A Comparison of Isokinetic Ankle Plantarflexion Force Generation in Knee Flexed and Knee Extended Positions

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A COMPARISON OF ISOKINETIC ANKLE PLANTARFLEXION
FORCE GENERATION IN KNEE FLEXED AND
KNEE EXTENDED POSITIONS

by

Reyn Hata
Delbert Peralta
Daniel Uyeunten
Bachelor of Science in Physical Therapy
University of North Dakota, 2003

A Scholarly Project
Submitted to the Graduate Faculty
of the
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 Reyn Hata, Delbert Peralta, and Daniel Uyeunten 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 Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

(Graduate School Advisor)

(Chairperson, Physical Therapy)
PERMISSION

Title A Comparison of Isokinetic Ankle Plantarflexion Force Generation in Knee Flexed and Knee Extended Positions

Department Physical Therapy

Degree Master of Physical Therapy

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Signature

Date December 19, 2003.
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Results of t-test for Paired Samples Comparing the Means of the K170 Versus the K155 Test Positions
ACKNOWLEDGMENTS

We would like to thank Mark Romanick, our advisor, for being extremely patient and helpful throughout this process. We encountered many obstacles during our project, yet we were able to persevere through it all. Your guidance will always be deeply appreciated. A special thanks also to Renee Mabey for her instrumental assistance in the statistical analysis of our study. Without your help, our study would have no meaning.

We also would like to extend a warm thank you to each UND Physical Therapy faculty and staff member. We deeply appreciate your knowledge, guidance, and encouragement throughout the three years of physical therapy school. You have passed on your knowledge and molded us into the physical therapists we are today. It is an honor to represent UND physical therapy and carry on the tradition.

We would also like to give a huge thanks to the participants in our study. Your volunteered time was well appreciated. Maybe we can try and do the testing a third time?

I would like to say thank you, Mom, for supporting me through all the years of school. It has been a long road and you have been by my side, helping me through it all. Words cannot express how much you really mean to me. Also thank you to my family and friends for the prayers and support. – Del Peralta
First and foremost, I would like to thank my parents for the love, support, and guidance. Without you, I would not have had the opportunity to accomplish my goal of becoming a physical therapist. Also, I would like to express my thanks to my grandparents for always being there for me. – Reyn Hata

I would like to thank my parents and grandparents for always providing me with the opportunities and the tools to be successful. Without your prevailing support, I would not have been able to accomplish all that I have. I hope I have made you all proud and I plan to continue to do so in my new career as a physical therapist. – Daniel Uyeunten
ABSTRACT

The triceps surae, composed of the soleus and the two heads of the gastrocnemius, is a very active muscle in all activities involving the lower extremities. This study compared the maximal force generated by these ankle plantarflexors in a knee extended and knee flexed position to determine relative contribution to plantarflexion force in varying positions. Eighteen male and female college students were tested for maximal concentric plantarflexor force generation isokinetically at 30/sec in both positions. Means of maximal force in knee extension and flexion, 242.56 lbs. and 227.22 lbs., respectively, were found to be statistically significantly different. The mean of the ratio of plantarflexion force in knee flexed to knee extended positions was 93.68%. These findings suggest that the soleus muscle is a significant contributor to plantarflexion force generation in both knee extended and knee flexed postures.
CHAPTER I
INTRODUCTION

The triceps surae muscle complex serves as one of the most frequently used muscle groups in the human body being involved in virtually every activity.\(^8\) Without a properly functioning triceps surae complex, the individual expends a significantly increased amount of energy during ambulation.\(^10\) The two muscles that make up the triceps surae are the gastrocnemius and the soleus. Plantarflexor force at the ankle is mainly exerted by this muscle complex. The gastrocnemius originates at the femoral condyles and crosses the knee joint, while the soleus originates below the knee at the posterior surface of the tibia and fibular head. Both muscles insert into the Achilles’ tendon which then inserts into the calcaneous.\(^12\)

Problem Statement

The activity of the triceps surae is affected by the lever arm at the ankle and varying knee positions. Other studies that measured torque or force generated by the triceps surae were most often tested using an isometric maximal voluntary contraction. The literature does not report how varying knee positions affect the amount of force generated by the triceps surae using an isokinetic concentric force.
2

Purpose

The purpose of this study is to determine the ratio of force that the soleus muscle generates by itself in relation to the triceps surae muscle group at varying knee positions during a concentric isokinetic plantarflexion motion.

