2003

The Effects a Total Knee Arthroplasty Has on Static and Dynamic Balance

Connie Christensen
University of North Dakota

Nicole Riddle
University of North Dakota

Nicole Sukut
University of North Dakota

Cara Uyema
University of North Dakota

THE EFFECTS A TOTAL KNEE ARTHROPLASTY HAS ON STATIC AND DYNAMIC BALANCE

by

Connie Christensen, Niccole Riddle, Nicole Sukut, Cara Uyema
Bachelor of Science in Physical Therapy
University of North Dakota, 2002

A Scholarly Project

Submitted to the Graduate Faculty of the

Department of Physical Therapy

School of Medicine

University of North Dakota

in partial fulfillment of the requirements

for the degree of

Master of Physical Therapy

Grand Forks, North Dakota
May
2003

This Independent Study, submitted by Connie Christensen, Niccole Riddle, Nicole Sukut, and Cara Uyema 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.

(Faculty Advisor)

(Chairperson, Physical Therapy)

PERMISSION

Title The Effects a Total Knee Arthroplasty has on Static and Dynamic Balance

Department Physical Therapy

Degree Master of Physical Therapy

In presenting this Scholarly Project Report in partial fulfillment of the requirements for a graduate degree from the University of North Dakota, we agree that the Department of Physical Therapy shall make it freely available for inspection. We further agree that permission for extensive copying for scholarly purposes may be granted by the professor who supervised our work or, in his/her absence, by the Chairperson of the department. It is understood that any copying or publication or other use of this scholarly project or part thereof for financial gain shall not be allowed without our written permission. It is also understood that due recognition shall be given to us and the University of North Dakota in any scholarly use which may be made of any material in our Scholarly Project Report.

Signature Nicole Sukut

Signature Nicole Riddle

Signature Lara Lyscma

Signature Connie Christensen

Date December 18, 2002

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACKNOWLEDGEMENTS

We would like to thank Dr. Briggs, Linda Lohnes, Cliff LaFreinere, Renee Mabey, and Altru Health Systems for their contributions to our study. To our families, thank you for your support and encouragement during our times of frustration throughout these years. Thank you for believing in us and providing us with the basic foundation that has allowed us to become who we are today.

A special thank you to our advisor, Meridee Danks, for her patience, dedication, and hard work throughout this project. Also, for the many laughs and drafts she provided us with. Who knew a scholarly project could be so fun?

We would like to extend a thank you to the Physical Therapy Department at the University of North Dakota for providing us with this wonderful opportunity to write this scholarly project. We appreciate all the guidance and advice you have given us.

Finally, we would like to thank each other: Cara, Connie, Niccole, Nicole. It was a pleasure working with all of you! Thanks for the friendship, listening ears, and the shoulders to cry on through the difficult times we have encountered throughout the past three years. Thanks for the great times, as well...may we never lose touch!

ABSTRACT

In the United States today, the total knee arthroplasty (TKA) has become one of the most commonly performed surgeries of the lower extremity. A generous amount of information exists regarding joint proprioception after a joint replacement, however no studies have been done testing postural control after a TKA. With the increasing popularity of the TKA procedure, a need appears for research evaluating static stability and functional mobility of TKAs.

The purpose of this study was to determine the effects a TKA, 6 months postoperative or beyond, has on static and dynamic balance. The balance of 8 female volunteers and 4 male volunteers with ages ranging from 51 to 78 years (mean age = 64) was tested. Participants took part in a one-time session which consisted of assessing the Unilateral Stance (US) and Sit-to-Stand (STS) components of the NeuroCom Balance Master (NBM), version 7.1, the sitting to standing and the standing on one foot components of the Berg Balance Assessment, the Timed Up and Go (TUG), knee extensor strength, and knee flexion and extension range of motion (ROM). The participants also completed a SF-36 Health Status Survey and a brief questionnaire.

This study indicates that further research must be completed to assess the effects a TKA has on static and dynamic balance. Due to the small sample size, this study was unable to obtain any analytical statistics which were significant in answering the research questions. However, comparisons were made between the data components using

descriptive statistics, which provided information relative to ROM, strength, US, STS, and differences between the involved lower extremity and uninvolved lower extremity. The information helped address this study's research questions.

CHAPTER I

INTRODUCTION/LITERATURE REVIEW

Over 267,000 total knee arthroplasties (TKAs) were performed in the United States in 1999.[1] This procedure has become one of the most commonly performed orthopedic procedures of the lower extremities. Joint arthroplasties are usually performed to restore function, relieve pain, and improve quality of life in patients whose joints are damaged extensively usually by rheumatoid arthritis or osteoarthritis.[2,3] According to Roach and Miles, [4] for persons who have not undergone a TKA, the mean value of knee flexion is 132° for 40-59 year olds and 131° for 60-74 year olds. A knee prosthesis currently allows knee flexion of 100-110° which is sufficient for most activities of daily living, such as walking on level surfaces, ascending and descending stairs, rising from and sitting in a chair, and tying shoes.[4] Patients usually report considerable improvement in physical and social functioning, quality of life, mental health, pain, and energy levels. However, although improvements may be demonstrated in some areas, limitations may be present in others.

Numerous studies have shown patients' still have decreased functional capacity following a TKA procedure.[5,6] Studies have shown that one-year after a TKA, patients report functioning at approximately 80% of their normal function.[6] Functional deficits such as slower walking speeds were reported for males (13% decrease compared to

normal pace) and females (17% decrease compared to normal pace). Pain did not contribute to this decrease in walking speeds. Stair climbing was compromised one year after a TKA due to a decrease in strength. Decreased sit-to-stand tests and slower Timed Up and Go Tests have been postoperative effects reported after one year. Quadriceps muscle weakness is a post-TKA deficit shown in recent studies. Maxey and Magnusson[5] found one year postoperative, the knee extensors were weaker by 37-39% for males, and 28-29% for females.

Muscles, ligaments, and the joint capsule are disrupted during TKA surgery which can have a significant impact on muscle strength and joint proprioception.[1,7,8] These two components have been known to affect postural stability. Literature, up to date, has not assessed TKA balance deficits related to muscle strength and joint proprioception.[1] Total hip arthroplasty patients have shown a decrease in balance in which deficits in muscle strength and joint proprioception can be contributing factors.

Balance is defined as the ability to maintain a posture keeping the body's center of gravity (COG) over the base of support (BOS) with minimal sway.[9] Center of gravity is a point in the body where the gravity force appears to act, located at approximately the second sacral segment.[9,10] Balance is maintained through a complex process involving sensory recognition (visual, vestibular, and proprioception) of body motions, incorporation of sensory motor data within the central nervous system, and performance of proper musculoskeletal responses.[1,9,11,12] Any one of these components can be disrupted during a TKA procedure.[1] Numerous factors contribute to provide safe and functional balance control.[11] Optimal functioning and performance of activities of daily

living rely on balance.[13,14] Assessment of balance system integrity is critical to assess the risk of one's safety and risk of falls.

Balance deficits often lead to falls. There also may be a decrease in mobility due to a fear of falling.[9,15-17] Falls are the leading cause of injury to older adults. Every year approximately one third to one half of the elderly population, 65 and over, experience falls.[15] Of those who fall, half will repeatedly fall. Falls are dangerous, occur too often, and are costly. The high incident of falls greatly impacts the quality of life, therefore it is important to screen the mature population to assess their overall balance and mobility in order to identify their risk for falling.

The sit-to-stand transition is a movement that can be used to assess dynamic balance.[18] This movement is functionally relevant because a person's performance can be correlated to the risk of falls in older adults. The unilateral stance can be used to assess static balance. The importance of this ability is essential for functional activities such as donning clothes, walking, climbing stairs, etc. The sit-to-stand transition is an important skill for the elderly to maintain in order to live an independent life style.

Balance Assessment Tools

A variety of tools are available for the physical therapist to assess balance. One tool used to assess balance deficits is the NeuroCom Balance Master (NBM).[19] This tool is an interactive computerized system designed to assess balance and can also be used as a training device. This instrument measures static and dynamic balance using quantitative and objective measurements.[11,20,21] Treatment and training programs can be specifically designed from this objective data, focusing on the patient's functional limitations.

The NBM has tests which are standardized and provide assessments of balance, impairments, and functional limitations.[20] Two of the assessment protocols are Unilateral Stance (US) and Sit-to-Stand (STS). The US assesses the patient's postural sway while standing on one leg for 10 seconds on the forceplate. This is a sensitive test, however a variety of independent factors can influence performance. Some of these factors include lower extremity strength, sensory balance control, prior practice with the task, and weight bearing control. The STS assesses the patient's ability to move from a seated position, without arm rests, to a standing position. The STS measures weight transfer time, left and right weight symmetry, rising index, and sway velocity.[9] A slow transfer time decreases the momentum used to move the COG forward, which increases the muscle contraction needed to perform this functional task. A study by Su et al[18] found that patients with a TKA have an increased rising time from a sit-to-stand position as compared to subjects without any knee pathologies. Quadriceps femoris muscle weakness post-TKA will affect sit-to-stand performance and will increase the sit-to-stand time.[13,22,24] This weakness can be seen in TKA's more than 2 years after surgery.[23,25]

A generous amount of information exists regarding joint proprioception after a joint replacement, however no studies have been done testing postural control after a TKA.[18] Postural control is the ability to maintain both dynamic and static stability of the body's center of mass in response to forces which can affect equilibrium, leading to risk of falls.[1,10,16] In the Su et al[18] study, conclusions were drawn that a TKA did not affect balance.

Two commonly used standardized clinical tools to assess balance are the Berg Balance Assessment and the Timed Up and Go (TUG) test. Both are screening tests and

are safe, easy to use and cost effective.[17,26] The Berg Balance Assessment and TUG are tests that assess an individuals function, such as turning while walking and rising from a chair, respectively.

The Berg Balance Assessment, is comprised of 14 items that are representative of daily tasks requiring balance.[27] This assessment is a functionally-based test constructed to determine the risk for falls and balance deficits.[26,27] Each task is given a score between 0-4, all tasks compiling a possible total of 56 points. The lower the score the higher the risk for falls exists.[26,27] A score of 45 or greater usually indicates that a person is less likely to fall, performs ambulation safely, and needs no assistive device. A score of 37 or greater usually indicates safe ambulation with an assistive device. A score of 36 or lower relates to 100% risk of falls in the elderly community dwelling population. Two of the subsets of the Berg Balance Assessment are sitting to standing and standing on one foot.

