support to the upright human posture and weight bearing ability. The articulating surface of this bone is composed of a medial and lateral condyle which interface with the tibia. The medial condyle extends more inferiorly than its lateral partner.²⁰ This bony extension puts the knee into an angle known as physiological valgus which is measured as 170°.¹⁸ This angle is determined via the lateral bisection of 2 lines of reference. The first line bisects the femoral shaft and the second bisects the tibial shaft. Between the 2 condyles lies the intercondylar groove that provides a track in which the patella glides superiorly and inferiorly relative to the femur during arthrokinematic motion.¹⁸ On the anterior surface of the femoral condyles, adjacent to the intercondylar groove, are the medial and lateral patellar surfaces. These surfaces assist the patella in remaining in its track during knee motion. The lateral surface is projected further anterior than the medial surface.^{18,21} This anteriorly raised lip of bone deepens the patellar groove which decreases the propensity of the patella to ride out of its track. All of the joint structures work synchronously with the tibia to allow ambulation.

The tibia is the second largest bone in the human body and accepts the femur to provide support during weight bearing.¹⁸⁻²⁰ The proximal articulating surface of this bone is comprised of medial and lateral plateaus that accept the corresponding femoral condyles. The surface area of the medial plateau is 50% larger than that of the lateral side. This increased area allows the tibia to accept the large medial femoral condyle.^{18,20} Between the 2 plateaus are roughened, raised areas known as intercondylar tubercles. These are attachment sites for ligamentous support which will be discussed later. The mechanics of the femur and tibia are not fully complete until they are considered along with the patella.

The patella is a sesamoid bone which acts as an eccentric pulley and provides a mechanism to reduce friction between the quadriceps tendon and the femoral condyles. It has 2 primary functions which are protecting the anterior knee joint and increasing the angle of insertion for the quadriceps.^{18,19} In order for the femur, tibia, and patella to work together in a fashion that will provide premium support and function, further reinforcements are required. These reinforcements include both static and dynamic stabilization. Static stabilizers include the passive structures, such as the joint capsule and the ligaments.^{19,20} These supportive structures involve the anterior/posterior cruciate and medial/lateral collateral ligaments.

The anterior cruciate ligament attaches to the anterior tibia and runs in an upward and lateral direction attaching to the medial side of the lateral femoral condyle in the intercondylar notch.²⁰ It prevents excessive anterior translation and hyperextension of the tibia on the femur while the knee is in a flexed

position.²⁰ The posterior ligament attaches to the posterior tibia and runs in an upward and medial direction attaching to the lateral side of the medial femoral condyle in the intercondylar notch.²⁰ It prevents excessive translation of the tibia on the femur in the posterior direction while the knee is flexed.²⁰ These two ligaments act synergistically in order to prevent medial rotation of the tibia when the knee is in extension.

The medial and lateral collateral ligaments become taut in extension and prevent the tibia from externally rotating on the femur.¹⁹ The medial collateral ligament is a flat, broad triangular band that attaches proximally on the medial femoral condyle and distally on the medial surface of the tibia. It also meshes and blends with the medial meniscus and the knee joint capsule. Its main function is to prevent excess valgus of the knee.^{19,20} The lateral collateral ligament begins proximally at the lateral femoral condyle and inserts distally on the head of the fibula. Its primary function is to prevent excess varus of the knee.^{18,19} In addition to these supportive ligaments, the knee also needs an efficient way of absorbing shock due to activities involving ambulation. The knee contains 2 shock-absorbing pads known as menisci.

There are 2 menisci in the knee. They are known as the medial and lateral menisci. The lateral meniscus is loosely attached to the tibia and is less prone to injury due to this mobility. It is attached posteriorly to the popliteus muscle and the menisco-femoral ligament.²⁰ Anteriorly, it attaches to the patella through the menisco-patellar ligament. The medial meniscus is larger and more oval than its lateral counterpart.²⁰ It is, however, less mobile due to additional

attachments to the joint capsule and medial collateral ligament. Posteriorly, the meniscus is attached to the semimembranosus muscle, and anteriorly, it is bound to the patella via the menisco-patellar ligament.¹⁸⁻²⁰ The 2 menisci work together to deepen the superior surface of the tibia and provide a more congruent surface for articulation with the femur. The menisci carry roughly 50% of the load across the knee joint when weight bearing.²⁰ Once the knee is set into motion, a support cast needs to be activated to maintain alignment and properly move the bony components through their range of motion. These supporters are collectively known as the dynamic stabilizers of the knee joint.

The dynamic stabilizers include the following muscles and aponeuroses: the quadriceps femoris, adductor muscle group, popliteus, biceps femoris, semimembranous, extensor retinaculum, and pes anserine (semitendinosis, sartorius, and gracilis tendons).²⁰ This study only considered the quadriceps and adductor musculature.

The quadriceps muscle group consists of the rectus femoris, vastus lateralis, vastus medialis, and the vastus intermedialis muscles. All 4 of these muscles combine to form a tendinous insertion on the superior portion of the patella which in turn is attached to the patellar ligament that inserts into the tibial tubercle on the anterior portion of the tibia.^{18,19} The rectus femoris is known as the "kicking muscle" and runs straight down the front of the thigh. This is a two-joint muscle that crosses the hip and the knee.^{18,19} The vastus lateralis lies on the lateral side of the thigh and is the largest of the quadricep muscle group. The vastus medialis covers the medial portion of the thigh and is said to contain

2 distinct types of fiber orientation, vertical and oblique. The vertical fibers are more proximal than the oblique fibers and are known as the vastus medialis longus.¹⁹ The oblique fibers are distal in location and are known as the VMO. Finally, the vastus intermedius lies deep to the rectus femoris and between the medialis and lateralis.¹⁹

The musculature in the medial compartment of the thigh includes the adductor longus, brevis, and magnus. Adductor longus is a large fan-shaped muscle and is the most superficial of the adductors. The adductor brevis lies deep to the pectineus and is largely covered by the adductor longus.¹⁹ The adductor magnus is the largest of the 3 adductors. This muscle is triangular in shape and has 2 parts, the adductor portion as well as a hamstring portion. These 2 parts have separate nerve supply. This knee anatomy lays the foundation for the description and explanation of the biomechanics concerning the lower extremity.

