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A Comparison of the Maximal Torque Production of the Quadriceps Muscle during Morning and Afternoon Strength Assessment

Shawn McCoul
University of North Dakota

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A COMPARISON OF THE MAXIMAL TORQUE PRODUCTION OF THE QUADRICEPS MUSCLE DURING MORNING AND AFTERNOON STRENGTH ASSESSMENT

by

Shawn McCoul
Bachelor of Science in Physical Therapy
University of North Dakota, 1998

An Independent Study
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 Master of Physical Therapy

Grand Forks, North Dakota
May 1999
This Independent Study, submitted by Shawn Lee McCoul 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 Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

(Signature)
(Faculty Preceptor)

(Signature)
(Graduate School Advisor)

(Signature)
(Chairperson, Physical Therapy)

ii
PERMISSION

Title A Comparison of the Maximal Torque Production of the Quadriceps Muscle During Morning and Afternoon Strength Assessment.

Department Physical Therapy

Degree Master of Physical Therapy

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Signature

Date 12/10/98
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ABSTRACT

The purpose of this study was to compare maximal quadriceps torque production in early morning hours to afternoon hours. Thirty male subjects volunteered to participate in this study and were randomly assigned to an AM or PM testing session. At least one week after the first test, the subjects completed a similar test in the opposite time slot. Each subject was positioned on the Kin-Com (Chattecx Corp., Chattanooga, TN) dynamometer and performed six maximal concentric isokinetic repetitions of knee extension at 600/s between the ROM of 10° and 80° of knee flexion. The AM/PM ratios indicated no significant difference between the two trial times. Also, t-test for paired samples calculations were not significantly different for the sample. Pearson’s Correlation calculations ranged form .82 to .97. The data support the null hypothesis that there is no significant difference in maximal quadriceps peak torque production in morning versus afternoon hours.
CHAPTER 1

INTRODUCTION

In the quest to provide the highest quality of care to their patients, physical therapists collect large amounts of objective and subjective data. They then transform this data into information to be used in the measurement of patient recovery. This information helps direct the patient’s rehabilitation course and allows the physical therapist to introduce variables into the treatment to observe the results. The data come from many sources. Subjectively, the patient may rate pain on a visual analogue scale or simply describe his or her feelings of the rehab process. Objective data may come from well developed questionnaires, girth measurements, or even isokinetic dynamometry.

Physical therapists, however, are not the only people who require this information. The patient’s referring physician uses it to map the patient’s progress and evaluate for the presence of a differential diagnosis or underlying pathology. Also, third party payers use the information for reimbursement issues. Virtually all aspects of the patient’s rehabilitation, from the doctor’s orders to the payment of services, are affected from the data gathered in physical therapy sessions.

As the demand is increasing for objectivity in muscle testing, one can appreciate the need for the data collected by the physical therapist to be as accurate as possible. There needs to be documentation that indicates that progress, even minimal, is being
made in rehabilitation. Therefore, the clinician needs to use tools that demonstrate reliability and validity when collecting data. When using isokinetic dynamometry to test a patient's strength through peak torque produced by a joint, for example, the therapist needs to use equipment and procedures that are sure to provide reliable results.

When dealing with isokinetic testing, while the machine in itself has demonstrated reliability and validity, there is little information available to assess the need for the test to be time dependent. For example, if a therapist performs an isokinetic evaluation to collect data on a patient, is it necessary, in the future, to perform a retest at the same time of day in order to achieve reliable results? The answer to this question will persuade physical therapists to develop or maintain accurate testing procedures that will help to ensure quality patient care.

The purpose of this study, in order to help determine the relationship between isokinetic testing and time of day, is to compare maximal quadriceps torque production in early morning hours to maximal quadriceps torque production in afternoon hours.

The significance of this study is to determine if time of day affects maximal torque production of the quadriceps muscle. The results may be applied to clinical objective testing procedures and may lead to further research into optimal training times for athletes. Perhaps most importantly, the study may help clinicians obtain data regarding their patients that is more accurate. This will help fill the demand for objective numbers and demonstrate that there has been improvement in patient functioning as a result of treatment.
As the study was performed, several research questions developed. For example, what effect does time of day have on quadriceps peak torque? Will differences in the data be consistent for all of the test subjects or will individual differences predominate? Will the isokinetic machine be sensitive enough to reveal differences between the morning and afternoon testing sessions? Will the results be significant to the point that isokinetic tests and retests should be performed at the same time of day? All of the above questions are relevant to the practicing physical therapist and may lead to the adaptation of traditional methods of testing clients isokinetically.

The null hypothesis of the study is that time of day does not significantly affect maximal quadriceps peak torque production when measured by a Kin-Com isokinetic dynamometer. If the null hypothesis is accepted, strength assessment can be performed throughout the day to accurately measure and compare muscle torque production regardless of the time of day the previous testing was performed.