The TUG measures the time it takes to rise from an armchair, walk 3 meters, turn around, return to the chair, and sit.[27-30] Neurologically intact, independent adults who do not have any balance or mobility deficits are able to safely complete the test in 10 seconds or less. Adults who were dependent in mobility and most daily living activities took more than 30 seconds to perform this test.[27]

Health Assessment Tool

The Short Form (SF)-36 is a health status survey designed for research and use in clinical practice.[31] This survey is composed of 36 items that assesses 8 topics of health.[31,33] The scoring of this survey is norm-based and ranges from 0-100. The higher the score, the better the individual perceives his or her health status. For the general American population, the average score is 50. When interpreting scores, 50 or above is

considered better than the average for the general population. On the other hand, scores below 50 are considered worse. After a knee arthroplasty, SF-36 health status surveys have shown patients are generally satisfied with their new knee. One study reported that 81% of the respondents were satisfied, 11% were unsure, and 8% were dissatisfied.[34] Satisfaction was defined in regards to the fact that they have had pain relief and their function had improved. Preoperative diagnoses were shown to affect satisfaction levels, individuals with rheumatoid arthritis reporting the highest level of satisfaction, followed by individuals with osteoarthrosis. The chronic onset of disease leading to knee replacement is directly related to postoperative levels of satisfaction. The SF-36 health status survey can be used to help identify the level of impairment, determine functional limitations as perceived by the individual, and find out patient satisfaction.

Purpose

The purpose of this study was to determine the effects a TKA has on static and dynamic balance using the NBM, Berg Balance Assessment, and the TUG. There is a need for this study because virtually no literature exists discussing the impact that a TKA has on unilateral stance. The research questions that will be addressed are:

1. Following a TKA, is there a significant difference in ROM between the involved and uninvolved extremity?
2. Following a TKA, is there a significant difference in strength between the involved and uninvolved extremity?
3. Following a TKA, does a decrease in ROM/strength affect US?

4. Is there a significant difference between postural sway and the ability to statically stand on one leg for 10 seconds on the involved extremity versus the uninvolved extremity?
5. Following a TKA, does a decrease in ROM/strength affect STS?
6. Is there a significant difference in weight symmetry between the involved extremity and the uninvolved extremity during STS?

The first hypothesis is that there is a decrease in ROM in the involved extremity compared to the uninvolved extremity. The null hypothesis is that there will be no difference in ROM between the involved extremity and uninvolved extremity. The second hypothesis is that there is a decrease in muscle strength in the involved extremity compared to the uninvolved extremity. The null hypothesis is that there will be no difference in muscle strength between the involved extremity and uninvolved extremity. The third hypothesis is that a decrease in ROM/strength will significantly affect static balance. The null hypothesis is that a decrease in ROM/strength will not significantly affect static balance. The fourth hypothesis is that there will be a significant decrease in US of the involved extremity compared to the uninvolved extremity. The null hypothesis is that there will be no significant decrease in US of the involved extremity compared to the uninvolved extremity. The fifth hypothesis is that a decrease in ROM/strength will significantly affect STS. The null hypothesis is that a decrease in ROM/strength will not significantly affect STS. The sixth hypothesis is that there will be significant difference in weight symmetry between the involved extremity compared to the uninvolved extremity during STS. The null hypothesis is that there will be no significant difference

in weight symmetry between the involved extremity compared to the uninvolved extremity during STS.

Clinical Application

Effective and efficient physical therapy is needed to rehabilitate a patient after a TKA.[17] This study may help physical therapists better understand what factors contribute to balance deficits, specifically after a TKA. If factors can be identified that lead to a decrease in functional status, health care professionals can begin to provide more efficient and cost effective health care to patients with TKA.

CHAPTER II

METHODOLOGY

Before beginning this study, final approval was obtained from Altru Health Systems and the University of North Dakota (UND) Institutional Review Board for the use of human subjects. A copy of the Human Subjects Review Form from UND and Altru Health Systems is located in Appendix A. All participants interested in participating were provided a detailed explanation of the components in this study. Each participant was provided a written consent form that was signed prior to participating. A copy of the consent form is located in Appendix B. Participants were asked to complete a SF-36 Health Status Survey and a brief questionnaire, performed in an interview style. Copies of these questionnaires are located in Appendix C.

Confidentiality of the participants' information and results of the study was maintained by assigning a random number to represent the data. The research data and the consent forms from this study will be stored separately in locked cabinets in the Physical Therapy Department at the University of North Dakota. This information will only be available to the investigators conducting this study. The research data will be kept for at least 3 years after this study and will be discarded appropriately.

Participants

Participants in this study were recruited using word of mouth from the researchers and the UND Physical Therapy faculty. Inclusion criteria for balance assessment of each

participant required him/her to have undergone a total knee arthroplasty (TKA) at least 6 months prior to this study. Exclusion criteria for each participant were as followed; under the age of 50, use of medications that affect balance (i.e., pain killers, hypertensive agents, etc.), history of symptoms suggesting vestibular or neurological disorders, and recent history of medical problems since TKA surgery. Twelve subjects, 7 females and 5 males, ages 51-78 (mean age = 64) met the inclusion/exclusion criteria and were asked to participate in this study. Four out of the 12 participants had bilateral TKA surgery. Participants were tested in a one-time session lasting approximately one hour.

Questionnaires

The SF-36 Health Status Survey (Quality Metric Inc. 640 George Washington Hwy, Lincoln, RI 02865) is a self-administered questionnaire that takes approximately 5-10 minutes to complete.[31-33] The questionnaire consists of 36 questions covering 8 domains relating to the participants general health. The 8 domains are categorized into a Physical Health Summary and Mental Health Summary. The Physical Health Summary components consist of the following: physical functioning, role functioning, bodily pain, general health, and perception. The Mental Health Summary components consist of the following: vitality, social functioning, role functioning, and mental health. Results can be easily calculated from this survey and normative data are readily available for comparison of results. The SF-36 Health Status Survey is a valid and reliable survey that is widely accepted and used frequently in the health profession.

An additional questionnaire created by the researchers was used to cover information not included in the SF-36 Health Status Survey. Information was needed in order to properly obtain all of the inclusion/exclusion criteria for balance assessment.

Questions in this survey were related to past medical history, TKA surgery, medications, assistive devices, physical therapy treatment, exercise programs, history of falls, and activity levels. All participants met the criteria and were involved in the study.

NeuroCom Balance Master

The NeuroCom Balance Master (NBM) version 7.1 (NeuroCom International Inc., 9570 SE Lawnfield Road, Clackamas, Ore 97015-9611) is a computer software program that will collect and interpret data on the 2 forceplates (9"x 60") on which the participants stand.[11,21] The 4-load cells under the forceplates measure forces exerted from the participant's feet. The computer in turn receives the data, analyzes it, and displays an overall report of the participant's results. In general, the NBM demonstrates good to excellent reliability. However, the US component has a poor to moderate reliability and the STS component has a moderate to high reliability.[21] Pictures of the NBM are located in Appendix D.

The NBM has a wide variety of standardized balance assessments and training programs.[21,35] Two of the balance assessments used in this study included Unilateral Stance (US) and Sit-to-Stand (STS). The US measures postural sway velocity by having the participant stand quietly on one leg for 3 trials, 10 seconds in length, with eyes open. This test was performed on the right and on the left leg. Three components of balance were measured including: center of gravity (COG); time standing on one leg with eyes open; and mean COG sway velocity. The definitions, as defined in the NBM Operator's Manual,[21] are as follows:

1. COG – an imaginary point in which the total mass of the body may be considered to be concentrated with respect to the pull of gravity. In normal individuals

standing quietly erect, the COG is located at the level of S1-S2 and located very slightly in front of the ankle joints.

2. COG sway velocity – velocity is a ratio of distance to time (d/t). The COG sway velocity is the ratio of the distance traveled by the COG (expressed in degrees per second).
3. Mean COG sway velocity – the average of COG sway velocity scores from the combined 3 trials; the sum of the scores divided by the number of the trials.
4. Time standing on one leg with eyes open – the total time the participant was able to stand on one leg for each 10 second trial.

The STS test was performed using a standard chair (height of 46 cm).[21,35] The STS measures various movement characteristics while the participant rises from a seated to a standing position in 3 trials.[21] The second trial was used for data analysis. These movements included weight transfer time, rising index, and sway velocity. Right and left weight symmetry was also analyzed through the duration of the movement. The definitions, as defined in the NBM Operator's Manual,[21] are as follows:

1. Mean weight transfer – is the amount of time between the onset of the cue to move and the arrival of the COG over the feet, expressed in seconds. The mean is calculated by adding the 3 individual trial scores and dividing by 3.
2. Mean rising index – is the amount of force exerted by the legs during the rising phase, expressed as a percent of body weight. The mean is calculated by adding the 3 individual trial scores and dividing by 3.
3. Mean cognitive sway velocity – is the average amount of COG sway during the rise to stand for the first 5 seconds following the rise, expressed in degrees per

second. The mean is calculated by adding the 3 individual trial scores and dividing by 3.

4. Left/Right weight symmetry – is the relative amount of weight borne by each leg during the rise to stand for the first 5 seconds after the rise, expressed as a percentage.

Following testing of the US and the STS, results were discussed with each participant. A computer-generated analysis of his/her balance results was sent to each participant following completion of the study. An example of the US analysis is located in Appendix E and STS analysis is located in Appendix F.

Berg Balance Assessment and Timed Up and Go

Two other balance assessment tools that were implemented in this study were the Berg Balance Assessment and the Timed Up and Go (TUG). These are observational tests that measure functional balance, which gives a good prediction for the risk of falls in the elderly population.[27,28] The Berg Balance Assessment is easy to administer, safe, brief, and has been shown to have strong intra- and inter-rater reliability and test-retest reliability. For this study, only 2 of the 14 components were tested. These components are standing on one foot, which measures static balance; and sitting to standing, which measures functional mobility and dynamic balance. These subsets can be used independently and have been shown to be reliable.[36] In the sitting to standing component, the instructions are to have the participant stand up, trying not to use their hands for support.[27] When scoring this component: 4 - able to stand independently without using hands, 3 - able to stand independently using hands, 2 - able to stand using hands after several tries, 1 - needs minimal assistance to stand or stabilize (with chair arm

rest or physical assistance), and 0 - needs moderate or maximal assistance to stand. In the standing on one foot component, the instructions are to stand on one leg as long as the participant can hold that position. When scoring this component: 4 - able to lift leg independently and hold > 10 seconds, 3 - able to lift leg independently and hold 5-10 seconds, 2 - able to lift leg independently and hold = or > 2 seconds, 1 - tries to lift leg unable to hold 3 seconds but remains standing independently, and 0 - unable to try or needs assistance to prevent falls.

The TUG, which is shown to have a high intra- and inter-rater reliability in the elderly population, measures the time is takes to rise from an armless chair (height of 46 cm), walk 3 meters, turn around, and return to the chair, and sit.[27-30] Performance is measured using a 5-point scale, consisting of the following: 1 – normal, 2 - very slightly abnormal, 3 - mildly abnormal, 4 - moderately abnormal, and 5 - severely abnormal. Performance is also measured using a timed scale, consisting of the following: > 30 seconds - identifies people who are more dependent; < 20 seconds - independent transfers, independent toilet transfers, most often independent climbing stairs, most often independent community dwellers; and < 10 seconds - free mobility.