Biomechanics

The muscles that directly and indirectly affect the patella tracking mechanism are made up of the quadriceps and adductors. The muscles with a direct effect include the quadriceps femoris muscle group. The muscles with an indirect effect on the patellar tracking mechanism include the adductor magnus and adductor longus.

The vastus intermedius and rectus femoris provide a more superior tracking of the patella during knee extension. The fibers of the vastus lateralis and vastus medialis longus lie approximately 15° from the longitudinal axis of the

femur.⁴ The VMO, which is approximately 25% of the most distal portion of the vastus medialis longus, is found to have a 50° to 55° orientation to the longitudinal axis of the femur.⁴ The longus portion provides a mostly vertical (superior) force on the patella and the VMO a mostly medial and superior force. The orientation of pull of the VL causes a strong lateral tracking force on the patella due to the 170° physiological varus between the femur and tibia. This lateral pull is countered by the vastus medialis longus/VMO muscle which provides a medial pull on the patella. Developing the proper strengthening program to isolate the VMO and its function continues to be a common goal of practitioners in the field of physical therapy.

Muscle Function

Isotonic contractions involve constant tension applied to the muscle throughout the entire range of motion. An example would include the use of a barbell in an elbow flexion strengthening exercise. The force required by the muscle to move the weight will change with the angle of the joint, but the tension remains constant.

Isotonic exercises are made up of concentric and eccentric contractions. Concentric contractions involve shortening the muscle and eccentric contractions relate to lengthening of the muscle under stress. In the example of the elbow flexion (biceps curl), bringing the weight towards the shoulder will shorten the biceps (concentric contraction) and lowering the weight back towards the thigh will lengthen the biceps (eccentric contraction). Isokinetic contractions are similar to isotonic in that they allow an individual to move throughout the complete range of motion. The major difference involved with an isokinetic contraction is that it provides a constant angular velocity throughout the entire range of motion.²³ With this type of contraction, momentum is unattainable which in turn leads to a more effective targeting of specific muscle groups. If deficits are seen at a specific position in the range of motion, isokinetic focus may be narrowed to target a smaller range or isometric activity may be used.

An isometric contraction is a static contraction during which the muscle neither shortens nor lengthens during activity. The angle of the joint at which the muscle force is being provided will show the greatest strength gains. There is also an overflow phenomenon that occurs with isometric contractions. This means that strengthening will occur 15° above and below the stationary muscle angle. In other words, if a person were to perform an isometric contraction at 40° of elbow flexion, the muscle strength would improve in the range of 25° to 55° of elbow flexion. This type of contraction is also stated as being most beneficial in isolating specific muscle groups.²³

For the purpose of strengthening and rehabilitation, muscle action may be performed by utilizing open or closed kinetic chain exercise. Disagreement as to which exercise is the most beneficial continues to exist within the literature. The controversy exists over which of the 2 exercise types is the most productive and least painful when working with patients who have been treated surgically as well as non-surgically.

Closed kinetic chain (CKC) exercises have become more popular in rehabilitation of the VMO with emphasis on CKC functional capabilities. CKC exercises require that the distal lower extremity is fixed (e.g., the foot is placed firmly on the floor). A few examples of the CKC exercises involve stair stepping, partial standing squats, and utilization of leg press machines.^{15,24} Doucette and Child¹⁵ feel that the use of CKC exercises are more functional than open kinetic chain (OKC) exercises because they incorporate joint loading and proprioceptive feedback in addition to synergistic contractions of the muscles involved during movement. One of the limitations of CKC exercises is the compressive force placed on the patellofemoral joint during weight bearing activities. Morrison⁴ previously determined the patellofemoral compression force during ambulation to be equivalent to one-half of a person's body weight and over 3 times greater for ascending/descending stairs. Due to this increase of patellofemoral compression force, OKC exercise was utilized for this study.

Open kinetic chain exercises for the lower extremity require that the distal portion (the foot) is not in a fixed position. In other words, the limb is able to move freely in space. Some of the most frequently used OKC exercises for strengthening the quadriceps consists of the straight leg raise, short arc quadriceps extension, and terminal knee extension.^{15,24} OKC exercises have historically been noted as the "traditional" method for rehabilitating the quadriceps.^{5,15,24} Short arc quadriceps extensions and straight leg raises are often the treatment of choice to strengthen the VMO for patellofemoral dysfunction.²⁵ A limiting factor when using OKC exercise is the presence of a

non-functional movement pattern as opposed to that of CKC exercise.²⁵ Functional refers to the events that contribute to everyday movement patterns that involve proprioception activities such as walking, stair climbing, etc.

Electromyography Overview

Electromyography is the study of electrical impulses arising from action potentials within the motor units of muscles. Thus, the source of the EMG signal is the motor unit's action potential.²⁶ Individual motor units within any given muscle are numerous and fire, creating action potentials, which causes contraction of the muscle. Motor unit recruitment is dependent on the external force applied to the individual muscle. The greater the external force, the more motor units are required to facilitate the muscle contraction. It is the summation of these motor unit action potentials that give rise to the intensity of the EMG signals.²⁶

Signals provided for EMG are received through various types of surface and intra-muscular electrodes. These signals are rectified and displayed by the computer interface utilized during this study. In comparison to intra-muscular recordings, surface EMG signals have a low spatial selectivity caused by a decrease filtering affect by the tissues.²⁷ This decreases the electrodes' sensing capabilities which makes them slightly less effective than intra-muscular electrodes. Electromyographic signals outside the electrode placement regions can cause heightened EMG activity over the area of muscle to be studied due to low filtering effects. This increase in activity is referred to as cross talk or overflow and can also be influenced by electrode placement.²⁷ Typically, electrode placement is directly over the muscle belly and parallel to the muscle fibers under study, with electrodes within 1 to 2 cm of each other.²⁶ Cowan et al ⁴ placed electrodes on the vastus lateralis 10 cm superior and 8 cm lateral to the superior border of the patella and 15° to the vertical. The electrodes on the VMO were placed 4 cm superior and 3 cm medial to the superior border of the patella and oriented 55° to the vertical.⁴ This arrangement of surface electrodes, which are less invasive than intra-muscular electrodes, will be utilized for this study. To improve the efficacy of surface electrodes, proper measures need be utilized to reduce impedance.