Conversely, the alternate hypothesis is that maximal quadriceps peak torque production is significantly affected by time of day. If the null hypothesis is accepted, it will support the need for strength assessment and reassessment to be performed at similar times of the day in order to achieve accurate results.
Assigning a reliable quantitative value to strength is a difficult task. Perhaps the most common strength test, the manual muscle test, is one of the least reliable. The interrater reliability of manual muscle testing of the middle trapezius and gluteus medius muscles was low according to a study performed by Frese et al. in 1987. He demonstrated that only 50-60% of therapists obtained the same MMT grade or were within one third of a grade for those muscles. In 1992, however, Florence et al. demonstrated reliable intrarater MMT grades in boys with Muscular Dystrophy. Perhaps Westers stated it best by explaining that manual muscle testing may be subject to inconsistencies but still provides a quick and “global assessment of strength.” Still, however, the need for reliable strength tests is of great importance to healthcare professionals as areas of concern are evaluated and screened.

Advancements in technology, such as isokinetic dynamometers, have helped clinicians obtain more accurate strength assessments. Not only do the machines provide a certain amount of precision for accurate documentation, but they are also useful for exercise programs and motivation as the patient sets goals for each treatment. Obtaining a reliable muscle test, however, goes beyond the technology of the instruments used. In
the clinic many factors may influence a muscle test. For example, pain and swelling in a joint may physiologically inhibit patient output. Also, patient stiffness, the use of modalities, patient arousal, and even patient learning may yield unreliable results. It is possible for a patient to become familiar with a testing procedure and therefore produce remarkable strength gains that may not be representative of the client’s progress.\textsuperscript{8,10} Likewise, it is possible for a patient to become familiar with a testing procedure and therefore skew test results through patient learning.\textsuperscript{10} Other factors that may influence a muscle test include the surroundings (i.e. illumination, noise, distractions), intensity of manual or mental work, anxiety, illness, pain, and boredom. All of the above factors may induce or inhibit patient fatigue and therefore facilitate or inhibit the results of a strength test.\textsuperscript{8}

Chronobiology

The study of the relationship between time of day and physiological variables is called chronobiology. Likewise, circadian rhythms are a component of this science, as they are 24 hour recurring variations. It is known that most physiological attributes are time of day dependent. These circadian rhythm cycles, found also in plants and other animals, consist of variations in body temperature, blood cell counts, oxygen uptake and heart rate. For example, human body temperature follows a rhythm of higher temperatures in the evening and lower temperatures in the early morning. The minimum temperature is reached from 5 to 6 AM and the maximum temperature is reached at approximately 4 PM.\textsuperscript{11,12,13}
Similarly, adrenocorticotropic hormone (ACTH) release has been shown to follow a certain physiologic pattern. A pituitary hormone, ACTH stimulates the cortex of the adrenal glands, enabling the production of cortisone. Cortisone is known primarily as an anti-inflammatory agent but also plays an important role in the metabolism of fats, proteins, and carbohydrates.\textsuperscript{14} ACTH is secreted in bursts and manifests itself as a rise in plasma cortisol. The ACTH bursts are most common (75\% of daily production) between 4 and 10 AM.\textsuperscript{15} The cortisol levels decrease throughout the day, at rest, and during exercise.\textsuperscript{13}

While much information is lacking on the effects that time of day has on exercise and strength, it is apparent that the two subjects are related on some level.\textsuperscript{16,17,18} In a study by Torii et al,\textsuperscript{19} three groups of men, who exercised at different times of day, were studied. The observer’s conclusions revealed that training is affected by time of day. Afternoon training appeared to be the most effective in regards to $\textit{VO}_2\text{max}$ and heart rate. Also, the blood lactate response to exercise showed the most improvement in the afternoon.

Another study by Freivolds et al,\textsuperscript{11} explained job performance by looking at variations in capability of shift workers. The results revealed 24-hour fluctuations in physiological, neurological, and psychomotor reactions. The study revealed peak performance periods and poor performance periods.

In a study designed to assess validity and reliability of a portable dynamometer, a time of day effect was noted in relation to strength.\textsuperscript{20} One part of the study required four subjects’ back and leg strength to be assessed with a portable dynamometer at six
different times of day. Test trials took place at 2, 6, and 10 AM, and 2, 6, and 10 PM. At least eight hours separated each test session. Also, a familiarization session was given with the dynamometer before the tests were initiated. Results of the study revealed that average peak torque times were at 4:53 and 6:20 PM.