Goniometry

The goniometer is an apparatus used to measure the joint angles created by the bones of the human body using the proximal and distal bones of the joint being evaluated.[4,37] The recommended position for testing of the knee range of motion is supine and goniometer alignment is measured as follows: center the goniometer fulcrum over the femur on the lateral epicondyle; using the greater trochanter, align the proximal arm along the lateral midline of the femur; and using the lateral malleous and fibular

head, align the distal arm along the lateral midline of the fibula. Using an universal goniometer, measurement of joint range and joint position has been shown to have a good to excellent reliability and validity.[4]

Dynamometer

In this study, muscle strength was measured using a Microfet hand-held dynamometer (HHD) (Hoggan Health Industries, 111 E. 12300 S., Draper, Utah 84020). This instrument objectively measures isometric muscle forces and is usually positioned at the distal end of the segment being tested.[35] This force value is used to calculate torque produced by human joints. This ability of the HHD to gauge torque provides an advantage due to its sensitivity, unlike manual muscle testing (MMT) which is rather insensitive to differences in the ability to generate torque. The guidelines of application when using the HHD are as follows:

1. Maintain consistency in the test position from one test to another
2. Ensure that the joint position is the same from test to test
3. Offer maximum stabilization to ensure maximum reliability
4. The same examiner should perform all testing
5. Gain experience before beginning testing
6. The number of trials should depend on how consistent the examiner is
7. Test in gravity-eliminated positions whenever possible
8. Apply the HHD at a known location, perpendicular to the site
9. The amount of time is most commonly standard at 3 to 5 seconds.

The position of the hand-held dynamometer (HHD) is crucial for reliability purposes. Numerous studies have analyzed the reliability of the HHD, yet controversy exists.[35,37] To ensure the best reliability the guidelines above were followed.

Assessment Procedure

Participant testing took place at Altru Health Institute in the Physical Therapy Department. This study began with the participants filling out the SF-36 Health Survey and being interviewed with a brief questionnaire. Following the questionnaire, researchers used a HHD to assess the participant's muscle strength/performance of the knee extensors of both legs. Each participant's leg was positioned, on a high plinth, using a gait belt at 80° of knee flexion to maintain consistency between testing of each knee and each participant. Active knee motion of both legs was measured using a goniometer. The participants were tested in the recommended supine position first with the heel slid back towards the buttocks as far as possible; then with the heel resting on a towel roll in full extension. The participants performed a one-trial session of the TUG with their shoes on, and were timed by a researcher. Participants were taken to the NBM for final testing and asked to take their shoes off, and instructions were given on how to perform the US and STS tests. Participants were then positioned appropriately on the NBM to assess three, 10-second trials on each leg for US. Participants were repositioned and performed 3 trials of STS testing. At the same time, a second researcher assessed and scored the participants for the Berg Balance Assessment and spotted the participant. Rest breaks were given between each trial and each test. A copy of the data collection score sheet is located in Appendix G. Following testing, results were discussed with each

participant and a computer generated analysis of their balance results was mailed to them following the study.

Data Analysis

The data collected for all participants included the questionnaire, SF-36 Health Status Survey, US, STS, Berg Balance Assessment, TUG, goniometry, and dynamometry. Data was entered into the SPSS Version 10.0 software system. Comparisons were made between the data components using descriptive statistics.

Reporting of Results

Upon completion of this study, a copy of the results of this scholarly project was given to the University of North Dakota Department of Physical Therapy and the Harley E. French Library of the Health Sciences. This study was completed to fulfill the requirements of the University of North Dakota School of Medicine and Health Sciences Physical Therapy Program.

CHAPTER III

RESULTS

The results consisted of Unilateral Stance (US) and Sit-to-Stand (STS) scores from the NeuroCom Balance Master (NBM), version 7.1. The Berg Balance Assessment and Timed Up and Go (TUG) scores as well as goniometry and dynamometer data were used for analysis. Comparisons were also made between test results, questionnaire, and SF-36 Health Status Survey. Statistical tests were run using the data above to determine if any significant relationships or differences existed.

Participant Profile

Twelve participants, 8 females and 4 males, ages 51-78 (mean age = 64 years), took part in this study. Four of the 12 participant's had bilateral TKAs. All participants were included in this study and no data were discarded. This study consisted of a one-time testing session on the NBM, in conjunction with goniometry, dynamometry, TUG, and Berg Balance assessments.

Analytical Statistics

Analytical statistics were used to determine if any significant relationships or differences in static and dynamic balance existed relative to total knee arthroplasties (TKAs). After running numerous statistical tests at an alpha level of .05, no significant differences were found between the following:

1. Following a TKA, is there a significant difference in ROM between the involved and uninvolved extremity?
2. Following a TKA, is there a significant difference in strength between the involved and uninvolved extremity?
3. Following a TKA, does a decrease in ROM/strength affect US?
4. Is there a significant difference between postural sway and the ability to statically stand on one leg for 10 seconds on the involved extremity versus the uninvolved extremity?
5. Following a TKA, does a decrease in ROM/strength affect STS?
6. Is there a significant difference in weight symmetry between the involved extremity and the uninvolved extremity during STS?

Statistical tests were discontinued due to lack of significant findings as a result of the small sample size and minimal variability between participants.

Descriptive Statistics

The following comparisons were made using the data collected during the one-time testing session. Only the components found to be meaningful and of importance to the researchers were used for comparisons. The following components were compared: the questionnaire, ROM, strength, TUG, Berg Balance Assessment components, SF-36 Health Status Survey, and the NBM tests (STS and US).

Range of motion was assessed comparing the involved versus the uninvolved lower extremities. The average knee flexion for the involved lower extremity was 111°. The average knee flexion for the uninvolved lower extremity was 119°. Seven out of the 12 participants showed an average decrease of 18° in knee flexion on the involved

compared to the uninvolved extremity. Two out of the 12 did not have the minimal reported amount of knee flexion sufficient for functional daily activities; 100° is adequate for most daily activities.[4] See Table 1. See Figure 1, Appendix H.

The average knee extension for the involved lower extremity was –4°. The average knee extension for the uninvolved lower extremity was –3°. Five out of the 12 participants were lacking a greater amount of knee extension in the involved compared to the uninvolved lower extremity. See Table 1. See Figure 2, Appendix H.

Table 1. Knee Flexion and Extension Range of Motion

Participants	Right Knee Flexion (°)	Left Knee Flexion (°)	Right Knee Extension (°)	Left Knee Extension (°)
1	***96***	134	***-14***	-2
2	111	***111***	***-6***	***-5***
3	***115***	139	***2***	-1
4	***112***	109	***-2***	-3
5	119	***118***	-5	***-2***
6	***128***	126	***-1***	-5
7	***116***	***124***	***2***	***1***
8	***124***	***115***	***-4***	***-4***
9	***111***	***122***	***-4***	***-4***
10	***118***	***119***	***0***	***-2***
11	***76***	110	***-5***	-6
12	***109***	***103***	***-2***	***-5***

Key: **Bold** denotes involved extremity. Participants 7-10 and 12 have bilateral TKAs.

The involved and uninvolved quadriceps strength was compared isometrically, with the lower extremity positioned in 80° of knee flexion. The average muscle force for the involved lower extremity was 52.89 ft lbs. The average muscle force for the uninvolved lower extremity was 52.31 ft lbs. Six out of the 12 participants displayed a

decrease of muscle force on the involved extremity. See Table 2. See Figure 3, Appendix H.

Table 2. Knee Extensor Muscle Force

	Average Muscle Force (ft. lbs.)	
Participants	Right	Left
1	***47.00***	53.33
2	***41.00***	***47.33***
3	***65.33***	67.67
4	***53.00***	51.33
5	61.00	***55.33***
6	***100.00***	87.00
7	***84.67***	***83.00***
8	***28.67***	***28.00***
9	***30.00***	***44.00***
10	***46.00***	***42.67***
11	***40.33***	21.67
12	***44.00***	***40.00***

Key: **Bold** denotes involved extremity

The one-legged stance component of the Berg Balance Assessment showed 5 out of the 12 participants scored lower on the involved extremity compared to the uninvolved, with an average of one level lower. See Table 3. Seven out of the 12 participants demonstrated less stability on the involved extremity during the US component on the NBM. Three out of the 12 were equally unstable on both extremities. One of the 12 participants was undetermined due to same day bilateral TKA. See Figure 4, Appendix H.

Results from the sitting to standing component of the Berg Balance Assessment showed that all participants were able to come to a stand independently without upper extremity use. The weight transfer time and the rising index scores were compared to the appropriate age group norms. On the STS component of the NBM, 2 out of the 12

participants demonstrated an increase in weight transfer time which resulted in abnormal time values. See Figures 5 and 6, Appendix H. One participant displayed a decrease in rise index that was abnormal. See Figures 7 and 8, Appendix H. All participants showed a normal COG sway velocity once standing. Two of the 12 participants showed bias toward one side. See Figure 9, Appendix H.

Table 3. Berg Balance Assessment Components

Participants	Sitting To Standing	Standing On One Leg Right	Left
1	4	4	2
2	4	3	4
3	4	3	4
4	4	3	4
5	4	3	2
6	4	1	2
7	4	2	3
8	4	1	1
9	4	3	3
10	4	3	1
11	4	3	1
12	4	3	3

Timed Up and Go scores ranged from 8.47 to 13.00 seconds, with a mean score of 10.13. Seven of the 12 participants scores were within the normal standards, which is less than 10 seconds. See Figure 10, Appendix H. Generally, times exceeding 10 seconds correlate with increased risk of falls. Out of the 5 participants whose scores exceeded 10 seconds, only 2 reported falling on the questionnaire. Results from the questionnaire showed 4 out of the 12 participants fell at least once in the past year. Two of the 4 who reported falling reported they did not participate in weekly physical activity.

Eight out of the 12 participants reported engaging in weekly physical activities at least one day per week. Participants named activities they were unable to perform but

desire to do. Kneeling and increased walking distance were the most desired activities. See Figure 11, Appendix H.

The Physical Component Summary (PCS) and the Physical Functioning Component (PF) of the SF-36 Health Status Survey were looked at to compare participant scores to the respective population mean for the age groups. Six out of the 12 participants were at or above the PCS population mean for the designated age groups. For the PF, only 2 out of the 12 were above the standard mean for the designated age groups. See Table 4, Appendix H.

CHAPTER IV

DISCUSSION

The results of this study show that little to no significant findings could be determined related to the research questions presented. This was due to the fact that the sample size used was too small and this led the researchers to a different approach of interpreting the data. Interpretations and comparisons were made using previous research from the literature review and the data collected in this study. Interpretations are discussed below addressing the research questions that were asked previously.