Impedance, a resistance to electrical current flow, can be influenced by a number of factors, such as adipose tissue, hair, oils, and dead cell layer of the skin.²⁶ Impedance is reduced when the skin overlaying the muscle under study is properly prepared. This preparation includes abrading the skin vigorously with alcohol wipes and shaving hair from the skin. In addition, a medium is also utilized to decrease the resistance between the skin and electrodes. The electrodes used in this study are pre-gelled adhesive which provides a contact medium for decreasing impedance. It is important to remember that the impedance must be low enough to provide a clean signal.²⁶

Kinetic Communicator (Kin-Com)

The Kin-Com is a computerized dynamometer utilized to monitor torque generated during eccentric, concentric, and isometric activities.²⁸ This equipment provides the opportunity to assess the knee joint in a multitude of angle placements. In addition, it allows easy adaptations to differing leg length

and provides biofeedback capabilities with use of a computer monitor. The reliability of force, angle, and velocity has obtained intra-class correlation coefficients above .99. ²⁸

This chapter was intended to provide specific information concerning every facet of the study. It will help to clarify and provide a precursor to understanding the detailed issues discussed in the methods (Chapter #3). With a knowledge base involving the components of this study as well as the research supporting it, the methods involved during its conduction can now be discussed.

CHAPTER III METHODS

Subjects

The subjects utilized in this study were chosen strictly on a voluntary basis. The inclusionary criteria consisted of the following: No surgical procedures or debilitating trauma involving the right knee, must be between the ages of 18 and 50, and have no allergies to latex or isopropyl alcohol. Thirty-one healthy individuals, 22 females and 9 males, volunteered to participate in this study which was conducted over a 2-week period of time. Each subject completed a demographic questionnaire (Appendix A) prior to participation in the study. In addition, each subject read and signed a consent form (Appendix B) which explained the specifics, risks, and benefits of the research. This study was conducted on the University of North Dakota campus in the School of Medicine and Health Sciences. The project was approved by the University of North Dakota Institutional Review Board and designated as project number: IRB-200305-263 (Appendix C). The research testing was completed in a private room in the Department of Physical Therapy in order to ensure privacy and confidentiality of each participant. The subjects in this study received no compensation for their participation.

Electromyography

Electromyographical data were collected during extension, adduction, and combined extension/adduction via signals emitted during muscle contraction. These data signals were collected utilizing a Noraxon Telemyo 8 telemetry unit (Noraxon USA, 13430 North Scottsdale Rd., Scottsdale, AZ 85254), which was sheathed and attached to a waist belt. The collected data signals were digitalized by an analog digital interface board in the Peak Analog Software (Peak Performance Technologies, 7388 S. Revere Parkway, Suite 601, Englewood CO 80112-9765).

Electrode Placement

Subjects were asked to arrive at the research facility wearing shorts in order to allow adequate access to the entire right lower extremity. The subject's skin was prepared for electrode placement by shaving excess hair and cleaning the skin with alcohol wipes. Once the skin was prepared, the pre-gelled, self-adhesive electrodes were placed on the subject's right leg over the muscle belly of the following muscles: 1) Vastus Lateralis, 2) Vastus Medialis (VMO portion), 3) Rectus Femoris, and 4) Adductor Longus (Fig. 1). The electrode placement sites were determined utilizing a placement tool (Fig. 2) which was fabricated by the researchers. The information used to construct this tool was obtained from the measurements used in the research study conducted by Cowen and Bennell.⁴ Modifications to their measurements, however, were necessary.

The measurement changes for this study required measurements for the vastus lateralis at 15 cm superior, 8.5 cm lateral to the mid-superior border of the

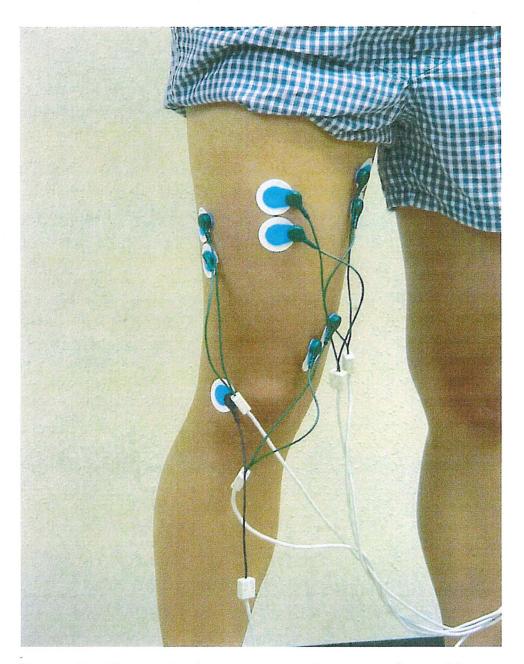


Figure 1. Electrode placement over the vastus lateralis, vastus medialis, rectus femoris, adductor longus, and lateral proximal tibia (ground).

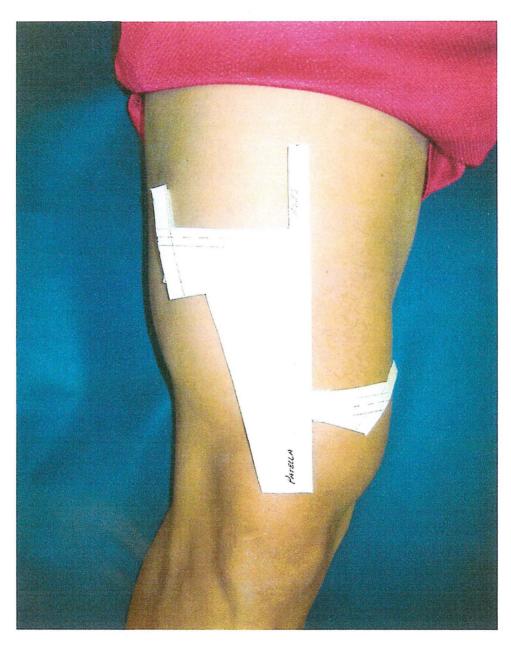


Figure 2. Electrode placement tool used to standardize electrode placement.

patella, and 15° to the vertical. The vastus medialis placements were 5 cm superior, 6 cm medial to the mid-superior border of the patella, and 55° to the vertical. It was found that these revisions placed the electrodes over the muscle bellies more consistently than did those described by Cowen and Bennell.⁴ The tool provided consistent placement of the electrodes with all subjects regarding the two noted quadriceps muscles.