Wyse et al.\textsuperscript{21} examined time of day isokinetic leg strength dependence and interday variability. Nine male college athletes participated in the study. Each subject completed a series of nine test sessions. Three tests were taken per day (8-9 AM, 1-2 PM, 6-7:30 PM) and each series of tests was separated by a rest of seven days. Results revealed significantly higher scores at the 6 to 7:30 PM test trial. Also, the researchers suggest that for test and retest data to be reliable, the patient or subject must retest within half an hour of the same time of day.

Reilly and Garrett,\textsuperscript{22} while performing a study on prolonged exercise, noted that high power output occurred in the evening over the first 30 minutes of the test but was compensated for by increased performance in the morning over the second 30 minutes (p<.05). They concluded that morning affected the pacing of endurance, but noted no overall effect. Likewise, Reilly and Baxter,\textsuperscript{24} in performing a study on high intensity aerobic effort, found exercise tolerance time, total work done, and peak lactate production were significantly higher in the afternoon than in the morning.

Providing more information into chronobiology and physiological attributes, Baxter and Reilly\textsuperscript{27} conducted a study to determine the influence that time of day has on all out swimming. The results show a significant linear trend between the athletes performance and the time of day. The steady improvement for the 100M was 3.5% and
2.5% for the 400M swim. Likewise, trunk flexibility of the athletes peaked in the afternoon. The researchers concluded that maximal swimming trials would best be scheduled in the evening.

A review of the literature helps to determine initially how difficult it is to assess muscle strength reliably. Secondly, the literature points to strength variation in respect to time of day and suggests that strength, like so many physiological variables, falls under the influence of chronobiology. Therefore, in order to assess the clinical implications of time of day and muscle strength, this study was developed.
CHAPTER 3
METHODOLOGY

Subjects

Thirty, healthy male subjects, between the ages of 21 and 43 volunteered to participate in this study. Fitness levels of the subjects was quite variable with some subjects exercising daily and others leading a very sedentary lifestyle. All subjects were currently enrolled as students of the University of North Dakota in Grand Forks, North Dakota. To participate in this study each subject agreed to not participate in any lower extremity strengthening or aerobic exercise and activities for one day prior to each testing procedure. Volunteers excluded from this study included subjects with any neurological disorders and/or any leg or knee pathology within the last year. Also, subjects were excluded if they had any current knee dysfunction or muscle soreness/fatigue prior to the testing procedure. The subjects were randomly assigned to either an early morning (no longer than 1.5 hours after awakening from a 6 hour or longer sleep) test group or an afternoon (must have been awake for longer than 8 hours but less than 16 hours) test group. The AM and PM testing session were completed between 7:30 – 9:30 AM and 2:30-5 PM respectively. Participants were informed of the testing procedures and took part in a familiarization session with the researchers and equipment. The volunteers were informed of their rights as a participant in accordance with the Institution Review Board
procedures at the University of North Dakota. Each subject signed an informed consent form prior to voluntary participation in the study (see appendix).

**Instrumentation**

The Kin-Com (model 125AP with software version 4.06, Chattecx Corp., Chattanooga, TN) dynamometer was used to evaluate peak torque values in this study. A dynamometer is a hydraulically driven, microcomputer-controlled device designed to measure torque and work during eccentric and concentric isokinetic loading.\(^5\) Torque refers to the ability of any force to cause rotation of a lever. It is a product of the magnitude of the applied force and the perpendicular distance that force lies from the axis of rotation.\(^{25}\) In relation to the dynamometer, torque is the product of the muscle force measured at the resistance pad multiplied by the pad’s perpendicular distance from the axis of rotation. The distance from the pad to the axis of rotation is entered into the computer for each individual subject before the testing begins.\(^2\) The dynamometer is capable of measuring the precise amount of torque generated by supplying a graded resistance to the limb that is attached to the machine’s lever arm. The graded resistance occurs when the lever arm reaches a predetermined speed that is selected by the operator. This graded resistance remains throughout the range of motion as long as the speed remains at the set level; speeds above the maximal level are prevented by the resistance the device provides.\(^{26}\) Peak torque is the highest torque produced at one point in the range of motion.\(^{27}\) Work is accomplished when a force is applied to an object in the direction of motion of the object. The magnitude of work is directly proportional to the
applied force and to the magnitude of movement produced. Work equals force times distance.25

The dynamometer is one of the unique machines that is able to assess isokinetic muscle contractions. In isokinetic exertion, both eccentric and concentric, the angular velocity of the muscle is held constant by the mechanical device throughout the range of motion. The resistance produced by the machine is directly proportional to the torque produced by the involved muscle at all points in the range. As the muscle torque increases, the resistance proportionally increases.25 The two types of isokinetic contractions assessed by the dynamometer, eccentric and concentric, are differentiated by the muscle action. In both types of contraction, the muscle is exerting a force. During a concentric contraction, work is achieved as the muscle moves the body part in the direction of the muscle pull. The muscle shortens as it contracts. During an eccentric contraction, the muscle will lengthen as it exerts its force.25