Current literature shows that a knee prosthesis allows 100-110° of knee flexion, which is sufficient for daily activities.[4] In a past study, Roach and Miles[4] found that the mean value of knee flexion is approximately 131° for 40 years of age and older. According to the data collected and relating to the research question, is there a significant difference in ROM between the involved and uninvolved lower extremity after a TKA, the following was found in this study. Ten out of the 12 participants did have at least 100° (mean = 111°) of knee flexion on the involved knee. Seven out of the 12 participants showed a decrease in knee flexion on the involved compared to the uninvolved lower extremity. For the 7 participants that demonstrated a decrease in knee flexion, a mean of 107° of knee flexion was calculated for the involved lower extremity and a mean of 124° of knee flexion was calculated for the uninvolved lower extremity. Eleven of the 12 participants were lacking full knee extension on the involved lower

extremity and 5 out of the 12 participants were lacking a greater amount of knee extension on their involved lower extremity as compared to their uninvolved lower extremity.

The second research question looked at if a difference in strength exits between the involved and uninvolved lower extremities. According to recent studies, quadriceps muscle weakness is another deficit found up to two years after a TKA.[5,6] Studies by Maxey and Magnusson[5] and Walsh et al[6] found that knee extensors were weaker by 37-39% for males and 28-29% for females. In this study, no relationship existed between the percentage of knee extension strength between the involved and uninvolved for the males (mean involved = 71.17 ft. lbs., mean uninvolved = 68.67 ft. lbs., percent difference = 3.6%) and females (mean involved = 43.75 ft. lbs., mean uninvolved = 43.91 ft. lbs., percent difference = -.37%). Data from this study showed that 6 out of the 12 participants displayed a decrease in strength of the involved compared to the uninvolved lower extremity. A mean of 44.44 ft. lbs. was assessed for the involved lower extremity, and a mean of 50.67 ft. lbs. was assessed for the uninvolved lower extremity of those 6 participants displaying a decrease in involved strength (percent difference = 12.3%).

Static balance (US) may have been affected by lack of full knee extension. An exact determination could not be determined due to the fact that more than just the 5 participants with a decrease in knee extension performed below average on this test. Another factor which may have affected US is stability of the lower extremity. Data reported that 7 of the 12 participants were less stable on the involved extremity and 3 out of the 12 participants were equally unstable on both lower extremities. Four of the 7 participants that were unstable on their involved lower extremity also showed a decrease

in knee extensor strength on their involved lower extremity. One study by Wallmann[1] found that total hip arthroplasty patients showed a decrease in balance in which deficits in muscle strength and joint proprioception were possible contributing factors. These same factors could also be reasons for the instability and variations in postural sway found in the TKA participants in this study; although, further research would be needed before conclusions could be made. The factors listed above provide information that applies to the research question presented earlier relating to if a decrease in ROM and strength affect US following a TKA; and whether a significant difference between postural sway exists during US between the lower extremities. It is difficult to make an assumption as to whether a TKA has an effect on stability relative to postural sway due to the reported poor to moderate reliability of the US component of the NBM and the inability to run analytical statistics.[21]

Addressing the research question relating to whether ROM and strength affects the sit-to-stand transition following a TKA, this study found that knee flexion was at an adequate range and had little to no effect on dynamic balance (sit-to-stand transition). Previous studies have reported that decreased sit-to-stand times are postoperative effects evident beyond one year.[5,6] Studies have reported that weakness in knee extensors will affect sit-to-stand performance and can be seen for more than two years after surgery.[22-25] However, as seen from the knee extensor strength means and percentage differences recently stated, this study's percentage difference is considerably lower than the percentages reported in previous studies. This leads to the conclusion that strength did not affect STS in this study. The majority of the participants scored in the normal range for the NBM and the Berg Balance Assessment. All participants demonstrated the ability

to stand independently without the use of upper extremity support during the STS component of the NBM, as well as during the sitting to standing component of the Berg Balance Assessment. Although sit-to-stand transitions were completed independently and all participants demonstrated normal COG sway velocity, there were participants whom presented outside the normal ranges for weight transfer time, rising index, and weight symmetry. In this study, it was found that 2 of the 12 participants had a decreased weight transfer time (which represents sit-to-stand time) and only one of these had a TKA beyond one year. As for the rising index, one participant was below the normal range. A possible reason for these abnormal values may be lower extremity weakness which is the main cause of inadequate force production.[21]

The final research question asks if there is a significant difference in weight symmetry between the involved and uninvolved lower extremity during STS. With respect to the two participants who demonstrated abnormal weight symmetry, small deviations from midline are expected during normal STS transitions. However, extreme bias towards one side may signal problems such as poor proprioception, which was an exclusion criteria in this study. Other factors that may lead participants with a TKA to be more partial to one side are strength loss, sensory loss, joint restriction, and pain associated with the involved lower extremity. Although these are factors which can affect STS transitions, further research is needed to determine if these are the main factors contributing to the deficits.

Other differences noted in this study that were not previously addressed as research questions are discussed below. Independent adults, who are neurologically intact and do not have any balance or mobility deficits, are able to complete the TUG in

10 seconds or less.[27] Previous studies have reported that slower TUG times are often seen one year postoperatively.[5,6] Scores in this study ranged from 8.47 - 13.00 seconds (overall mean = 10.13 seconds, mean females = 10.12 seconds, mean males = 10.15 seconds) and 4 of the 12 participants were at or above 10 seconds (mean = 11.39 seconds) and were participants that had undergone a TKA beyond one year. The results from this study showed that TKAs could have an affect on normal walking pace. Functional deficits such as slower walking have been reported in males (13% decrease) and females (17% decrease) following a TKA.[5,6]

In looking at the SF-36 Health Status Survey it was determined that 6 out of the 12 participants were at or above the Physical Component Summary (PCS) population mean for the designated age groups. For the Physical Functioning (PF) component of the survey, only 2 out of the 12 were above the standard mean for the designated age groups. These data show that participants in this study have an overall good attitude towards their physical health (i.e. increase in endurance, no bodily pain, no illnesses, etc.). The participants reported their TKA had an affect on physical functioning (i.e. walking, climbing stairs, activity level, etc.). These activities are similar to the ones reported by the participants on the questionnaire.

The overall results that were collected justify further exploration of TKA effects on balance postoperatively. Future studies are necessary in order to allow a better understanding of the effects a TKA has on functional mobility and balance. Hopefully, further research will increase the knowledge in the field of physical therapy and create a more effective and efficient way to treat patients that have undergone a TKA.

Limitations

Many of the statistical results did not directly relate to the hypotheses. This could have been due to many of the limitations which were encountered throughout the study. Some of these limitations included: sample size, lack of participant variability, extraneous factors which may have impacted balance, and variations in the time of day in which subjects were tested.

The sample size (n = 12) for this study was considerably smaller than needed for statistical significance. Recruitment was difficult due to limited resources such as: small population size, limited time-frame, and use of only one physician's patients' records. Analytical significance could not be achieved due to this small sample size. As a result of the small sample size, there was minimal participant variability. In general, participants demonstrated a high level of function. Research indicates that volunteers differ from non-volunteers.[38,39] Volunteers tend to be more educated, feel more strongly about the issue at hand, are more successful, and are more extraverted than non-volunteers.

There are many factors that can impact balance. Some examples include: individual variability, age, vision, disease processes, functional level, proprioception, and pathology. This study did try to eliminate as many of these factors as possible by using exclusion criteria. Although this study primarily focused on ROM, strength, and components of dynamic and static balance, it is impossible to totally eliminate extraneous factors.

Participants were seen at various hours throughout the day. The difference in testing times may have affected the performance of the participant due to prior daily activities and fatigue levels. The time constraints of the researchers and participants may have had an impact on the results.

Recommendations

Many recommendations can be made in regards to this study. The recommendations below address the limitations along with other factors that could improve the results of future studies. As this study's results show, further research is warranted relative to the effects a TKA has on balance. It is suggested that the following recommendations be considered in order for future results to be significant.

First, and most importantly, further research studies should obtain a larger sample size (at least 30) to allow for analysis of statistical significance. In addition, with a larger sample size a greater variability of subjects will more likely be obtained. To increase the sample size and variability, broader recruitment methods should be used. Posting flyers in the community, a longer period of recruitment time, limiting postoperative time frames to greater than 6 months and less than two years, testing either all bilateral or all unilateral TKAs, contacting more physicians, and having the physicians recommend participation in the study are a few methods that would be beneficial.

Secondly, limited amount of variables should be used so that more direct comparisons can be made. Although several variables were used in this study, after data collection were completed it was determined that some of the variables were not meaningful. Three trials of the Berg Balance Assessment were recorded when only one needed to be performed. The information the participants provided regarding the

exercises performed before and after surgery was not meaningful for data analysis. Some of the variables did not seem appropriate or specific enough for analysis, such as using the TUG. Alternate tests that could have been performed are the Tinnetti Balance and Gait Assessment or the Walking Test component of the NBM. For muscle strength it may have been better to use an isokinetic machine (i.e. Cybex) rather than a hand-held dynamometer. The isokinetic machine provides a greater variety of strength assessments, assesses different types of contractions (isometric, isokinetic, etc.), can better isolate joints, and has a greater rate of standardization. The disadvantages of the isokinetic machine are that it is not readily available, it is more expensive, requires more intensive training/expertise to use, and the testing is more time consuming. Functional tests such as stair climbing may have been more appropriate than the US due to the fact that it is an everyday task. One-legged standing is not normally performed in a 10 second interval in the elderly population. Selection of only a few variables would allow for more focused and substantial results.

Thirdly, although this study tested participants at various hours throughout the day, no remarkable discrepancies in performance were noted. It is recommended that participants be tested within a certain time interval to decrease possible factors that may impact balance performance. For example, schedule all participants during the same time of day such as morning, afternoon, or evening.

Fourthly, although valuable information was collected from the brief questionnaire, many supplemental questions could be beneficial. Several questions that could have been added to the questionnaire are: date of birth, gender, hand dominance, reason/cause of falls, and type of physical activities performed. Some questions could

have been worded differently for more clarity. Instead of writing, "rate your activity level before your total knee arthroplasty to your current activity level after your total knee arthroplasty," it is recommended (by the researchers) to reword the question as "do you feel your activity level now, after your TKA, is better or worse than prior to your TKA surgery?" Also, categories used in the questionnaire regarding activity level had overlapping time frames, for instance, 1-2 days, 2-3 days, etc. It is recommended to use 1-2 days, 3-4 days, etc. See Appendix C.

Finally, although this research study only used an assessment approach, it would be beneficial to perform a long-term research study on the effects of a TKA. This may include a preoperative and postoperative comparison of TKAs effects on static and dynamic balance using variables of the same nature of this study.

CHAPTER V

CONCLUSION

This study indicates that further research must be completed to assess the effects a TKA has on static and dynamic balance. Due to the small sample size, this study was unable to obtain analytical statistics, which were significant in answering the research questions. However, some descriptive statistics were found that showed slight differences and offered data, which helped provide information needed to address this study's research questions.

When looking at ROM, 92% of the participants displayed greater than 100° of knee flexion which is sufficient for daily activities. When comparing the involved lower extremity to the uninvolved lower extremity, it was found that 58% of the participants had decrease range on their involved. Knee extension ROM results showed that 92% of the participants were lacking full knee extension on the involved lower extremity and 42% of the participants were lacking a greater amount of knee extension on the involved as compared to the uninvolved lower extremity. No significant finding were made correlating lack of knee flexion or extension and below average scores on any of the variables used.