The rectus femoris and adductor muscle electrode placements were not mentioned in the literature. However, it was found that 20 cm from the midsuperior border of the patella in line with the anterior-superior-iliac-spine placed the electrode over the muscle belly of the rectus femoris consistently with all subjects. The adductor longus muscle was palpated during adduction for placement of the electrode over the muscle belly. The same individual prepared all subjects in order to optimize the consistency of the electrode placements. At each site, positive as well as negative electrodes were placed within 1 to 2 cm of each other parallel with the participating muscle's fiber orientation. One final electrode was placed on the lateral proximal tibia in an area of little soft tissue in order to act as a ground for the 4 EMG channels.

Kin-Com

The isometric testing for this study was performed on the Kin-Com AP dynamometer (Chattex Corporation, 101 Memorial Drive, P.O. Box 42887, Chattanooga, TN 37405). The forces were measured utilizing a load cell which was strapped to the subject's proximal tibia. This strap originated from a fixed lever arm. The force detected by the load cell was relayed to a computer screen

which provided the patient with biofeedback information. In addition, the Kin-Com provided the appropriate stationary angles utilized for the isometric testing.

Procedure

During the research session, the subject performed 2 maximal voluntary contractions involving isometric knee extension, 2 maximal voluntary contractions involving isometric hip adduction, and 3 combined contractions involving a submaximal isometric adduction and a maximal isometric knee extension simultaneously. After electrode placement, each subject performed a 3-minute warm-up on a stationary bike. The warm-up pace was instructed to be intense enough to begin sweating, but not so intense that the legs were exhausted. Following the warm-up activity, the subject was positioned for the extension component. This involved aligning the subject's right leg in line with the arm of the Kin-Com and fixing the knee at 50° of flexion.

The positioning for the adduction component comprised of having the subject align the publis with a marker line on the seat set at 0° of hip abduction. Once this position was established, the right hip was abducted to another marker line on the seat which was placed at 25° relative to the original 0° marker. In this position, the knee was also fixed at 50° of flexion by strapping the subject's lower leg to the preset lever arm of the Kin Com (Figs. 3 & 4). For the extension/adduction combination contraction, the subject was in the same position as the isometric adduction trials. During all trials, the subject was held in a fixed position with 2 straps crossing the upper torso and a strap crossing the waist. The subject's legs were secured to the Kin-Com with Velcro strapping and



Figure 3. Frontal Kin-Com view.

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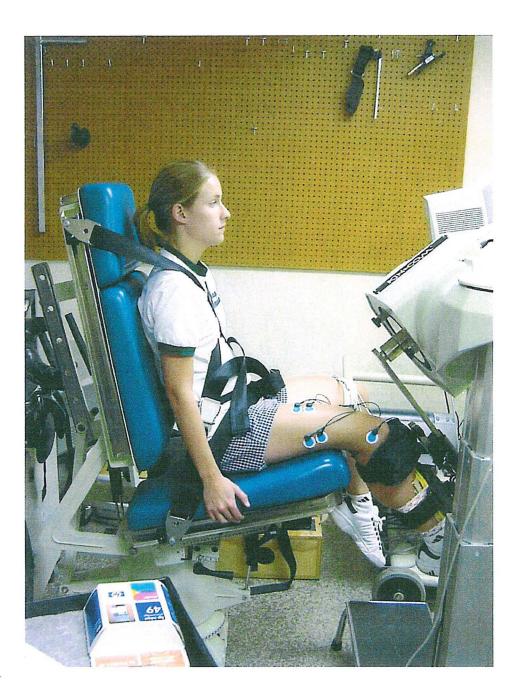


Figure 4. Sagittal Kin-Com view.

paper towels were utilized to provide a sanitary barrier between skin and machine.

For the extension component, the subject was instructed to extend the lower leg (knee extension) as hard as possible in order to elicit a MVC. It was explained that the contraction needed to be held for 5 seconds. Following the first trial, the participant was given a 1-minute rest which was immediately followed by the second trial.

Next, the subject was repositioned for the adduction component and asked to provide a MVC involving adduction of the hip for 5 seconds. Following each trial, the subject was given 1 minute of rest. Each contraction provided a numerical value for the force exerted, expressed in pounds, which represents the force of contraction. This number was obtained from a computer read-out which was a direct result of the force applied to the load cell by the leg. The load cell was connected to the restraint that held the leg. As the leg presses against this restraint, the load cell accepts the force and provides a digital readout that is read by the researchers. Twenty-five percent of this maximal contraction was calculated and utilized as the minimum static force needed during the adduction portion of the combination trials.

The 25% value obtained from the adduction MVC was used in conjunction with visual biofeedback for the adduction/extension combination trials. A red line on the Kin-Com computer screen represented the 25% value. As the subject adducted the hip, a blue bar rose vertically toward the red line. During the combination component, the individual was instructed to adduct until the blue bar

extended up to or beyond the red line, at which point they were instructed to initiate a MVC involving knee extension. This position was held for 5 seconds. Between trials, the participant was allotted a 2-minute rest break. At the end of the research session, the subject was assisted in climbing down from the Kin-Com, the electrodes were removed from the leg, and the excess gel was wiped from the leg with alcohol wipes. Each subject was thanked for his/her participation and escorted to the door.

Data Analysis

The collected EMG data were transported and refined by the Noraxon Myoresearch software package. EMG data were recorded in 5-second intervals during every isometric trial (extension, adduction, combination). To find the most precise data representation within the 5-second window, data from seconds 2 through 4 were used for data analysis. Once these values were obtained, all data were transferred to the Statistical Package for Social Sciences (SPSS for windows) spread sheet. To decrease the variance, an average of the 3 combination trials was compiled and utilized for statistical analysis. A single sample t-test ($\alpha = .05$) was utilized to compare the affects of the combination of hip adduction and knee extension with that of knee extension without adduction.

CHAPTER IV

RESULTS

Demographics

Demographic analysis has been compiled for all 31 subjects who participated in this study. The make-up of this study consisted of 22 female and 9 male participants between the ages of 21 and 48 years. The mean age was 24.8 years of age. The mean weight was 159.1 pounds with a range of 120 to 235 pounds. The mean height equaled 67.6 inches with a range of 61 to 75 inches. Twenty-seven subjects reported their right leg to be dominant and 4 declared themselves left leg dominant.