Significance

The triceps surae is used in gait, stair ambulation, and powerfully in many athletic maneuvers. Deficits in the strength of the triceps surae will contribute to reduced function of these activities. Understanding the percentage of the amount of force each muscle that make up the triceps surae contributes will aid in the ability for therapists and athletic trainers to strengthen the muscle complex more efficiently for functional recovery.

Research Questions

1. Is there a significant difference in the amount of force generated by the triceps surae in a straight knee position compared to a bent knee position?
2. What is the percentage of force that soleus generates alone compared to the triceps surae muscle complex?

Hypothesis

Null 1: There is no significant difference in the amount of force that the triceps surae produces in a straight knee position compared to a bent knee position during an isokinetic concentric plantarflexion motion.
CHAPTER II
LITERATURE REVIEW

Previous studies have found that changes in the knee angle will change the gastrocnemius' length, thus affecting the ability of that muscle to contract because of its origin. The gastrocnemius originates at the femoral condyles of the femur, crosses the knee joint, and inserts into the calcaneus. When the knee is flexed, the length of the gastrocnemius is shortened and when the knee is extended, the gastrocnemius is lengthened, assuming that the ankle is held at a constant position. The muscle length of the gastrocnemius is also affected by the position of the ankle. When the ankle is dorsiflexed, the gastrocnemius is placed on stretch with the knee at a constant position. When the ankle is plantarflexed, the gastrocnemius is shortened. The shortening and lengthening of a muscle will affect the ability of the muscle to contract and generate force with greater force generation as muscle length increases.

The soleus, on the other hand, is not affected by the position of the knee as it originates below the knee along the posterior aspect of the tibia and fibula. One study stated that the soleus is as much as 95% the size of the gastrocnemius, suggesting that it is physically able to generate a comparable amount of force at the ankle. Studies have shown cross sections of 23 cm$^2$ and 20 cm$^2$ for the gastrocnemius and the soleus, respectively. The soleus is
comprised of mostly type I slow twitch muscle fibers and is consistently active in standing balance, walking, and all other bipedal activities. Both muscles may be at an anatomical position to generate plantarflexion force. Extensive EMG and histochemical studies have shown that the soleus muscle is primarily responsible for producing the plantarflexion tension on the calcaneus.\textsuperscript{12,19}

In addition to flexion of the knee and plantarflexion of the ankle, the triceps surae may also extend the knee when it is placed in a closed chain position with the foot fixed. Due to the gastrocnemius' origin, it can be placed on stretch by the quadriceps and facilitated to generate a more forceful contraction. With the foot fixed to the ground and the quadriceps contracting to extend a bent knee, the triceps surae can produce a plantarflexion force and pull the tibia back at the ankle aiding in the extension of the flexed knee.\textsuperscript{19,20}

Miyamoto et al\textsuperscript{1} determined through isometric contractions of the triceps surae at varying knee angles that a knee angle of 60° yielded 50% of the torque generated at a knee angle of 180°. They also determined that plantarflexor torque increased with an increase in the knee angle with the ankle held at a constant 90°. Murray et al\textsuperscript{9} determined that additional torque from plantaris, peroneus longus, flexor hallucis longus, and flexor digitorum muscles contributed 20% to 30% of the total amount of plantarflexion force. Loscher et al\textsuperscript{5} determined that the gastrocnemius contributes 40% of the total plantarflexion force at the ankle.

Changes in the lever arm length at the ankle have also shown a change in the amount of torque and force that the triceps surae can generate.\textsuperscript{2,3,8} Nagano
et al\textsuperscript{3} determined that greater muscle force was developed with a longer moment arm. A greater amount of plantarflexion force was developed when the speed of the motion was small (30° to 90°/sec) compared to a smaller amount of plantarflexion force developed when the magnitude of the speed of motion was large (120° to 210°/sec). This is consistent with properties of muscle physiology which state greater force can be generated with slower speeds of muscle contraction.\textsuperscript{22}

Leardini et al\textsuperscript{8} determined that the gastrocnemius has a maximum lever arm length of 5.4 cm at 7° dorsiflexion, with a total lever arm length excursion of 1.0 cm. The soleus has a maximum lever arm length of 5.3 cm at 0° flexion, with a total lever arm length excursion of 0.7 cm. The gastrocsoleus muscle complex will be able to generate its greatest amount of force around these angles because of the leverage it gains.