The reliability and validity of the Kin-Com to assess isokinetic torque during successive sessions has been established in several previous studies. Snow and Blacklin2 found that within sessions, the interclass correlation coefficients (ICC) ranged from .94 to .98 for 30°/s and from .92 to .97 at 180°/s. Between sessions trials (1 week apart) ranged from .94 to .98 for 30°/s and from .75 to .88 for 180°/s. The data represent a higher reliability for slower speeds. In an analysis of the reliability and validity of the kinetic communicator exercise device by Farrell and Richards,3 both static and dynamic tests resulted in a difference of 3.2% or less for force measurements and were felt to be due to calibration error and not an indication of inaccuracy in the Kin-Com system. In addition,
they found lever arm speed to be within 1.5% of the target speed and no discrepancy noted in position measurement. A study by Reitz et al.\textsuperscript{4} reported a correlation coefficient for the Kin-Com ranging from .95 to .98 for parameters of 60°/s, 120°/s, and 180°/s. The work of Tredinnick and Duncan\textsuperscript{5} resulted in an interclass correlation coefficient for intertest reliability of concentric torque at 60°/s to be .89 and a coefficient of .85 for concentric work.

The dynamometer is a versatile machine that is capable of testing both the upper and lower extremities. It can be set in either an evaluation mode or training mode.\textsuperscript{28} In this study the right lower extremity concentric isokinetic contractions were tested in the evaluation mode. The range of motion (ROM) for the lever arm was set to an anatomical zero for each subject. From that point the machine was programmed to allow for motion of testing between 10° and 80°. The acceleration and deceleration settings of the Kin-Com lever arm at end range were set on high. The high settings allowed for the subject’s limb to accelerate and decelerate from a constant velocity in the shortest possible time period, thus maximizing the amount of time the subject’s limb moved at a constant velocity.\textsuperscript{28} The velocity of the lever arm was set at 60°/s. This speed was selected due to reports from previous studies that suggest a high correlational coefficient (.89) for concentric torque at this speed.\textsuperscript{5} This data has also been reinforced by Snow and Blaklin\textsuperscript{2} who concluded that slower speeds reveal a higher rate of reliability. In addition, this speed is commonly used in clinical settings to assess patient progression.
Procedure

Four examiners administered the testing, with at least two present at each session. Prior to subject use, the team members conducted a training session and established a written protocol for testing procedure. All four individuals conducting the study strictly followed the protocol. It has been shown reliable measurements can be achieved by multiple examiners with variable isokinetic testing experience.

Each subject was first oriented to the Kin-Com machine in a familiarization session one week prior to the actual testing procedure. Before being positioned on the Kin-Com, each subject warmed up on a Monark stationary bike for a period of two minutes. Each subject’s name, weight, and age were then recorded. Each subject was positioned on the Kin-Com to fit his specific physical dimensions. The subject’s settings were saved during the familiarization session on the computer to ensure the exact position could be recalled for future testing procedures. Position settings for each subject were also established and recorded at this time following the protocol of the Kin-Com Basic Training Course Workbook (Chattecx Corp., Chattanooga, TN). Each subject was tested in a seated position with two restraining belts around the trunk and one restraining belt around the waist. Each subject’s right knee rotational axis was aligned with the dynamometer’s axis of rotation using the femoral epicondyles as the center. The subject’s right lower leg was then secured to the dynamometer arm with a double shin pad and the right thigh was stabilized with a restraining pad. At this time, the subject was instructed to perform six submaximal concentric contractions of the quadriceps and to relax all musculature on the return of the dynamometer arm to the flexed position after
each repetition. After a rest period of two minutes, the subject performed six maximal repetitions of knee extension. Concentric isokinetic testing was performed at 60°/sec to test the maximal quadriceps torque between the ROM of 10° and 80° of knee flexion. At this time in the familiarization session, the subject was asked if he was comfortable with the Kin-Com machine and the testing process. The set of six repetitions was repeated if the subject was uncomfortable with the process. If the subject felt comfortable, the session ended. He was then scheduled for a testing time no less than 3 days from the familiarization session.

All subjects were randomly assigned to I of II groups with 15 subjects in each group. The first group was initially tested in the early morning. The second group was initially tested in the afternoon. The groups were then retested in the opposing time slot following a minimum of 3 days between tests. The testing procedure followed the same format as the familiarization session with a warm up on the stationary bike, a submaximal set of six concentric knee extensions, and the recorded maximal set of six contractions.