EMG Data Analysis

A two-tailed single sample t-test, utilizing an alpha level of .05, was performed to determine whether or not there was significance in EMG activity at the VMO under 2 different test conditions. The first test condition required knee extension only, followed by the second consisting of a hip adduction contraction in conjunction with knee extension.

It was found that the addition of hip adduction, in conjunction with knee extension, had a significant effect on EMG activity at the VMO, t(30) = -2.635, p < .05, two-tailed, with an observed power of .997. Conversely, when observing the results based on gender, there was no significant difference in men

t(8) = 1.844, p > .05, two-tailed with an observed power of .410, or women t(21) = .064, p > .05, two-tailed, with an observed power of .410.

This single sample t-test revealed that addition of hip adduction prior to isometric knee extension is statistically significant for increased EMG activity at the VMO. This significance is a result of the 31-subject sample size. However, significance is not found when samples are analyzed based on gender. This lack of statistical significance is due to the small number of subjects (9 males, 22 females) in regard to power of analysis.

CHAPTER V

DISCUSSION AND CONCLUSION

Discussion

The results of this study indicate a statistically significant increase in EMG activity at the VMO when combining isometric hip adduction with isometric knee extension. The authors have rejected the null hypothesis which states that there will be no change in EMG activity. These results were compiled from 31 subjects and are in agreement with the research performed by Hanten and Schulthies.¹⁷

Although this study is in agreement with other research, the issue of gender was not noted in the literature. The effects of gender were secondary to the main research question, to ascertain whether or not it would have an effect on the outcome of EMG activity at the VMO. When the data from 31 participants were analyzed on the basis of gender, no significant difference was found in EMG activity for the combined activity of hip adduction with knee extension. It is believed that the individual sample sizes of both males and females were too small, 9 and 22 respectively, indicating that a small sample size can decrease the power of analysis and produce different outcomes. For future studies, it may be advantageous to incorporate a larger subject pool for males and females to determine if gender has an effect.

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As noted in the literature,^{2,7,9,17} the difference in muscle activity of the VMO may be influenced by the orientation of fibers and their connection to the adductor fascia when adduction precedes knee extension. This increase in EMG activity of the VMO utilizing hip adduction in conjunction with knee extension may indicate possible rehabilitation strategies for clinicians. As noted by Hanten and Schulthies,¹⁷ the addition of resistive hip adduction may be beneficial in rehabilitation of patellofemoral dysfunction. The results of the present study reinforce this potential for improved rehabilitation of the VMO.

Kin-Com Considerations

The purpose of utilizing the Kin-Com in this study was threefold. The first was to allow for positioning of the hip at 25° of abduction and the knee at 50° of flexion. The second reason was to provide a method of recording a numerical value of hip adduction strength. Finally, the third function was to provide the subject with biofeedback during the combination of isometric adduction and isometric knee extension.

The ability to maintain the proper knee angle of 50° during testing was verified with periodic checking using a goniometer. This angle was managed despite the variability in leg length between subjects. In addition, hip abduction was also maintained using two pieces of masking tape placed on the seat of the Kin-Com at the prescribed 25° angle. The tape provided a landmark for placement of the subject's inner thighs. However, inconsistencies were noted during testing with internal and external rotation of the hip and/or tibia. Although slight, this rotation, in effect, may have altered the EMG readings of the VMO,

creating different values than might have otherwise been obtained with a neutral hip/tibial alignment.

When recording maximal strength of the adductor muscles, the Kin-Com provided a numerical value in pounds. From this value, an approximate 25% adduction force was utilized in conjunction with the MVC of knee extension. When establishing testing protocol, it was found that 25% adduction contraction was held more consistently than the maximal adduction contraction when combined with knee extension. This 25% value was utilized for testing purposes through the use of visual biofeedback. The combination of hip adduction/knee extension with the addition of biofeedback may have increased the level of difficulty which requires the subject to perform a multi-task function. This increase in difficulty may result from the inability to multi-task without adequate time to learn the activity.

The biofeedback portion of the test required the subjects to view the Kin-Com monitor while performing the adduction contraction. The screen provided a red horizontal line which represented 25% of their adduction MVC and a movable blue bar that indicated current force being generated by the adductor muscle group. Subjects were asked to maintain the blue bar at or above the height of the red line throughout the MVC knee extension contraction. The amount of adduction contraction equals the 25% level varied between subjects. This variability may also have influenced EMG readings at the VMO.

In addition, EMG activity at the VMO muscle may have also been influenced in response to overflow (irradiation) from surrounding musculature. Although surface electrodes are preferred over fine-wire electrodes when human subjects are involved, they are less selective in their electrical detection from surrounding tissue.⁹ These limitations pose several questions for future research.

Questions to be addressed in future studies should include: 1) Would statistical significance be acquired within gender groups if both had larger sample sizes? 2) Is there a learning curve that needs to be addressed when applying more than one stimulus? 3) How do you limit internal/external rotation without restricting the subject's capabilities? 4) What is the relationship between overflow (irradiation) from the surrounding musculature activity of the other guadriceps and adductor muscles with that of the VMO?

Conclusion

It was determined from this study that VMO activity can be augmented through the addition of an isometric adduction contraction while performing an isometric knee extension. These findings are important for clinicians dealing with patients who are experiencing difficulty initiating a VMO muscle contraction. Earlier initiation of contraction of the VMO may allow the patient to advance through rehabilitation at an accelerated pace. This increase could possibly shorten overall rehab time which can save the patient time and money. APPENDIX A

ID#

Subject Demographic Information

Name:			

Age:_____

Education Major:_____

Current Occupation:_____

Height:_____

Weight:

Dominant Leg:______(Leg used to kick a ball)

Gender: M or F

- 1. Have you ever experienced any type of knee problems? Y or N (circle one) If yes, please indicate which knee and what problems you have experienced.
- 2. Do you have allergies related to adhesives, latex or alcohol? Y or N (circle one)
- 3. Please note your type and duration of physical activities during the course of a week (i.e. running, walking, weight lifting, tennis, work etc.)