However, Nourbakhsh et al\textsuperscript{2} determined that changes in the moment arm do not have a significant effect on the gastrocnemius in relation to a change in knee angle when generating plantarflexion torque at 10% to 30% of maximal voluntary contraction (MVC). They also determined that varying knee angles produced differences in the amount of motor unit firing even between the two heads of the gastrocnemius.

A study by Hwang et al\textsuperscript{7} found that slower concentric plantarflexion and dorsiflexion speeds of 30°/sec or 60°/sec induced an increase in knee muscle recruitment. They determined that synergistic coactivation of the knee muscles is dependent on the contraction velocity of the ankle joint. Slower speeds
increased the captivation of the knee muscles on the ipsilateral side. They also determined that the synergistic patterns are different between isokinetic plantarflexion and dorsiflexion. Plantarflexion stimulated a response of the knee flexors and dorsiflexion enlisted a response of the knee extensors.

Research by Nadau et al\textsuperscript{13} involved relationships between torque, velocity, and power output. The authors found isokinetic testing to be more relevant than isotonic testing when measuring muscular strength during movement at selected constant velocities. Using a Biodex dynamometer, isokinetic testing utilized a range of $-12^\circ$ dorsiflexion and $+47^\circ$ plantarflexion. But, mean results demonstrated that subjects could only achieve $-10^\circ$ and $+30^\circ$ plantarflexion. Although a 2-second maximal preloading action was used prior to movement, isokinetic evaluation was performed at a speed of $30^\circ$/sec as the speed was found to produce the highest values of torque when compared with isotonic modes of testing.

According to Tamaki et al\textsuperscript{23} the triceps surae musculature consists of the medial gastrocnemius (MG), lateral gastrocnemius (LG), and soleus (Sol) which function as synergists in movements; however, the orientation of their fibers and structural properties differ. The soleus is a monoarticular muscle that has its origin at the head of the fibula and a predominance of type I muscle fibers, whereas the medial and lateral gastrocnemius are biarticular muscles that originate from the condyles of the femur and have proportions of both types I and II fibers. Recruitment of each muscle can vary depending on ankle angle and movement. For example, the MG and Sol are mainly recruited in plantar flexion
(PF), but the LG has no activity at ankle angles between 90° and 120° at 10% maximal voluntary PF contractions. Also, the LG, MG, and Sol perform reciprocal EMG activity corresponding to the velocity and style of different exercises, therefore demonstrating different recruitment of the ankle extensors, facilitating the LG, MG, and depression of the slow ankle extensors of the soleus.

According to Levy\textsuperscript{24}, the soleus muscle produces greater reflex contraction than gastrocnemius during ankle jerk suggesting there is a greater density of muscle spindles in the soleus muscle. Herman and Bragin\textsuperscript{25} also found differences with gastrocnemius and soleus musculature. They found that the gastrocnemius is more sensitive to conditions of length, strength, and rate of contraction, while soleus plays a more constant role and is more active in ankle dorsiflexion and minimal contractions under low force. Campbell et al\textsuperscript{26} used fine wire electrodes and placed them on the gastrocnemius and soleus. What they found was that the medial part of the soleus was more of a strong mover of the foot on the leg and a stabilizer of the leg on the foot. However, the lateral part of the soleus gave little power to moving the ankle and is largely a stabilizer. The gastrocnemius are usually quiet until motion is required at the ankle, thus acting in plantar flexion. Campbell et al\textsuperscript{26} found the medial part of the soleus to be the main dynamic and static plantarflexor.

Based on the aforementioned studies, the researchers of this study hypothesize that plantarflexion force will be greater in the K170 knee straight position verses the K155 knee bent position and that the soleus is a substantial
contributor of plantarflexion of the triceps surae muscle complex because it is comparable in size to the gastrocnemius and is independent in force generation irrespective of knee position.
CHAPTER III

METHODS

Subjects

Twenty (20) subjects (12 female and 8 male college students) with no history of neuromuscular disorders were used in this study. All the subjects were educated about the procedures and signed consent forms were obtained.