Data Analysis

Data analysis was completed using the SPSS 7.5 for Windows program. The right quadriceps muscle of each subject was measured for the highest peak torque during a set of six concentric isokinetic contractions at 60°/s. These values were identified using the Kin-Com software. The highest peak torque value for each test, one for the AM session and another for the PM session, were recorded for each subject. The group mean, standard deviation, and range were determined for each test session. Ratios comparing the AM and PM session were also analyzed. Descriptive statistical methods were used to describe the
data with the use of a t-test for paired samples. In addition, Pearson’s Correlation analysis was performed. All of the above data interpretations were analyzed for the entire sample and for two groups. Group I consisted of 15 subjects who participated in an AM session for their first recorded trial. Group II consisted of 15 subjects who participated in a PM session for their first recorded trial.
As mentioned in the Methods, the subjects performed two separate recorded trials, one in the AM and one in the PM. The maximal peak torque value (ft-lb) for each subject was determined by the highest torque produced during each six repetition trial at $60^\circ/s$.

The mean value for the maximal peak torque production in the AM trials was 185.1 ft-lb. The mean value for the maximal peak torque production in the PM trials was 186.6 ft-lb.

For the group (n=15) who performed their first recorded trial in the AM, Group I, the mean value of maximal torque production in the AM was 184.6 ft-lb and 181.6 ft-lb in the PM.

The mean value of maximal torque production for the group (n=15) who performed their first recorded trial in the PM, Group II, was 185.7 ft-lb in the AM and 191.7 ft-lb in the PM.

Additional data is presented in Table 1.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean (ft-lb)</th>
<th>Standard Deviation</th>
<th>Range (ft-lb)</th>
<th>AM/PM Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
</tr>
<tr>
<td>Entire Sample (n=30)</td>
<td>185.1</td>
<td>186.6</td>
<td>35.6</td>
<td>41.1</td>
</tr>
<tr>
<td>Group I (n=15)</td>
<td>184.6</td>
<td>181.6</td>
<td>31.3</td>
<td>38.9</td>
</tr>
<tr>
<td>Group II (n=15)</td>
<td>185.7</td>
<td>191.7</td>
<td>40.6</td>
<td>43.9</td>
</tr>
</tbody>
</table>
The AM/PM ratios indicate that there was no significant difference between the two trial times as they all are nearly a 1:1 ratio. This data is reinforced by the use of a t-test for paired samples which revealed that the mean peak torque values were not significantly different for the sample ($t(29) = -0.46, p < .05$, two-tailed). In addition, Group I ($t(14) = +0.52, p < .05$, two-tailed) and Group II ($t(14) = -2.14, p < .05$, two-tailed) both failed to display any significant difference between tests performed in the AM and the PM. Data from the t-test for paired samples is presented in table 2.

<table>
<thead>
<tr>
<th>Sample</th>
<th>t</th>
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</thead>
<tbody>
<tr>
<td>Entire Sample (n=30)</td>
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</tr>
<tr>
<td>Group I (n=15)</td>
<td>+0.52</td>
</tr>
<tr>
<td>Group II (n=15)</td>
<td>-2.14</td>
</tr>
</tbody>
</table>
Calculations using the Pearson’s Correlation revealed extremely high coefficients. The correlations ranged from .82 to .97. Table 3 contains the correlations between AM and PM sessions for the entire sample as well as for each group.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Correlation Value</th>
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</thead>
<tbody>
<tr>
<td>Entire Sample (n=30)</td>
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</tr>
<tr>
<td>Group I (n=15)</td>
<td>0.82</td>
</tr>
<tr>
<td>Group II (n=15)</td>
<td>0.97</td>
</tr>
</tbody>
</table>
CHAPTER 5
DISCUSSION

The results of the research reveal no significant difference in maximal peak torque values when comparing the AM/PM groups. Also, the use of a t-test for paired samples failed to reveal any significant differences between the groups. In examining the data, there does not appear to be a learning curve. This is deduced by the fact that for each group (Group I consisted of 15 subjects who participated in an AM session for the first recorded trial; Group II consisted of a similar 15 subjects who participated initially in a PM session) the higher mean was attained during the first recorded session. Taken as a whole, the data does not support the theory that reliable muscle strength assessment is time dependent. Therefore, the data supports the null hypothesis that there is no significant difference in maximal quadriceps peak torque production in morning versus afternoon hours. Based on these results, general strength assessments can be performed throughout the day to accurately assess and compare muscle torque production regardless of previous testing times.