According to recent studies, quadriceps muscle weakness is another deficit found after a TKA up to two years.[5,6] Relative to knee extensor strength, it was found that 50% of the participants did show a minimal decrease in strength of the involved versus the

uninvolved. Although there was a decrease in strength, it was substantially less than what was reported in other studies and was not of significance in this study.

As seen from the results above, overall effects of knee extensor strength and knee extension range of motion could not be associated with US (static balance). This is due to the fact that more than just the participants who displayed decrease knee extension ROM and knee extensor strength also performed below average on the US. Due to extraneous factors that could not be eliminated, it is difficult to make an assumption as to whether a TKA had an effect on US.

In reference to stability when standing on one leg it was noted that 58% of the participants were less stable on his/her involved lower extremity. However, these results do not accurately depict stability issues relating to postural sway because only one of the participants was in the normal range when performing the US. The overall conclusion relative to stability is that a significant correlation could not be determined due to outside factors and inconsistencies seen within the participants.

In regards to the effects knee flexion ROM and knee extensor strength has on dynamic balance (STS) following a TKA, no significant impact was noted. Every participant was able to transition from sit-to-stand independently without the use of upper extremity support. Therefore, when referring back to the knee extensor strength findings, no correlation could be determined because of the minimal decrease in strength found between extremities. The same can be said for knee flexion ROM because 92% of the participants had at least 100° which is sufficient for activities of daily living (i.e. sitting to standing transitions).

Finally, no significant findings were reported showing a difference in weight symmetry between the uninvolved lower extremity and the involved lower extremity as there were only 2 of the 12 participants who showed an extreme bias towards their involved side while performing STS. All participants were able to stand independently without any upper extremity assistance when transitioning from sit-to-stand. This leads to the assumption that numerous variables postoperative can effect balance. In this study TKAs have little or no effect on sit-to-stand components and movements due to the fact that there was no significant deficits involving strength and ROM.

Overall, participants in this study performed at a normal functioning level for their age group. Due to this level of function, no significance or major impacts could be noted relative to the effects a TKA has on static and dynamic balance. The need for future studies exists relative to TKA effects using the recommendations discussed earlier. This may help provide a better understanding and increase the knowledge surrounding TKAs and their affect on balance.

APPENDIX A

Altru Health System

Institutional Review Board

Research Project Action Report

Date: September 19, 2002 IRB # UND-21

Principal Investigator: Meridee Danks and UND Students

Department: Physical Therapy Phone # 777-3861

Address to which notice of approval should be sent: UND, P.O. Box 9037, Grand Forks, ND 58202-9037

Research Coordinator: Meridee Danks Phone #

Project Title: The Effects a Total Knee Arthroplasty has on Static and Dynamic Balance.

The above referenced project protocol and informed consent was reviewed by the Altru Health System Institutional Review Board on _____ and the following action was taken:

CONDITIONAL APPROVAL:

☐ Project conditionally approved on _____ pending modifications. This study cannot be started until revisions have been made and submitted, and final approval has been granted.

FINAL APPROVAL:

☐ Final project approval granted on _____ Next scheduled review is on _____ If no date is given, then review will be required in 12 months. (See REMARKS SECTION for any special conditions.

☒ Project approved. **EXPEDITED REVIEW NO.** 4 Next scheduled reviewed is on _____

☐ Project approved. **EXEMPT CATEGORY NO.** _____ No periodic review scheduled unless so stated in REMARKS SECTION.

☐ Project approval deferred. (See REMARKS SECTION for further information)

☐ Project approval denied. (see REMARKS SECTION for further information)

☐ Amendment approved _____

☐ Administrative change approved _____

☐ Protocol revision approved _____

☐ Revised consent form approved _____

☒ Other **New Project**

REMARKS:

Any changes in protocol, adverse occurrences or deaths in the course of the research project must be reported immediately to the IRB chairperson or the IRB office (780-6161).

Signature of Chairperson or Designated IRB Member
Altru Health System Institutional Review Board

10/7/02
Date

If the proposed project is to be part of a research activity funded by a federal agency, a special assurance statement or a completed 596 Form may be required. Contact the IRB office to obtain the required documents.

MLR 8/01/02

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 Investigator: Meridee Danks (Advisor),Connie Christensen, Niccole Riddle, Nicole Sukut, Cara Uyema

Telephone: 777-2831 Address: 501 N. Columbia Road, PO Box 9037, Grand Forks, ND 58202-9037

E-mail address: mgreen@medicine.nodak.edu

School/College: University of North Dakota Department: Physical Therapy

Student Adviser (if applicable): Meridee Danks

Telephone: (701) 777-3861 Address: University of North Dakota Physical Therapy Department P.O. Box 9037, Grand Forks, ND 58202-9037

E-mail address: mgreen@medicine.nodak.edu

School/College: Univ. of North Dakota Department: Physical Therapy

Project Title: The Effects a Total Knee Arthroplasty has on Static and Dynamic Balance

Proposed Project Dates: Beginning Date: 9/10/02 Completion Date: 5/01/03

Funding agencies supporting this research: N/A

(A copy of the funding proposal for each agency identified above MUST be attached to the proposal when submitted.)

___ YES or _x_ NO 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 has been or will be submitted to another Institutional Review Board (s), Please list those boards below along with the status of each proposal.

Altru Health Systems Date Submitted: 8-29-2002 Status: ___Approved _x_ Pending

Date Submitted: ___ Status: ___Approved ___Pending

Type of Project: Please Check Yes or No to the following.

_x_ YES or ___ NO New Project

___ YES or _x_ NO Dissertation/Thesis

___ YES or _x_ NO Continuation/Renewal

_x_ YES or ___ NO Student Research Project

___ YES or _x_ NO Protocol Change for previously approved project
(resubmit "Human Subjects Review Proposal" with changes bolded or highlighted and signed)

Cooperating Institution:

___ YES or _x_ NO **Will any institution of agency personnel assist in the Proposed Project?**
Copies of letters indicating the willingness of the institution/agency to cooperate in the study and an understanding of the study MUST be attached. 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
_____ Pregnant Women/Fetuses
_____ Persons with impaired ability to understand their involvement and/or consequences of participation in this research
_____ UND Students
__x__ Other Individuals 50 years of age or older who have undergone a total knee arthroplasty at least 6 months ago.

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.

_____ New Drugs (IND)
_____ Non-approved Use of Drug(s)
_____ Recombinant DNA
_____ Fetal Tissue
_____ Stem Cells
_____ Other (Discarded tissue, fluids, blood, etc.)
__x__ None of the above will be involved in this study

I. Project Overview

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

Over 267,000 total knee arthroplasties (TKA) were performed in the United States in 1999. This procedure has become one of the most commonly performed surgeries of the lower leg. Following this procedure, one major complaint is loss of mobility. Due to the invasiveness of this procedure balance components such as muscle strength, sensory systems, and neuromuscular coordination may be disrupted. This disruption may be a factor in the loss of mobility. Balance, in individuals who have had TKA, has yet to be assessed as an outcome in the literature. With the increasing popularity of the TKA procedure, a need appears for research evaluating static stability and function mobility of TKA's. The purpose of this study is to determine TKA effects, six months and beyond, on single leg stance and sit to stand transition. Balance testing consisting of the sit to stand and single leg stance will be assessed using the NeuroCom® Balance Master and components of the Berg Balance test. The Timed Up and Go will be incorporated to assess functional mobility. This will provide information regarding dynamic and static balance with patients who have undergone a TKA, which is becoming more prevalent as the society ages.

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 will subjects 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.
Recruitment will be carried out by researchers by word of mouth at Altru Health Institute. They will be recruited September through November 2002.

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.
The participants will have undergone a TKA at least six months ago. Research literature indicates, 6 months or greater is a reasonable time frame for patients to regain functional independence.

c) Describe your exclusionary criteria and provide a rationale for excluding subject categories.
The exclusion criteria includes: use of assistive walking device, under the age of 50, use of medication that affects balance, symptoms suggesting vestibular or neurological disorders (dizziness/light headedness), recent history of medical problems (heart/blood pressure/low back or leg injuries/etc.) since TKA surgery. TKA's are most common in the elderly population, so 50 and over age group was selected. This study is looking at the effects of the TKA on balance and in order to determine this all other extraneous variables/factors (assistive device, medication, vestibular or neurological disorders, recent medical problems) must be eliminated.

d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects.
There will be a group of approximately 30 volunteer participants. The data of the volunteers will be compared to normative data for age groups. The reason for having 30 participants is due to the fact that statistical data suggests a large number of participants in order to get adequate reliability.

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

2. Description of Methodology.

a) Describe the procedures used to obtain informed consent.
The participants will read, comprehend, and sign the informed consent form prior to testing.

b) Describe where the research will be conducted.
The research testing will be performed at Altru Health Institute in the Physical Therapy department.

c) Indicate who will carry out the research procedures.
The PI's, UND physical therapy students under the direction and supervision of their advisor (Meridee Danks), will be performing the following research procedures: short questionnaire, SF-36 Health Survey, balance and mobility testing and range of motion measurements. Muscle strength of the knee flexors and extensors will be tested using the Cybex isokinetic machine by Altru physical therapy personnel that normally perform this type of testing.

d) Briefly describe the procedures and techniques to be used and the time required to complete them.
Participants will be involved in an one-time session which will last approximately one hour. The study will begin with the participants' filling out a SF-36 Health Survey, which is a questionnaire consisting of 36 questions relating to the participants general health, and another brief questionnaire. The brief questionnaire covers information not asked in the SF-36 Health Survey. Questionnaires will take approximately 10-15 minutes to fill-out. Sit to stand and single leg stance functional assessments will be measured using the NeuroCom® Balance Master. The Balance Master is a computer software program which will collect and interpret data from the two forceplates on which the participants stand. Single Leg Stance test requires the participants to stand on one leg for three trials of 10 seconds each, testing the left and then right. Adequate rest periods will be given between trials. This test will take approximately five minutes to perform. The Sit to Stand test requires the participant to perform three transitions of sit to stand from a chair. This test will take approximately five minutes due to the rest periods given between trials. The Berg Balance test is an observational test which measures functional balance. Each component is graded on a scale of 0-4 depending on the level of performance. The single leg stance and the sit to stand sub components which will be used, will be graded during the Balance Master testing. The Timed Up and Go (TUG) is a timed observational test which requires the participant to rise from a seated chair, walk ten feet, turn around, walk back to the chair, and sit down. The Timed Up and Go will take approximately five mintues to perform. (See attached.) The Cybex isokinetic machine, commonly used in physical therapy field and in previous TKA studies, will assess the participant's muscle strength/performance of the knee flexors and extensors on each leg, and will take approximately 10 minutes to perform. Active knee motion measurements will be performed using a goniometer, which is a hand-held instrument commonly used in physical therapy to measures angles of joints. This will take approximately five minutes to assess.