Force Measurements

Testing of the subjects was done on a dynamometer model KinCom AP (Rehab World, 6431 Pythian Road, Harrison Tennessee, 37341-3902). The subjects were allowed one day prior to the actual test date to familiarize themselves with the experimental protocol and to ask questions about the actual testing date. The subjects were able to sit on the KinCom seat and run through a mock trial as a learning opportunity prior to the test day. The subjects were instructed to wear comfortable clothing and to wear athletic shoes. On the actual test day, the subjects entered the facility one at a time and were allowed to stretch their gastrocsoleus until they felt they were ready. The subjects were then positioned on the KinCom seat and were randomly assigned to one of the two test positions. One position (K170) placed the knee at a 170° knee extension angle with the knee just off the edge of the seat with the thigh restrained with a pad to eliminated hip and knee movement. This position was
chosen to enable the subjects to feel comfortable and relieve hamstring
tightness but place the gastrocnemius in a nearly fully lengthened position to
contract and have a significant effect in plantarflexion at the ankle joint. The
other knee position (K155) had the knee at a 155° knee extension angle which
placed the gastrocnemius in a shortened position to reduce contribution to
plantarflexion at the ankle joint. See Figure 1. The foot was then placed in the
apparatus and adjusted to place the ball of the foot at the end of the plate. The
foot was then restrained with Velcro straps. The foot was moved to a position of
35° plantarflexion and set as one stop angle then placed in a position of 10°
dorsiflexion and set as the other stop angle for a total range of motion of 45°.

Testing involved isokinetic contraction of the gastrocsoleus in a concentric
plantarflexion motion at a speed of 30°/sec. This study used the slower
isokinetic speed of 30°/sec to allow for greater force development by the
subjects for a near maximal force generation with movement. The subjects were
allowed to perform as many pretest repetitions as they wished until they felt
ready. This was allowed as a warm up and to prevent injury to the
gastrocsoleus. The subjects then performed 6 maximal voluntary contractions in
both positions and the highest force in pounds generated in each position was
recorded and used in the statistical analysis. The KinCom AP records actual
force that the body part exerts, whereas many other studies use torque which is
a function of force (torque = force x the moment arm length). At least 2 minutes
rest was given between the trials to avoid fatigue while the experimenters
repositioned the subject.
Figure 1. Photo displaying K155 (top) and K170 (bottom) test positions.
Statistical Analysis

Statistical analysis was run using SPSS Data Editor for Windows Version 11.5.0 (6 Sept 2002). Paired t tests with an alpha level of 0.05 were used to find a level of significance between the average force generated by the K170 and K155 knee positions. Individual subjects were also compared to themselves and displayed graphically. The SPSS Data Editor was also used to find the difference between the soleus versus the entire triceps surae muscle complex in the form of a percentage. These values were then displayed graphically using Microsoft PowerPoint 2002 (10.4205.4219) SP-2.
CHAPTER IV

RESULTS

The results of the study confirmed the hypothesis and are significant at an alpha level of 0.05. These results were able to achieve an alpha level of 0.027. The subjects scored higher in the K170 position when compared to the K155 position. The mean score of the K170 position for the group was 242.56 lbs. Compared to 227.22 for the K155 position which is a mean difference of 15.34 lbs. See Table 1 and Figure 2. In an average percentage, the K155 was 93.68% of the K170 position. Individual percentages are displayed in Figure 3. Some subjects’ percentages actually demonstrated greater force with the knee flexed than extended. The low score for the K170 position was 138 lbs. with a high score of 333 lbs. The low score for the K155 position was 135 lbs. with a high score of 306 lbs. Scores of the individual subjects comparing the different positions can be seen in Figure 4.
Table 1. Results of t test for Paired Samples Comparing the Means of the K170 Versus the K155 Test Positions.

<table>
<thead>
<tr>
<th>Position</th>
<th>n</th>
<th>( \chi ) (in lbs.)</th>
<th>SD</th>
<th>t</th>
<th>df</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>K170</td>
<td>18</td>
<td>242.56</td>
<td>59.01</td>
<td>2.42</td>
<td>17</td>
<td>0.027</td>
</tr>
<tr>
<td>K155</td>
<td>18</td>
<td>227.22</td>
<td>47.72</td>
<td></td>
<td></td>
<td></td>
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</table>
Figure 2. A comparison of force K170 versus K155 knee position

Figure 3. Percentages of subjects' soleus versus triceps surae force generation
Figure 4. Individual subject force generation comparison of K170 versus K155 test positions
CHAPTER V
DISCUSSION

The research questions focused on whether there was a significant difference in isokinetic plantarflexion with the knee extended at 170° versus a flexed position at 155° and if the soleus is a greater contributor to plantarflexion when compared to the gastrocnemius. If there is a significant difference between the two, what is the percentage that the two muscles contribute to ankle plantarflexion?