The protocol for testing was designed to limit factors that could bias the results; however, it is possible the results of the study are limited secondary to several aspects of the design. For example, inconsistencies between testers, poor subject stabilization, and
inconsistent subject stabilization may have effected the data and thus the results to some degree. Likewise, our data was obtained specifically using the Kin-Com dynamometer at a speed of 60°/s for concentric contractions. It is entirely possible that other dynamometers may offer less or greater stabilization efforts and limit clinician error through user friendly protocols and set up procedures. Along the same lines, different results may have been achieved by examining peak torque at speeds other than 60°/s. Also, total work and endurance data could be obtained using a similar protocol and be examined in respect to time of day differences. When analyzing the data, age gender, and activity levels of the subjects should also be a consideration. Lastly, generalizations of this study's results should be limited secondary to the small size of the sample.

Similar to a study performed by Tredinnick and Duncan, Pearson's Correlation statistics were run for this study. Corresponding variables between the two studies include: healthy male subjects, a Kin-Com dynamometer for testing sessions, and the dynamometer testing speed of 60°/s with concentric isokinetic contractions. The only significant difference between the studies is that Tredinnick and Duncan compared data collected on the same day of the week and the same time of day. Conversely, this study made an effort to vary the testing days between AM and PM sessions. With this difference aside, the studies are very similar. With the same time of day sessions, Tredinnick and Duncan found a correlation of .89, while this study, with varied times of day, found a correlation of .90.

When using isokinetic dynamometry to test a patient's strength through peak torque produced by a joint, the clinician needs to use equipment and procedures that are
sure to provide reliable results. The protocol used in this study is recommended to minimize external variables such as stabilization issues, knee alignment, warm-up, and machine parameters. Likewise, the results of this study suggest that for accurate analysis of patient recovery, muscle testing with a Kin-Com dynamometer does not have to be performed at similar times to previous tests.

For future studies examining these issues, suggestions include: using different testing speeds, including a larger sample size to include both genders and differing age groups, using different contraction types (eccentric isokinetic contractions), and testing other joints of the body.
In assessing quadriceps muscle peak torque production at different times of the day, this study found no significant difference in the torque produced at the differing times of the day. In AM versus PM testing sessions, the difference between mean peak torque values were 1.5ft-lb and the correlation coefficient was .90.

The purpose of this study was to help determine the relationship between isokinetic testing and time of day by comparing maximal quadriceps production in early morning hours to maximal quadriceps torque production in afternoon hours. The clinical implications of the study are that therapists do not need to perform isokinetic strength tests and re-tests at similar times of the day to achieve reliable results. Therefore, if following a testing protocol that limits external variables, the clinician will be able to collect objective information for the patient, physician, physical therapist, and third party payers independent of the time of day of the test.
APPENDIX A

UNIVERSITY OF NORTH DAKOTA HUMAN SUBJECTS REVIEW FORM FOR NEW PROJECTS OR PROCEDURAL REVISIONS TO APPROVED PROJECTS INVOLVING HUMAN SUBJECTS
X_EXPEDITED REVIEW REQUESTED UNDER ITEM 3 (NUMBER[S]) OF HHS REGULATIONS
___EXEMPT REVIEW REQUESTED UNDER ITEM ___ (NUMBER[S]) OF HHS REGULATIONS

UNIVERSITY OF NORTH DAKOTA HUMAN SUBJECTS REVIEW FORM
FOR NEW PROJECTS OR PROCEDURAL REVISIONS TO APPROVED
PROJECTS INVOLVING HUMAN SUBJECTS

PRINCIPAL
INVESTIGATOR: Shawn Doctor, Shawn McCoul, Michael Rexin, Denise Willardsen

TELEPHONE: (701)-777-9485

ADDRESS TO WHICH NOTICE OF APPROVAL SHOULD BE SENT: 3904 University Ave, #16,
Grand Forks, ND 58201

PROPOSEDSCHOOL/COLLEGE: University of North Dakota DEPARTMENT: Physical Therapy

PROJECT DATES: 3/1/98-12/18/98 PROJECT TITLE: A Comparison of the Maximal Torque Production of
the Quadriceps Muscle During Morning and Afternoon Strength Assessment.

FUNDING AGENCIES (IF APPLICABLE):

TYPE OF PROJECT (Check ALL that apply):

_X_ NEW PROJECT ___ CONTINUATION ___ RENEWAL ___ THESIS RESEARCH ___ RESEARCH PROJECT

___ CHANGE IN PROCEDURE FOR A PREVIOUSLY APPROVED PROJECT

DISSERTATION/THESIS ADVISER, OR STUDENT ADVISER: Mark Romanick

PROPOSED PROJECT: ___ DRUGS (IND) ___ USE OF DRUG ___ COOPERATING INSTITUTION

IF ANY OF YOUR SUBJECTS FALL IN ANY OF THE FOLLOWING CLASSIFICATIONS, PLEASE INDICATE THE
CLASSIFICATION(S):