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

f) Describe the qualifications of the individuals conducting all procedures used in the study.
The researchers carrying out the tests, with the exception of the strength testing, are physical therapy students at the University of North Dakota Physical Therapy department who have been trained, and are qualified to perform the procedures stated above. The Altru physical therapy personnel (Spring Bakke,ATC and Rachel Aure, Exercise Specialist) performing the isokinetic strength testing, are trained in use of the Cybex isokinetic equipment and assess patients regularly on this equipment. All procedures will be completed under the direction and supervision of advisor, Meridee Danks who is a licensed PT and has 19 years of clinical experience.

g) Describe compensation procedures (payment or class credit, etc.)
This study is voluntary and no payment reimbursements will be provided for participation.

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.
Although there is a risk for falls involved in the process of balance assessment, researchers feel the risks are minimal. Also, as a result of any type of exercise, muscle soreness may result from testing.

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.).
The participants will be encouraged to ask questions to clarify the testing procedures and are free to discontinue participation at any time. Through proper instructions and supervision with a spotter throughout testing procedures risk of falls will be reduced. Muscle soreness will be kept to a minimum by having the individual follow standard warm-up and cool-down exercises with the strength testing.

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.
There will be no direct way to link the participants' responses and data sheets to the consent forms.

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.).
Confidentiality of the participants' information and results of this study will be maintained. Participants will be assigned a random number and this will be used to represent the data.

b) Indicate that the subject will be provided with a copy of the consent form and how this will be done.
The participant will be required to sign two consent forms prior to testing or, if available, a photocopy will be made. One

copy will be issued to the participant and one will be kept in the participant's file for legal protection.

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.

Describe: a) the storage location of 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

The research data and the consent forms from the study will be stored separately in locked cabinets in the Physical Therapy Department at the University of North Dakota. This information will only be available to the investigators conducting this study. The research data will be kept for at least three years after this study and will be discarded appropriately.

d) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma etc.). In the event that this research activity results in a physical injury, medical treatment will be available as it is to a member of the general public in similar situations.

e) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.
Should injury occur during the testing process, the participant will receive proper medical attention. The University of North Dakota, Altru Health Systems, and the researchers are not responsible for any such injury or treatment. Payment for any such treatment must be provided by the participant and the participant's third party payer, if any.

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.

This study has the potential for benefits to both individual participants and society. Through assessment using the NeuroCom® Balance Master, the Timed Up and Go, components of the Berg Balance test and strength/range of motion measurements, each participant will learn about his/hers functional status following a TKA. Data results will help provide physical therapists and other health care professionals with information regarding the appropriate length of rehabilitation needed to enable TKA patients to resume more normal functional status. The outcomes of the study will also be available for review by either contacting any of the investigators or by visiting the Harley E French Library of the Health Sciences on the University of North Dakota Campus.

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. **Informed consent will be obtained through the attached consent form. Each participant will be required to sign two consent forms if they agree with the terms that are presented. Upon agreement, they will be included in the study.** **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) 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 you will dispose of the data. Be sure to list any mandatory reporting requirements that may require breaking confidentiality.

i) An explanation of compensation/medical treatment available if injury occurs

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

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

m) RE: 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: Cara K. Lyman Nicole Riddle Brooke Sakat

Date: 8-26-02

(Principal Investigator)

Date: 8-26-02

(Student Advisor)

Requirements for submitting proposals:

Additional information can be found at 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 as 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".

Federal regulations require that key personnel involved in human subject research complete educational training. The UND IRB has chosen an online educational course, which can be found at www.miami.edu/citireg, for this training. The online Educational Modules must be completed before approval is granted for a proposal. In addition, Principal Investigators must provide a list of the key personnel involved in the project to ORPD, so the office can maintain records of those individuals that have completed training.

Revised 7/27/2001

APPENDIX B

Consent Form

Title: The Effects a Total Knee Arthroplasty has on Static and Dynamic Balance.

You are invited to participate in a study conducted by students of the University of North Dakota Physical Therapy Program, Connie Christensen, Niccole Riddle, Nicole Sukut, and Cara Uyema, in collaboration with faculty member, Meridee Danks. The purpose of this study is to determine the effects that a total knee arthroplasty (TKA) has on dynamic and static balance using the NeuroCom® Balance Master and functional mobility and balance tests. The NeuroCom® Balance Master is a computerized machine that utilizes two force plates to assess balance. Strength testing, using the Cybex machine, and range of motion testing will be done to assess your knee function. The NeuroCom® Balance Master, Cybex machine and balance tests are clinically accepted and reliable tools which are commonly used to assess individuals in a physical therapy setting. All testing will be performed at the Altru Health Institute.

Participants involved in the study must have undergone a TKA at least 6 months ago. You will be asked to complete a brief health questionnaire prior to participation in this study to see if all inclusion criteria are met. The inclusion criteria are as follows: 50 years of age or older, no use of an assistive walking device, no medications that affect balance, no symptoms suggesting vestibular or neurological disorders (dizziness/lightheadedness), no recent history of heart/blood pressure problems since TKA surgery and no recent additional orthopedic problems involving the low back or legs. You will be asked to wear loose, comfortable clothing and will be barefoot during all balance testing.

Your participation in this study will be a one-time session involving the following: completion of the SF-36 Health Survey; an assessment on the NeuroCom® Balance Master, which will include standing on one leg at a time and rising from a seated position to standing; the Timed Up and Go functional balance test, which requires you to stand up and walk 10 feet, turn around and return to the chair; and objective strength and range of motion measurements of the knee. Testing will last approximately 50-60 minutes. This study is voluntary for participants and you are free to discontinue participation at any time. By participating in this study, this will in no way affect your relationship with the University of North Dakota and Altru Health Systems.

Although there is a risk for falls involved in the process of balance assessment, researchers feel the risks are minimal through proper instructions and supervision with a spotter throughout testing procedures. Also, as a result of any type of exercise, minimal muscle soreness may result from testing. In the unlikely event that this research activity results in a physical injury, medical treatment will be available as it is to a member of the general public in similar circumstances. The University of North Dakota, Altru Health Systems, and the researchers are not responsible for any such injury or treatment. Payment for any such treatment must be provided by you or your third party payer, if applicable.

This study has the potential for benefits to both individual participants and society. Through assessment using the NeuroCom® Balance Master, the Timed Up and Go, components of the Berg Balance test, and strength and range of motion testing, each participant will learn about his/her functional status following a TKA. Data results will help provide physical therapists and other health care professionals with information regarding the appropriate length of rehabilitation needed to enable TKA patients to resume prior functional status. The outcomes of the study will also be available for review by either 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 confidentiality of any subject information and results of this study. You will be assigned a random number and this will be used to represent your data. All information pertaining to this study will be stored in a locked cabinet at the Physical Therapy Department at the University of North Dakota. This information will only be available to the investigators/adviser conducting this study. These records will be kept for at least three years after this study, after which, all data will be shredded.

You will be provided with a copy of this consent form. The investigators are available to answer any questions you might have concerning this study now or in the future. Questions may be answered by contacting Connie Christensen (701) 777-9347, Niccole Riddle (701) 746-6904, Nicole Sukut (701) 777-9393, Cara Uyema (701) 777-9475, or our adviser, Meridee Danks, (701) 777-3861. If you have any other questions or concerns, please call the Office of Research and Program Development (ORPD) for Altru Health Systems at (701) 780-6161 or the ORPD for the University of North Dakota at (701) 777-4279.

I understand that my medical records and study records are confidential. However, representatives of the study sponsor, the U.S. Food and Drug Administration (FDA), or the Institutional Review Board (IRB) may need to inspect my medical and/or study records. By signing the consent, I am allowing this inspection.

I HAVE READ ALL OF THE ABOVE AND ALL MY QUESTIONS HAVE BEEN ANSWERED. I AM ENCOURAGED TO ASK ANY QUESTIONS CONCERNING THIS TEST SHOULD THEY ARISE. MY SIGNATURE BELOW INDICATES THAT I WILLINGLY AGREE TO PARTICIPATE IN THIS STUDY EXPLAINED TO ME BY CONNIE CHRISTENSEN, NICCOLE RIDDLE, NICOLE SUKUT, AND CARA UYEMA.

Participant's Signature **Date**

Witness **Date**

APPENDIX C

Reference # _____

The SF-36v2® Health Survey

Instructions for Completing the Questionnaire

Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble that best represents your response.

EXAMPLE

This is for your review. Do not answer this question. The questionnaire begins with the section ***Your Health in General*** below.

For each question you will be asked to fill in a bubble in each line:

1. **How strongly do you agree or disagree with each of the following statements?**

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
a) I enjoy listening to music.	○	●	○	○	○
b) I enjoy reading magazines.	●	○	○	○	○

Please begin answering the questions now.

Your Health in General

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

Excellent	Very good	Good	Fair	Poor	
O_1	O_2	O_3	O_4	O_5	GH01

2. **Compared to one year ago, how would you rate your health in general now?**

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago	
O_1	O_2	O_3	O_4	O_5	HT

Please turn the page and continue.

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

	Yes, limited a lot	Yes, limited a little	No, not limited at all	
a) **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	O_1	O_2	O_3	PF01
b) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	O_1	O_2	O_3	PF02
c) Lifting or carrying groceries	O_1	O_2	O_3	PF03
d) Climbing **several** flights of stairs	O_1	O_2	O_3	PF04
e) Climbing **one** flight of stairs	O_1	O_2	O_3	PF05
f) Bending, kneeling, or stooping	O_1	O_2	O_3	PF06
g) Walking **more than a mile**	O_1	O_2	O_3	PF07
h) Walking **several hundred yards**	O_1	O_2	O_3	PF08
i) Walking **one hundred yards**	O_1	O_2	O_3	PF09
j) Bathing or dressing yourself	O_1	O_2	O_3	PF10

4. **During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time	
a) Cut down on the **amount of time** you spent on work or other activities	O_1	O_2	O_3	O_4	O_5	RP01
b) **Accomplished less** than you would like	O_1	O_2	O_3	O_4	O_5	RP02
c) Were limited in the **kind** of work or other activities	O_1	O_2	O_3	O_4	O_5	RP03
d) Had **difficulty** performing the work or other activities (for example, it took extra effort)	O_1	O_2	O_3	O_4	O_5	RP04

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

	All of the time	Most of the time	Some of the time	A little of the time	None of the time	
a) Cut down on the **amount of time** you spent on work or other activities	O_1	O_2	O_3	O_4	O_5	RE01
b) **Accomplished less** than you would like	O_1	O_2	O_3	O_4	O_5	RE02
c) Did work or other activities **less carefully than usual**	O_1	O_2	O_3	O_4	O_5	RE03