Force Generated

As the statistical analysis confirmed, there is a significantly greater amount of force generated with the knee at 170° compared to 155°. This is probably due to the gastrocnemius’ ability to generate more force when it is placed in a lengthened position and contribute to the action of the soleus. The soleus was still able to generate a comparable amount of force in the K155 position, possible due to its relatively large size when compared to the entire triceps surae muscle complex.

Due to the limitations of the KinCom Dynamometer, it may not have been possible to completely isolate the soleus from the gastrocnemius, which would explain the greater force generation in the K155 position in 5 of the subjects. Although there were 5 subjects who generated a greater force in the K155
position, they did not have a significant statistical influence on the outcome of the study. Possible explanations for the relatively large contribution of force by the soleus muscle include:

1) The fact that the positions tested were non-functional. A more functional test might produce different results.\textsuperscript{27}

2) The gastrocnemius is a biarticular muscle, a characteristic that might lend its function to more of a proprioceptive nature than force generation. Signorile et al\textsuperscript{28} found that the individual heads of the gastrocnemius responded differently in EMG activity to knee positioning. This could support an overall functional difference between soleus and gastrocnemius in force generation independent of knee position.

3) The size of the soleus is comparable to that of the gastrocnemius. Tension development in muscle is a function of cross-sectional area, so the similar sizes would tend to demonstrate similar force generation if isolation of muscles is achieved. Muscles with larger cross-sections produce more tension than muscles with smaller cross-sections.\textsuperscript{29}

Limitations

One of the limitations of this study was the small sample size (n=18). There were 5 subjects who generated a greater force in the K155 position and, although this group represents 28% of the subjects, their results did not affect the normal distribution.

The ability to generate greater force with the knee in a more flexed position may be due to the positional limitations of the KinCom dynamometer.
and the amount of flexion in which the knee could be placed while maintaining the same position of the upper body and hips as with the K170 position. If allowed by the dynamometer, the knee could have been placed in a position of greater flexion to further shorten the gastrocnemius and isolate the soleus better.¹,⁵

Subjects who generated greater force with the knee in greater flexion commented that they “felt more comfortable” in the flexed position. The subjects may have felt more comfortable at K155 because they were placed in a position where the ankle was in a greater amount of weight bearing. This may be explained by the study done by Carlsson et al.¹⁷ describing greater isometric torque generation in a standing, closed chain position when compared to a prone and sitting open chain position.

Conclusion

Results of this study addressed the importance of the soleus as an important member of the triceps surae muscle complex and as a significant contributor to ankle plantarflexion. According to the results, the K155 position, which placed the gastrocnemius in a disadvantaged position and therefore better isolated the soleus, generated 93.8% of the amount of force that the K170 position generated. This leads the researchers to conclude that the soleus is possibly a greater contributor of plantarflexion force than previously believed. These results suggest that both major muscles of the triceps surae deserve attention in training programs designed to enhance plantarflexion and eccentric
dorsiflexion of the ankle. Future studies designed to better understand the role and contribution these muscles make in those actions are warranted.
APPENDIX
University of North Dakota Human Subjects Review Form

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

Please provide the information requested below:

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School/College: SCHOOL OF MEDICINE & HEALTH SCIENCES
Department: PHYSICAL THERAPY
Project Title: A COMPARISON OF BIOMECHANIC ANKLE PLANTARFUSION FORCE GENERATION IN KNEE FLEARED AND KNEE EXTENDED POSITIONS

Proposed Project Dates: Beginning Date: May 1, 2003 Completion Date: December 31, 2003
(Including data analysis)

Funding agencies supporting 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)

YES or NO

If your project has been or will be submitted to another Institutional Review Board(s), please list those boards below along with the status of each proposal.