___ MINORS (<18 YEARS) ___ PREGNANT WOMEN ___ MENTALLY DISABLED ___ FETUSES ___ MENTALLY RETARDED

___ PRISONERS ___ ABORTUSES ___ UND STUDENTS (>18 YEARS)

IF YOUR PROJECT INVOLVES ANY HUMAN TISSUE, BODY FLUIDS, PATHOLOGICAL SPECIMENS, DONATED
ORGANS, FETAL MATERIAL, OR PLACENTAL MATERIALS, CHECK HERE ___

IF YOUR PROJECT HAS BEEN/WILL BE SUBMITTED TO ANOTHER INSTITUTIONAL REVIEW BOARD(S), PLEASE
LIST NAME OF BOARD(S):

Status: ___ Submitted; Date _____________ ___ Approved; Date _____________ ___ Pending

1. ABSTRACT: (LIMIT TO 200 WORDS OR LESS AND INCLUDE JUSTIFICATION OR NECESSITY FOR USING
HUMAN SUBJECTS.)

The purpose of this study is to compare maximal quadriceps torque production in morning hours to maximal
quadriceps torque production in afternoon hours.

Twenty-five to fifty male subjects will take part in this study. A maximum torque will be assessed with a Kin-Com
isokinetic machine to compare the amount of quadriceps torque produced in early morning hours as compared to
afternoon hours. Each subject will be randomly placed in one of two test groups. The first group will be initially
tested in the morning. The second group will be initially tested in the afternoon. The groups will be re-tested in the
opposing time slot after at least three days have passed. A comparison will then be made between quadriceps
torque production in the morning and afternoon.

The significance of this study is to determine if the time of day affects maximal torque production of the quadriceps
muscle. The results may be applied to clinical objective testing procedures and may help with development of the
most efficient strengthening schedules.
PLEASE NOTE: Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate attach sections from your proposal (if seeking outside funding).

2. PROTOCOL: (Describe procedures to which humans will be subjected. Use additional pages if necessary.)

Subjects: Twenty-five to fifty male subjects between the ages of 19 and 45 will participate in this study. They will be randomly assigned into a morning (no longer than 1.5 hours after awakening from a 6 hour or longer sleep) training group and an afternoon (must be awake for longer than 8 hours but no more than 16 hours) training group. All subjects will complete a consent form in accordance with the University of North Dakota Human Subjects Review Committee. Exclusion criteria will consist of the following: 1) subjects who have had a history of neurological disorders or previous leg/knee trauma within the last year or have current knee dysfunction, 2) subjects who report any muscle fatigue or weakness due to activity prior to the testing time.

Instrumentation: The equipment used to perform the testing will consist of a Kin Com AP (Chattanooga Corp., Chattanooga, TN). The Kin Com AP is a commonly used exercise machine which is capable of measuring muscle strength through peak torque values. The warm up will be performed on a stationary bicycle provided by the Physical Therapy department.

Procedures: Before the testing begins, all of the subjects will experience a trial-run of quadriceps torque measure to familiarize the subject with the nature of the testing procedure. At this time, the parameters of the Kin-Com machine will be set and recorded for each individual.

On the first day of testing, the maximum torque production of each subject’s right quadriceps muscle will be assessed to determine the strength level of each subject. The subject will begin by performing a two minute warm-up on a stationary bicycle. A preliminary warm-up set will be performed to re-familiarize the subject with the testing procedure. The subject will then complete a concentric knee extension (type of exercise in which the muscle shortens while the force is being exerted) test consisting of 6 repetitions at sixty degrees per second. The results of this test are recorded by a dynamometer and stored in the computer’s data base.

The subjects will be re-tested at the opposite time of their initial test following the same procedure as previously stated.
3. **BENEFITS:** (Describe the benefits to the individual or society.)

The benefits of this study will determine if maximal torque production of the quadriceps muscle is affected by the time of testing. This may broadly be applied to strength assessment of other muscles. If significant variations do exist between time of day and torque production, then clinicians must take into account time of day when testing and re-testing. From this data, further studies may be conducted to compare training times for optimal strength gains and athletic performance.

4. **RISKS:** (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psycho-logical, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to insure the confidentiality of data obtained, including plans for final disposition or destruction, debriefing procedures, etc.)

Although any exercise poses certain minimal risks, our study is designed to further minimize these risks. Some precautionary measures include: 1) Instructions will be provided to the subject to terminate the procedure if at any time he is uncomfortable or experiences pain and will be provided a stop button ("kill switch") which will immediately stop the procedure. 2) A two minute warm up on a stationary bicycle will be performed to adequately prepare the muscles for activity. 3) A warm-up test set will be performed to further familiarize and prepare the subject for the test. 4) The Kin-Com machine is also equipped with electronic and mechanical stops to prevent movements outside of each subject's physiological range of motion (ROM). Although we have taken every measure to prevent risk, the remote possibility remains for a musculoskeletal injury, such as muscle strain.
5. **CONSENT FORM:** A copy of the **CONSENT FORM** to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no **CONSENT FORM** is to be used, document the procedures to be used to assure that infringement upon the subject’s rights will not occur.