6. **During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?**

Not at all	Slightly	Moderately	Quite a bit	Extremely	
O_1	O_2	O_3	O_4	O_5	SF01

7. **How much bodily pain have you had during the past 4 weeks?**

None	Very mild	Mild	Moderate	Severe	Very severe	
O_1	O_2	O_3	O_4	O_5	O_6	BP01

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

Not at all	A little bit	Moderately	Quite a bit	Extremely	
O_1	O_2	O_3	O_4	O_5	BP02

9. **These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time	
a) did you feel full of life?	O_1	O_2	O_3	O_4	O_5	VT01
b) have you been very nervous?	O_1	O_2	O_3	O_4	O_5	MH01
c) have you felt so down in the dumps that nothing could cheer you up?	O_1	O_2	O_3	O_4	O_5	MH02
d) have you felt calm and peaceful?	O_1	O_2	O_3	O_4	O_5	MH03
e) did you have a lot of energy?	O_1	O_2	O_3	O_4	O_5	VT02
f) have you felt downhearted and depressed?	O_1	O_2	O_3	O_4	O_5	MH04
g) did you feel worn out?	O_1	O_2	O_3	O_4	O_5	VT03
h) have you been happy?	O_1	O_2	O_3	O_4	O_5	MH05
i) did you feel tired?	O_1	O_2	O_3	O_4	O_5	VT04

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

All of the time	Most of the time	Some of the time	A little of the time	None of the time	
O_1	O_2	O_3	O_4	O_5	SF02

11. **How TRUE or FALSE is <u>each</u> of the following statements for you?**

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false	
a) I seem to get sick a little easier than other people	O_1	O_2	O_3	O_4	O_5	GH02
b) I am as healthy as anybody I know	O_1	O_2	O_3	O_4	O_5	GH03
c) I expect my health to get worse	O_1	O_2	O_3	O_4	O_5	GH04
d) My health is excellent	O_1	O_2	O_3	O_4	O_5	GH05

Questionnaire **Reference Number: _____**

Age: _____ Height: _____ Weight: _____
Total Knee Arthroplasty (TKA): (circle one) Right/Left/Both
Date of total knee arthroplasty surgery (mo/yr): _____
Have you had any previous surgeries/injuries other than the total knee arthroplasty?
Please indicate:

Past Medical History: (heart/blood pressure/vestibular/neurologic disorders, etc.)

Are you taking any medication(s)? Y/N
If so, please list:

Do you use an assistive walking device? Y/N
Please indicate the type of device and how often you use it.

Have you fallen at any time in the past week, month, or year? Y/N
How often does this occur? _____
Are you presently under the care of a physical therapist? Y/N
If yes, explain for what reason? _____

Did you perform exercises with your involved knee prior to TKA surgery? Y/N
If yes, what type and how often? _____
How many days were you in the hospital following your TKA surgery? _____
Did you receive outpatient PT or Home Health PT after TKA surgery? Y/N
If yes, for how long? _____
How long did you perform your TKA home exercise program given to you by your physical therapist? _____
Please indicate the type of exercises and how often you perform them.

Rate your activity level before your total knee arthroplasty to your current activity level after your total knee arthroplasty. (circle one)
Activity level equal Activity level greater Activity level less

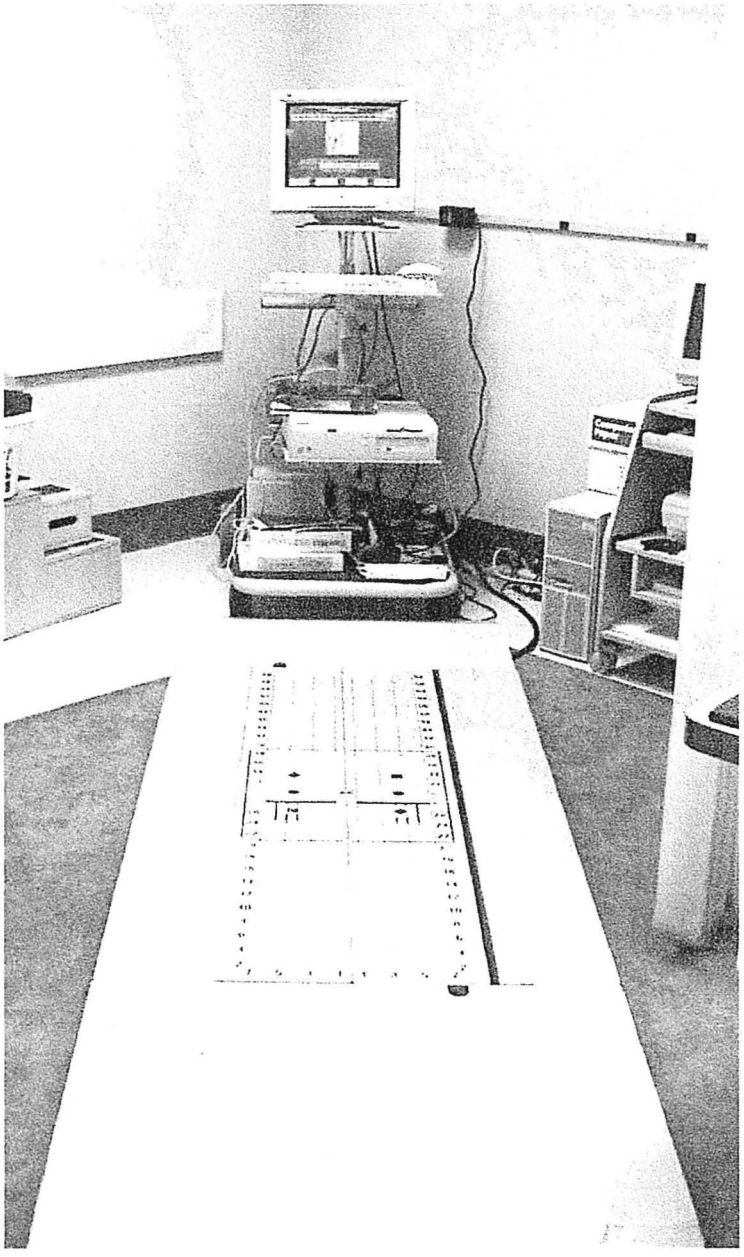
Please indicate the type of physical activity/exercise you presently participate in:

About how many times per week? (circle one)
1-2 days 2-3 days 3-4 days 4-5 days >5 days

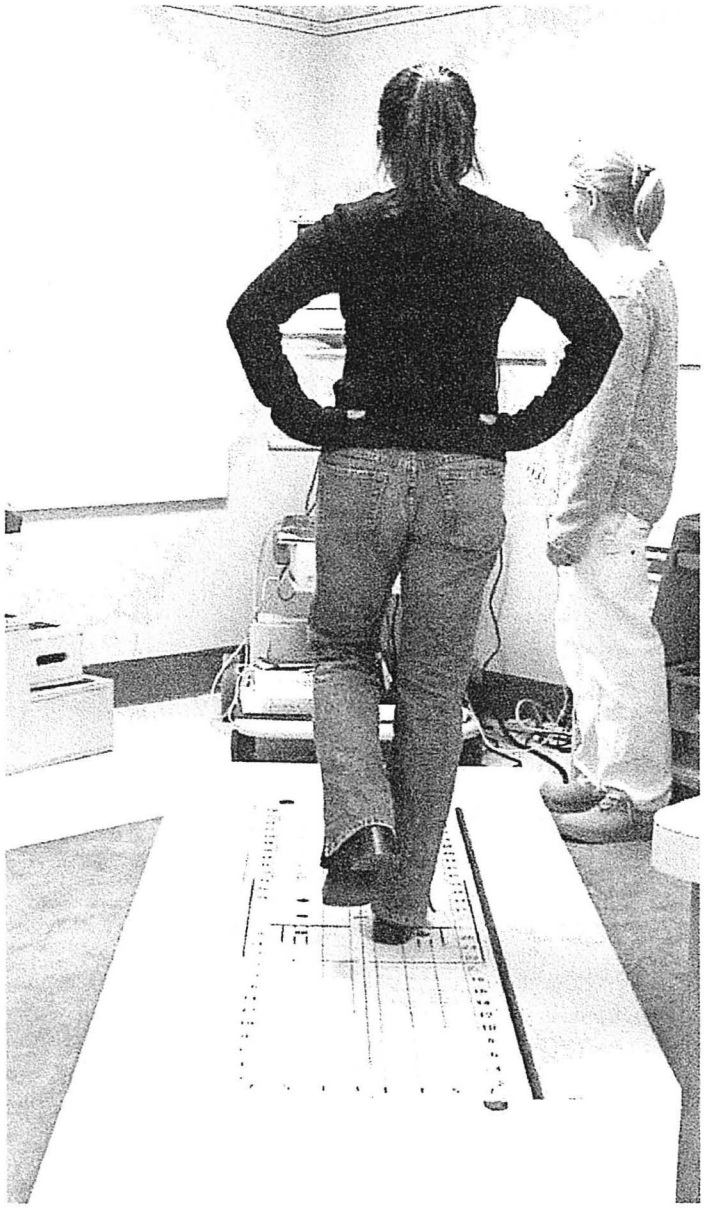
Approximately how long does each session last? (circle one)
10-20 min. 20-30 min. 30-45 min. 45-60 min. >60 min.

What would you like to do that you cannot do presently?