Date submitted: Date submitted: Status: __ Approved ___ Pending

Type of Project: Check “Yes” or “No” for each of the following.

YES or NO New Project YES or NO Dissertation/Thesis
YES or NO Continuation/Renewal YES or NO Student Research Project
YES or NO Is this a Protocol Change for previously approved project? If yes, submit a signed copy of this form with the changes bolded or highlighted.
YES or NO Does your project include Genetic Research? If yes, refer to Chapter 3 of the Researcher Handbook for additional guidelines regarding your topic.
YES or NO Does your project include Internet Research? If yes, refer to Chapter 3 of the Researcher Handbook for additional guidelines regarding your topic.
YES or NO Will subjects or data be provided by Altru Health Systems? If yes, submit two copies of the proposal. A copy of the proposal will be provided to Altru.
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?

___ YES or X NO

If yes, list all institutions:

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

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

- Minors (< 18 years)
- Prisoners
- Persons with impaired ability to understand their involvement and/or consequences of participation in this research
- Pregnant Women/Fetuses
- Other

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

This study will involve: Check all that apply.

- Deception
- Radiation
- New Drugs (IND)
- Non-approved Use of Drug(s)
- Recombinant DNA
- Stem Cells
- Discarded Tissue
- Fetal Tissue
- Human Blood or Fluids
- Other

None of the above will be involved in this study

I. Project Overview

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

II. Protocol Description

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

1. Subject Selection.

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

   b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the “Subject Classification” section above.

   c) Describe your exclusionary criteria and provide a rationale for excluding subject categories.

   d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects.

   e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method.

2. Description of Methodology.

   a) Describe the procedures used to obtain informed consent.

   b) Describe where the research will be conducted.

   c) Indicate who will carry out the research procedures.

   d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them.

   e) Describe audio/visual procedures and proper disposal of tapes.

   f) Describe the qualifications of the individuals conducting all procedures used in the study.
i) A description of how confidentiality of subjects and data will be maintained. Indicate that the data and consent forms will be stored separately for at least three years following the completion of the study. Indicate where, in general, the data and consent documents will be stored and who 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 name of Principal Investigator) at (insert phone number of Principal Investigator) or (insert name of Adviser) 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.

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

m) Regarding Participation in the study:
   1) An indication that participation is voluntary and that no penalties or loss of benefits will result from refusal to participate.
   2) An indication that the subject may discontinue participation at any time without penalty, with an explanation of how they can discontinue participation.
   3) An explanation of circumstances which may result in the termination of a subject’s participation in the study.
   4) A description of any anticipated costs to the subject.
   5) A statement indicating whether the subject will be informed of the findings of the study.
   6) A statement indicating that the subject will receive a copy of the consent form.

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

Signatures: 
(Principal Investigator) 
(Adviser) 
Date: 

Requirements for submitting proposals:
Additional information can be found at the ORPD website at www.und.nodak.edu/dept/orpd

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

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

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

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

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

Revised 4/14/03
REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW
University of North Dakota Institutional Review Board

Date: 6/13/2003  Project Number: IRB-200306-276

Principal Investigator: Uyenten, Daniel; Peralta, Delbert, Hata, Reyn

Department: Physical Therapy

Project Title: A Comparison of Isokinetic Ankle Plantarflexion Force Generation in Knee Flexed and Knee Extended Positions

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on June 17, 2003 and the following action was taken:

☑ Project approved. Expedited Review Category No.

☐ Next scheduled review must be before June 16, 2004

☑ Copies of the attached consent form with the IRB approval stamp dated June 17, 2003 must be used in obtaining consent for this study.

☐ Project approved. Exempt Review Category No.

☐ This approval is valid until ________________ as long as approved procedures are followed.

☐ No periodic review scheduled unless so stated in the Remarks Section.

☐ Copies of the attached consent form with the IRB approval stamp dated ________________ must be used in obtaining consent for this study.

☐ Minor modifications required. The required corrections/additions must be submitted to ORPD for review and approval. This study may NOT be started UNTIL final IRB approval has been received.

(See Remarks Section for further information.)

☐ Project approval deferred. This study may not be started until final IRB approval has been received.

(See Remarks Section for further information.)

REMARKS: Any adverse occurrences in the course of the research project must be reported immediately to the IRB Chairperson or ORPD.