Describe where signed consent forms will be kept and for what period of time.

The enclosed consent form will be signed by each subject involved in this study. The forms will be kept in the University of North Dakota Physical Therapy department in locked filing cabinets. The only access to these cabinets will be to the examiners, the student advisor, Mark Romanick, and the head of the Physical Therapy department, Thomas Mohr, P.T. PH.D. The forms will be kept on file for a period of 3 years after the last day of experimental study involving the subjects. The data collected and stored on the Kin Com AP computer is kept behind locked doors in the Physical Therapy department.

6. For **FULL IRB REVIEW** forward a signed original and thirteen (13) copies of this completed form, and where applicable, thirteen (13) copies of the proposed consent form, questionnaires, etc. and any supporting documentation to:

   Office of Research & Program Development  
   University of North Dakota  
   Grand Forks, North Dakota 58202-7134

On campus, mail to: Office of Research & Program Development, Box 7134, or drop it off at Room 105 Twamley Hall.

For **EXEMPT** or **EXPEDITED REVIEW** forward a signed original and a copy of the consent form, questionnaires, etc. and any supporting documentation to one of the addresses above.

The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of Human Subjects performed by personnel 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 procedures governing the use of human subjects.

**SIGNATURES:**

**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 RECORD

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

A Comparison of the Maximal Torque Production of the Quadriceps Muscle During Morning and Afternoon Strength Assessment.

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

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

STATEMENT OF INFORMATION AND CONSENT
INFORMATION AND CONSENT FORM

TITLE: A Study on the Maximal Torque Production of the Quadriceps Muscle During Morning and Afternoon Strength Assessment

You are being invited to participate in a study conducted by Shawn Docktor, Shawn McCoul, Michael Rexin, and Denise Willardsen, physical therapy students and Mark Romanick, a physical therapy instructor at the University of North Dakota. The purpose of this study is to determine if the time of day affects maximal torque production of the quadriceps muscle, by comparing maximal torque production in the morning and in the afternoon.

You will be asked to exercise on the Kin Com AP machine on 3 occasions – one familiarization session, one morning session, and one afternoon session. The Kin Com AP is a commonly used exercise machine which is capable of measuring muscle strength through peak torque values. At these sessions, you will be asked to perform a 2 minute warm-up on a stationary bicycle before being tested. You will then be required to perform maximum effort knee extensions while a computer records the amount of torque produced.

The study will take approximately 15-30 minutes of your time per session. You will be asked to report to the Physical Therapy Department at the University of North Dakota at an assigned time. You will then be asked to change into gym shorts for the experiment. We will first record your age, height and weight. During the experiment, we will be recording the amount of maximal torque production for your quadriceps muscles.

Although the process of physical performance testing always involves some degree of risk, the investigators in this study feel that the risk of injury or discomfort is minimal. In order for us to record the muscle torque, we will require you to exert your maximal force during an isokinetic knee extension movement on three separate days. One session will be for training purposes and the other two sessions will be for data collection. The data collection sessions will require you to participate in one morning and one afternoon session. For these sessions, you will be asked to perform a two minute warm up on a stationary bicycle, followed by the testing procedure consisting of 6 maximal efforts of knee extension. The amount of exercise you will be asked to perform will be minimal.

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. The data will be
identified by a number known only by the investigator. The investigator or participant may stop the experiment at any time if the participant is experiencing discomfort, pain, fatigue, or any other symptoms that may be detrimental to his health. Your decision whether or not to participate will not prejudice your future relationship with the Physical Therapy Department or the University of North Dakota. If you decide to participate, you are free to discontinue participation at any time without prejudice.

The investigator involved is 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 Mark Romanick at (701)-777-2831. A copy of this consent form is available to all participants in the study.

In the event that this research activity (which will be conducted at the University of North Dakota in the Physical Therapy Department) results in a physical injury, medical treatment will be available, including first aid, emergency treatment and follow up care as it is to member of the general public in similar circumstances. Payment for any such treatment must be provided by you and your third party payment, if any.

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. MY SIGNATURE INDICATES THAT, HAVING READ THE ABOVE INFORMATION, I HAVE DECIDED TO PARTICIPATE IN THE RESEARCH PROJECT.

I have read all of the above and willingly agree to participate in this study explained to me by Shawn Dockter, Shawn McCoul, Michael Rexin, Denise Willardsen or Mark Romanick.

Participant's Signature       Date

Witness (not the scientist)       Date
REFERENCES