APPENDIX B

ID#____

Informed Consent

You are being invited to participate in a research project conducted by Dr. Sue Jeno, an Assistant Professor, Jimmy Turner, and Dan Thielen, Graduate Physical Therapy students in the Physical Therapy Department at the University of North Dakota. The purpose of this study is to determine the relationship between different thigh muscles, while trying to straighten the leg against a fixed force. Electromyography (EMG), a recording device, will be used to record muscle activity of the right thigh during testing. Results of our testing will provide strengthening exercises to assist in the rehabilitation of leg muscles for practicing physical therapists. Only healthy persons between the ages of 18 and 50 years, who have no prior history of right knee problems, will be allowed to participate in this study. Exclusion from this study will involve a history of right knee problems and sensitivity to latex, adhesives or alcohol.

Self-sticking electrodes will be placed over various thigh muscles on the right leg. Excess hair in the area where the electrodes will be positioned, will be shaved with an electric razor and cleaned with alcohol wipes before electrodes are attached to the skin. The electrodes are connected to a belt attached around the your waist. EMG signals are then sent to a computer.

You will perform a 3-5 minute warm-up on a stationary bike. Following warm-up, you will be seated on testing equipment and secured in place with use of straps around your upper body and right thigh. You will then be asked to push against a fixed bar with your right leg to get a baseline measure of thigh muscle activity. This will be followed by 3 trials. Each trial will consist of holding a contraction of the thigh muscles for 6 seconds. A 1-3 minute rest period will be provided between trials. Following completion of all trials, the electrodes will be removed from the your leg. This will conclude your participation in the study. Results involving our study will be made available at your request.

Approximate time to complete this study will be one-half hour from start to finish. A time period will be assigned to you and you will be asked to report the University of North Dakota School of Medicine and Health Sciences room number 2541.

Although there is some degree of risk involved in physical activity testing, the risk of injury and discomfort should be minimal. However, slight muscle stiffness and soreness may be experienced following repeated activity. Redness of the skin in areas where the electrodes are placed may occur from the adhesive material on the electrodes. The EMG equipment will only monitor muscle activity and will not cause discomfort. If at any time you experience pain, discomfort, fatigue or any other uncomfortable symptoms you may stop your participation in this study. All

investigators are CPR certified. Medical treatment will be provided to you as needed, including first aid, CPR, and follow-up care as that provided to a member of the general public in a similar circumstance. All incurred medical expenses will be the responsibility of the subject and his/her third party payer.

Benefits to you as a participant in our study include but are not limited to: 1) obtaining information regarding the muscle activity of the thigh muscles and 2) increasing the researchers current understanding concerning muscle activity of these muscles. There will be neither cost associated nor any compensation to you the participant for contributing to our study.

Reports, as a result of our study, will be free of any identifying features of our subjects. All information will remain confidential and will be disclosed only with your permission. A number, known only to the investigators, will identify the data. All records will be collected and kept in separate locked file cabinets for three years following the completion of our study and will be shredded at that time. Your decision whether or not to participate in our study will not effect your future relationship with the University of North Dakota Physical Therapy Department. The researchers reserve the right to terminate your participation at any time if you are unable to perform the required testing or if continuation may cause increased risk of injury.

If you have any questions regarding our study, you may contact the investigators involved. In addition, if any questions arise in the future we encourage you to ask. All inquires can be made to Dr. Sue Jeno at 777-2831, Jimmy Turner 791-4983 and Dan Thielen 775-2403. Questions or concerns regarding our study may also be directed to the Office of Research and Program Development at 777-4279. A copy of this form will be kept separately from the data obtained from this study and available upon your request from Dr. Jeno.

I have read the above information and have been fully notified of the requirements of this study. I have a complete understanding of what is expected of me and willingly agree to participate in this study. I have received a copy of this consent form for my records.

Subject's Signature

Date

APPENDIX C

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University of North Dakota Human Subjects Review Form

Please Note: The policies and procedures of the University of North Dakota apply to all activities involving the use of Human Subjects performed by faculty, staff and students conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedure governing the use of human subjects. When preparing your Human Subjects Review Form, use the attached "IRB Checklist".

Please provide the information requested below:

Principal Investigators:		Dr. Sue Jeno, Jimmy Turner	Dan Thielen	
Telephone: _(701) 777-3	3662	Address:Box 9037	
E-mail address:	sujeno@	medicine.nodak.edu		
School/College:	Univers	rsity of North Dakota	Department:Physical Therapy	
Student Adviser	(if applic	cable): Dr. Sue Jeno		
Telephone: (7	01) 777-3	3662	Address:Box 9037	
E-mail address:	sujeno@)medicine.nodak.edu		
School/College:	Univers	rsity of North Dakota	Department: Physical Therapy	
Project Title: Ele	ectromyog	graphic Analysis of Isometric V	stus Medialis Oblique Contraction with A	dduction Component
Proposed Projec	t Dates:	Beginning Date:	May 1, 2003 Completion Date:May	15, 2004
Funding agencie	s support	ting this research:		
(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 interest in the results of this project? If yes, please submit, on a separate piece of paper, an additional explanation of the financial interest (other than receipt of a grant)				
If your project ha with the status of			itutional Review Board(s), please list thos	se boards below along
-		Da		Approved Pending
		Da	submitted: Status:	Approved Pending
Type of Project: X YES or		heck "Yes" or "No" for each of New Project	e following. YES or X NO Dis	sertation/Thesis
		Continuation/Renewal	X YES or NO Stu	
	X NO	Protocol Change for previousl (resubmit "Human Subjects R Does your project include Ger	approved project view Proposal" with changes bolded or hi tic Research?	ighlighted and signed)
YES or	X_NO	topic.	Researcher's Handbook for additional gu	
YES or	X_NO	Does your project include Inte Handbook for additional guide	net Research? If yes, refer to Chapter 3 o ines regarding your topic.	f the Researcher's

	-		
			Will subjects or data be provided by Altru Health Systems? If yes, submit two copies of the
	YES or	X NO	proposal. A copy of the proposal will be provided to Altru.
			Will research subjects be recruited at another organization (e.g., hospitals, schools, YMCA) or will
			assistance with the data collection be obtained from another organization If yes, please list all
			institutions: UND student body, Center Court Fitness Club.
V	VEC or	NO	

X YES or NO

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 and Faculty

Prisoners

Pregnant Women/Fetuses

Persons with impaired ability to understand their involvement and/or consequences of participation in this research

X Other Community Fitness Center

For information about protections for each of the special populations please refer to the protected populations section on the Office of Research and Program Development website.