Any changes in protocol or Consent Forms must receive IRB approval prior to being implemented. You must submit a memo with a copy of the Consent Form and a revised Human Subjects Review Form, with the appropriate signatures, to the Office of Research and Program Development for review and approval.

PLEASE NOTE: Requested revisions for student proposals MUST include adviser's signature. All revisions MUST be highlighted.

☑ Education Requirements Completed. (Project cannot be started until IRB education requirements are met.)

cc: Mark Romanick

Signature of Designated IRB Member  Date
UND's Institutional Review Board

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 310 Form may be required. Contact ORPD to obtain the required documents.
You have been invited to participate in a study being conducted by the University of North Dakota Physical Therapy Program, Daniel Uyeunten, Delbert Peralta, and Reyn Hata in collaboration with faculty member Dr. Mark Romanick PT, PhD. The purpose of this study is to determine the amount of plantarflexion (pointing the toes down by bending at the ankle) force that the gastrocnemius and the soleus muscles (large muscles of the calf) have at the ankle when working together and with just the soleus by itself. The machine that will measure the force at the ankle will be the KinCom dynamometer which is a reliable method of measuring such forces. All testing will be done at the University of North Dakota Physical Therapy Department.

Participants of this study must be in good health and have normal range of motion at the ankle. You will be asked a few questions about your general health and will undergo a quick assessment of your ankle’s flexion and extension range of motion. To participate, you must not be using any kind of assistive device such as a cane or walker, nor have any kind of lower body orthopedic or cardiopulmonary pathologies. You must be able to understand all directions given to you. You will be asked to wear tennis shoes and comfortable clothing on the date of your testing.

You will be able to see and familiarize yourself with the KinCom dynamometer and ask questions about the procedure prior to the actual testing date. On the testing date you will be allowed to stretch and warm up to your desire to prevent any strain or cramping. You will then be positioned in the KinCom in a manner that will use both muscles in your calf to plantarflex and you will be asked to push you foot down into the lever as hard as you can for 5 – 10 repetitions. You will then be positioned in a manner that will isolate your soleus muscle so that you are no longer using both muscles. You will be asked to push as hard into the lever as hard as you can again for 5 – 10 repetitions. Total testing time should not take more than 30 minutes. Participation is strictly voluntary.

There is a low risk for muscle strain, cramping, or soreness during or after the testing process as in any activity involving muscular force. Although unlikely, medical attention will be available to you if needed in the event of more serious injury. Payment for such treatments must be provided by you or a third party payer.

The study will benefit anyone who is interested in the strengthening of the calf muscles. This information will be used by physical therapists, athletic trainers and other health care professionals. Outcomes of this study will be available for review by contacting any of the investigators or by visiting the Harley E. French Library of the Health Sciences on the University of North Dakota Campus.

We will maintain full confidentiality of any information from this study. Only your weight, height, age and gender will be linked to the information provided from your testing. Your name or any other identifying information will not be used. All results from the study will be kept in a locked cabinet at the University of North Dakota and will only be available to the investigators/advisor participating in the study. These records will be kept for a minimum of three years after the completion of this study after which the records will be destroyed.

University of North Dakota
Institutional Review Board
Approved on 6-17-03
Effective on 6-16-04
You will be provided with a copy of this consent form. You are also free to contact the investigators Daniel Uyeunten (701) 777-9509, Reyn Hata (701) 777-8171, or Delbert Peralta (701) 777-9509 if you have any questions. The advisor Dr. Mark Romanick is also available for additional information at (701) 777-3668. You may also contact the Office of Research and Program Development at the University of North Dakota at (701) 777-4279.

I understand that my study records are confidential. However, representatives of the study sponsor, or the Institutional Review Board may need to inspect my study records. By signing this consent form I am allowing this inspection.

I HAVE READ ALL OF THE ABOVE AND ALL MY QUESTIONS HAVE BEEN ANSWERED. MY SIGNATURE BELOW INDICATES THAT I WILLINGLY AGREE TO PARTICIPATE IN THIS STUDY AS EXPLAINED TO ME BY DANIEL UYEUN TEN, DELBERT PERALTA, AND REYN HATA.

Participant’s signature       Date

Witness’s signature           Date

University of North Dakota
Institutional Review Board
Approved on 6-17-03
Expires on 6-16-04
REFERENCES