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	1

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). Isolated activation of the vastus medialis oblique (VMO) during rehabilitation can be beneficial in treating patient pathologies including patello-femoral pain syndrome (PFPS) and patellar tracking dysfunction (PTD). The current literature indicates no consensus in the area of effectiveness involving isolated VMO activation. It is the purpose of this study to measure muscle electromyographic (EMG) levels of the VMO, vastus lateralis, rectus femoris, and adductor magnus. These values will be compared with a knee extension baseline established by way of maximal voluntary isometric contraction of knee extension, absent of an adductor component. Because this information will be used to examine an adductor moment and its influence on EMG activity at the VMO, human subjects will be required for study.

A total of 30-50 human subjects ages 18-50 without history of knee pathology will be recruited for this study. All subjects will complete three trials of sub-maximal adduction in conjunction with a maximal isometric knee extension at 50 degrees of knee flexion. Surface electrodes will be placed on the VMO of the right lower extremity. Computer readouts will be obtained as the subjects perform the desired testing activities. Statistical analysis will be utilized for examination of collected data.

The obtained research results will provide some insight as to the validity and benefits of isolating VMO activity to bolster rehabilitation of PFPS, PTD and other VMO related pathologies.

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. Subjects will initially be recruited from the University of North Dakota by speaking with classes within departments on campus. Additional recruiting will involve members of Center Court Fitness Club in Grand Forks, ND. Sign up sheets and flyers will be used to confirm subject's interest in participating in our study. The recruitment process will run for approximately 4 weeks from IRB approval.

- 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. 30-50 male or female subjects ages 18-50 with no history of knee pathology will be recruited on a voluntary basis for our study. These subjects will be recruited from the University of North Dakota student body as well as members of Center Court Fitness Club.
- c) Describe your exclusionary criteria and provide a rationale for excluding subject categories. 1) History of knee pathology. Due to the possibility of muscular misrepresentation as a result of knee trauma, we will exclude these individuals to maintain consistency within our samples. 2) Age ranging from 18-50 years. The muscle physiology of those individual between 18-50 best represent a normative population.
- d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects. For this study, 30-50 subjects will be used to establish a baseline data on the EMG activity in all subjects during knee extension with hip adduction.
- e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method. To minimize error in this study, subjects will be randomly selected, bio-feedback will be utilized to maintain an adduction component, and each subject will be secured and positioned in the same way for each trial. In addition, a mean value from the three trials will be used to incorporate all scores. Standardized placement of the electrodes will reduce error in EMG data.

2. Description of Methodology.

- a) Describe the procedures used to obtain informed consent. Informed consent will be obtained through an information and consent form (see attached form). All individuals participating in this study will be capable of independent decision making and will sign a consent form stating their understanding and willingness to participate in this study. A copy of the consent form will be provided to each participant.
- b) Describe where the research will be conducted. Research will be conducted in research room #2541 within the University of North Dakota Department of Physical Therapy.
- c) Indicate who will carry out the research procedures. Sue Jeno, Jimmy Turner, Dan Thielen.
- d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them. During our study we will be measuring EMG activity of the VMO, vastus lateralis, rectus femoris, and adductor magnus muscles. This activity will be monitored through pre-gelled self-adhesive electrodes placed over the motor points of the above noted muscles in the right lower extremity. Precise electrode placement will be determined by standard electrode placement chart. Each subject will be asked to wear shorts. Body hair will be shaved with an electric razor and the skin cleansed with alcohol wipes prior to electrode placement. The electrodes will be connected to a transmitter, which will be placed in a belt attached around the subject's waist. EMG signals will be telemetered to a receiver and then to a computer monitor. Raw and rectified EMG data will be obtained for analysis. The subject will perform a maximal isometric knee extension contraction of the right lower extremity at a predetermined angle of 50°- knee flexion. This activity will be used as our method for normalization of electromyographic data. Additional normative data involving adduction will be obtained through an isometric maximal contraction of the adductors involving the right lower extremity. Both lower extremities will be fixed in 15°-30° of abduction. Twenty-five to seventy-five percent of the maximal adduction component will be utilized prior to a maximal isometric knee extension at the pre-set position of 50°.

Prior to testing, each individual will perform a 3-5 minute warm-up on a stationary bike involving minimal resistance. Immediately following the warm-up, the subject will be seated on the isometric testing device (KIN-KOM) and secured with two straps crossing diagonally over the torso for stabilization. The KIN KOM will be set-up for biofeedback monitoring of the adductor component to achieve the 25%-75% sub-maximal contraction. Hip abduction will be measured with a goniometer, with both lower extremities secured in an abducted position of 15°-30°. The extremity will be fixed by

way of straps surrounding the distal thigh, 3"-5" proximal to the knee joint line. The right lower extremity will be fixed at 50° of knee flexion via strapping. This strap will be placed 1"-5" proximal to the apex of the medial malleolus. The opposite end of the strap will be secured utilizing the KIN-KOM machine.

Prior to testing the researchers will read a standardized list of instructions informing the individual of the task to be completed. Immediately following warm-up the subject will be seated on the KIN-KOM and secured in place. One maximal isometric knee extension contraction, at 50° of knee flexion will be performed to establish a baseline value. Next, one practice repetition involving will be performed to ensure understanding of the instructions involved for completion of the adduction/extension task. This will be followed by 3 adduction/extension trials. A 1-3 minute rest period will be provided between trials. Each trial will consist of maintaining a 25%-75% sub-maximal isometric contraction of the adductors by way of biofeedback. The sub-maximal component will be attained and held until a maximal isometric knee extension at 50° is attained and measured via electromyography. Following completion of data collection, the electrodes will be removed from the subject's leg. This will conclude his/her participation in the study. Results involving our study will be made available at the subject's request. EMG data will be statistically analyzed and results will be reported.

- e) Describe audio/visual procedures and proper disposal of tapes. There will be no utilization of audio/visual procedures in our study.
- f) Describe the qualifications of the individuals conducting all procedures used in the study. Sue Jeno is an Assistant Professor in the Department of Physical Therapy at the University of North Dakota. Jimmy Turner and Dan Thielen are graduate physical therapy students at the University of North Dakota. All have been trained in the correct use of all the research equipment to be utilized in this study.
- g) Describe compensation procedures (payment or class credit, etc.). No compensation will be received for participation in our study.

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

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. Subject risk-factors involving this study will be minimal. The administration of electromyography is a non-invasive clinical procedure which involves the placement of surface electrodes secured to the skin. During isometric contractions there is the possibility of muscle strain and knee pain. Skin irritation due to strapping is also possible during trials. Due to muscle contraction, the subject may experience muscle soreness and fatigue. This soreness should not exceed that experienced during minimal physical activity.
- b) 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.). Subjects clear of prior right knee pathology will be recruited to help minimize risk factors. A warm up will be utilized to prepare the muscles for above noted activities. Non-abrasive cloth strapping in conjunction with patient clothing/toweling will provide separation between the belt and subject's skin for maximal protection. All subjects will be allowed to terminate their participation in our study at any time without prejudice.
- c) 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. The subjects in no way will be linked to the data/consent forms. Each participant will be assigned a randomly selected identification number at the beginning of our study, which will be known by the researchers only. All information involving the research study will be secured in a locked cabinet inside the physical therapy department located at the University of North Dakota.
- 4. Subject Protection.
 - a) Describe procedures you will implement to protect confidentiality (such as coding subject data, removing identifying information, reporting data in aggregate form, etc.). The information collected in our study will be kept completely confidential. The participating subjects names and personally identifying information will not be revealed during any time throughout the study. Confidentiality will be further upheld through presentation of aggregate data only. A hard copy of the statistically analyzed data along with the data collection sheets concerning the study will be secured in a locked cabinet

inside the physical therapy department located at the University of North Dakota. Unless our data is required for future studies, the information will be destroyed via shredding three years after the study has been completed.

- b) Indicate that the subject will be provided with a copy of the consent form and how this will be done. Subjects will be requested to sign a consent form prior to testing and will be provided a copy for their records (see attached form).
- c) 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. The information collected in our study will be kept completely confidential. Only the researchers will have immediate access to this information. Personal data will be made available to the subjects upon request. Personal information involving the subjects will not be revealed at any time throughout the study. A hard copy of the data collected will be secured in a locked cabinet in the physical therapy department located at the University of North Dakota. Consent forms and personal data will be stored separate from each other in a locked cabinet within the physical therapy department at the University of North Dakota. Unless our data is required for future studies, the information will be destroyed three years after the study has ended.

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

- b) who will have access to the data
- c) how the data will be destroyed
- d) the storage location of consent forms and personal data (separate from research data)
- e) how the consent forms will be destroyed
- d)Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.) In the event of an adverse reaction, the subject will be asked to terminate the exercise. All investigators are CPR certified. Medical treatment will be provided to each subject as needed, including first aid, CPR, and follow-up care as that provided to a member of the general public in a similar circumstance.
- e) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved. In the event of personal injury during our study, the subject will be prompted to seek immediate medical attention. All incurred medical expenses will be the responsibility of the subject and his/her third party payer.

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. Benefits to the participant in our study include but are not limited to: 1) obtaining information regarding the muscle activity of the knee extensors and 2) enhancing the researchers current understanding concerning muscle activity of the vastus medialis for rehabilitation purposes. There will be neither cost associated nor with any compensation to the participant for contributing to our study.

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.
- 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 has access. 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:

(m · · · ·	T \
(Principal	Investigator)
(1 Incibal	Investigatory
(

Date:

(Student Adviser)

Date:

Requirements for submitting proposals:

Additional information can be found at the Office of Research and Program Development website at www.und.nodak.edu/dept/orpd

Original Proposals and all attachments should be submitted to: Office of Research and Program Development (ORPD), P.O. Box 7134, Grand Forks, ND 58202-7134, or drop off at Room 105, Twamley Hall.

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.

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 attached "Student Consent to Release of Educational Record".

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Revised 7/15/2002

STUDENT RESEARCHERS: As of June 4, 1997 (based on the recommendation of UND Legal Counsel) the University of North Dakota IRB is unable to approve your project unless the following "Student Consent to Release of Educational Record" is signed and included with your "Human Subjects Review Form."

STUDENT CONSENT TO RELEASE OF EDUCATIONAL RECORD¹

Pursuant to the Family Educational Rights and Privacy Act of 1974, I hereby consent to the Institutional Review Board's access to those portions of my educational record which involve research that I wish to conduct under the Board's auspices. I understand that the Board may need to review my study data based on a question from a participant or under a random audit. The study to which this release pertains is

I understand that such information concerning my educational record will not be released except on the condition that the Institutional Review Board will not permit any other party to have access to such information without my written consent. I also understand that this policy will be explained to those persons requesting any educational information and that this release will be kept with the study documentation.

Date	Signature of Student Researcher

1Consent required by 20 U.S.C. 1232g.

APPENDIX D

Consent for Capturing and Publishing Photographs

Name:	Andrea Kresel
Location:	University of North Dakots School of Medicine and Health Sciences
Date:	June 26, 2003

In connection with Dan Thielen and Jimmy Turner's research study entitled, Electromyographic Analysis of an Isometric Vastus Medialis Oblique contraction with incorporation of an adduction component, I consent that photographs may be taken of me and may be published under the following conditions.

- 1) The photographs shall be used if the researchers, Dan Thielen and Jimmy Turner deem that medical research, education, or science will be benefited by their use. Such photographs may be published and republished, either separately or in connection with each other, in professional journals or medical books; provided that it is specifically understood that in any such publication or use I shall not be identified by name.
 - The aforementioned photographs may be modified or retouched in any way that the researchers, Dan Thielen and Jimmy Tumer may consider desirable.

Signed Witnes

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2)

Consent for Capturing and Publishing Photographs

Name:	Franz Yuen
Location:	University of North Dakota School of Medicine and Health Sciences
Date:	June 26, 2003

In connection with Dan Thielen and Jimmy Turner's research study entitled, Electromyographic Analysis of an Isometric Vastus Medialis Oblique contraction with incorporation of an adduction component, I consent that photographs may be taken of me and may be published under the following conditions.

- 1) The photographs shall be used if the researchers, Dan Thielen and Jimmy Turner deem that medical research, education, or science will be benefited by their use. Such photographs may be published and republished, either separately or in connection with each other, in professional journals or medical books; provided that it is specifically understood that in any such publication or use I shall not be identified by name.
- 2) The aforementioned photographs may be modified or retouched in any way that the researchers, Dan Thielen and Jimmy Turner may consider desirable.

Signed

Witness

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