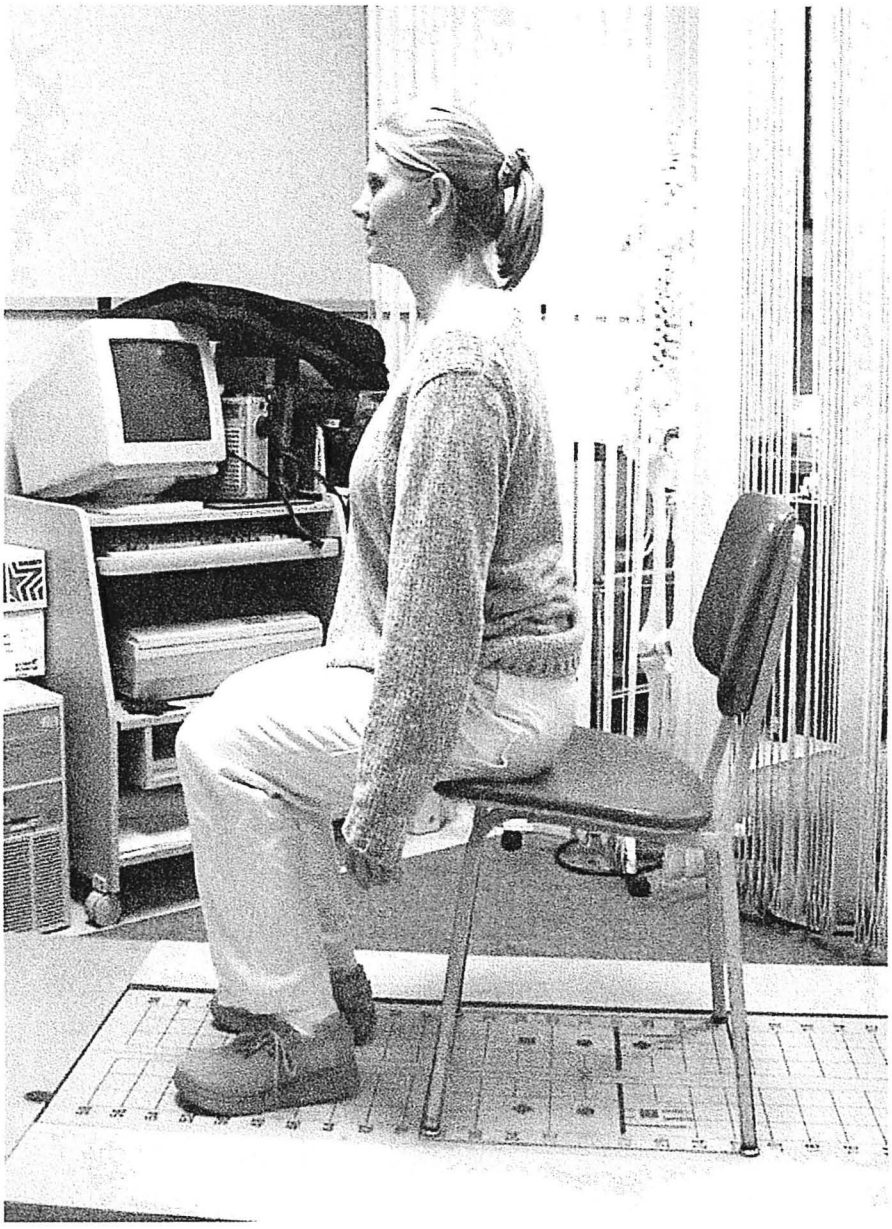
APPENDIX D



NeuroCom Balance Master
Computer and Forceplates



Beginning Position for the Unilateral Stance component of the NeuroCom Balance Master



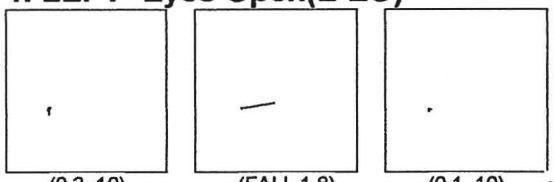
Testing Position for the Sit-to-Stand component of the NeuroCom Balance Master

APPENDIX E

Name: 10, 10	**Diagnosis:** Not Specified	**File:** FD114.DRX
ID: ATID00114	**Operator:** Not,Specified	**Date:** 10/24/2002
Date of Birth:	**Referral Source:** Not Specified	**Time:** 14:04:26
Height: 5'7"	**Comments:** (B) TKA, (R) TKA most recent	

Unilateral Stance

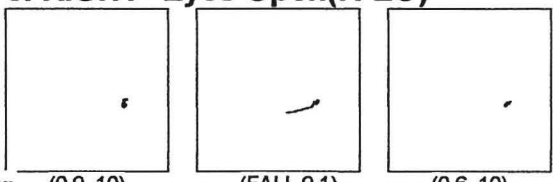
1. LEFT--Eyes Open(L-EO)



(0.3, 10) Trial 1 | (FALL,1.8) Trial 2 | (0.1, 10) Trial 3

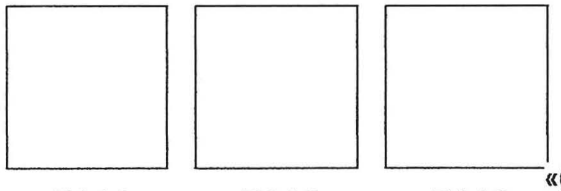
«(deg/sec)»

3. RIGHT--Eyes Open(R-EO)



(0.9, 10) Trial 1 | (FALL,9.1) Trial 2 | (0.6, 10) Trial 3

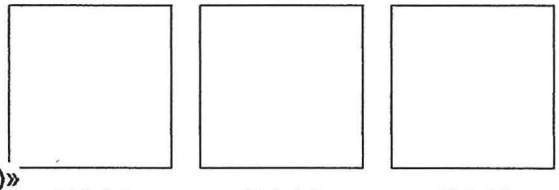
2. LEFT--Eyes Closed(L-EC)



Trial 1 | Trial 2 | Trial 3

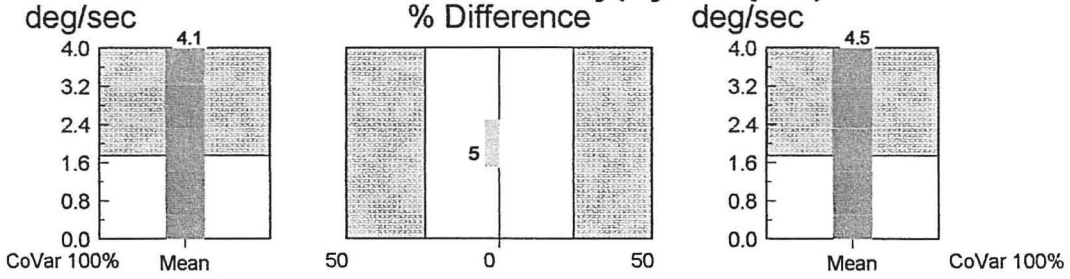
«(deg/sec)»

4. RIGHT--Eyes Closed(R-EC)

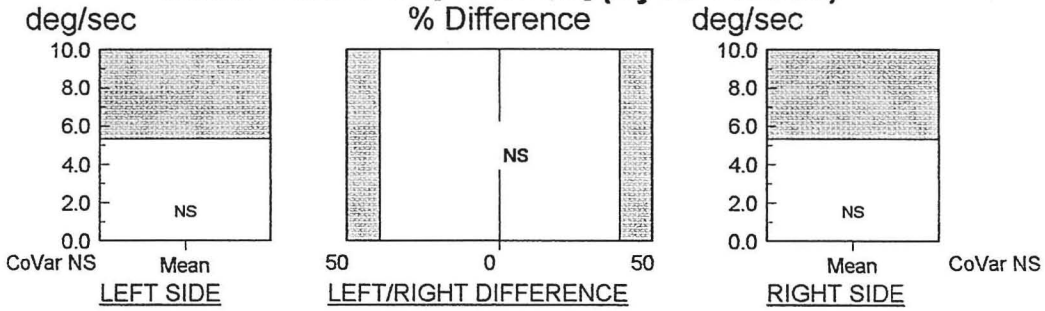


Trial 1 | Trial 2 | Trial 3

Mean COG Sway Velocity(Eyes Open)



Mean COG Sway Velocity(Eyes Closed)



Data Range Note: User Data Range: 60--69

Post Test Comment:

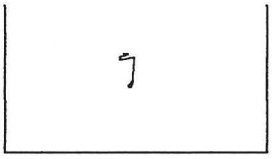
APPENDIX F

Name: 10, 10
ID: ATID00114
Date of Birth:
Height: 5'7"

Diagnosis: Not Specified
Operator: Not,Specified
Referral Source: Not Specified
Comments: (B) TKA, (R) TKA most recent

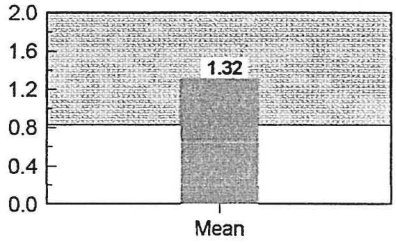
File: FD114.DRX
Date: 10/24/2002
Time: 14:34:43

Sit To Stand



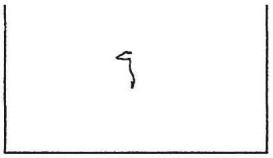
Trial 1

sec WT Transfer

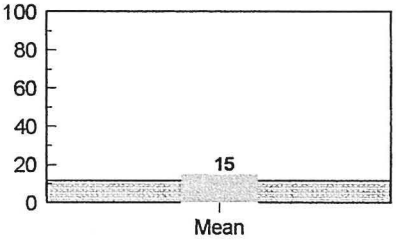


CoVar 21%

%Body Wt Rising Index

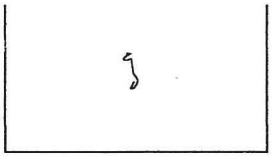


Trial 2

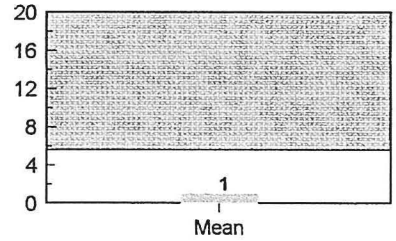


CoVar 16%

deg/sec COG Sway Velocity

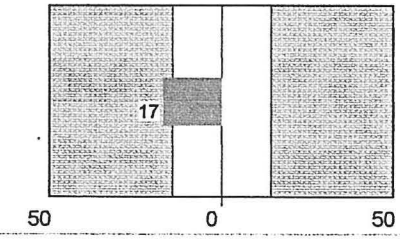


Trial 3



CoVar 22%

% Left/Right Weight Symmetry



CoVar 11%

Data Range Note:
User Data Range: 60--69

Post Test Comment:

APPENDIX G

Data Collection Sheet Reference # _____

Title: The Effects a Total Knee Arthroplasty has on Static and Dynamic Balance.

1. **Berg Balance Measure – 2 components**

Sitting to Standing

Instructions: Use a chair with arms. Ask the patient to stand up. If the patient stands up using the arms of the chair, ask the patient to stand up without using hands if possible.

Grading: Please mark the lowest category that applies.

(4) Able to stand, no hands and stabilize independently
(3) Able to stand independently using hands
(2) Able to stand using hands after several tries
(1) Needs minimal assist to stand or stabilize
(0) Needs moderate or maximal assist to stand

Trial 1 _____ Trial 2 _____ Trial 3 _____

Standing on One Leg

Instructions: Stand on one leg as long as you can without holding on to an external support.

Grading: Please mark the lowest category that applies.

(4) Able to lift leg independently and hold more than 10 seconds
(3) Able to lift leg independently and hold for 5 to 10 seconds
(2) Able to lift leg independently and hold up to 3 seconds
(1) Tries to lift leg, unable to hold 3 seconds, but remains standing independently
(0) Unable to try or needs assist to prevent fall

	Left	**Right**
Trial 1	_____	_____
Trial 2	_____	_____
Trial 3	_____	_____

2. **The Timed Up and Go (TUG)**

Instructions: The participant is instructed to perform the following tasks while a trained observer watches, evaluates and times the performance. The participant is asked to stand up from a chair, walk 3 meters, turn around, and return to the chair and to sit down.

Grading of Performance: Time: _____

(1) normal
(2) very slightly abnormal
(3) mildly abnormal
(4) moderately abnormal
(5) severely abnormal

3. **Objective Knee Measurements:**

		Left	**Right**
AROM: (supine)	Flexion	_____	_____
	Extension	_____	_____
Strength: (isokinetic)			
Muscle Torque	Flexion	_____	_____
	Extension	_____	_____
Total Work	Flexion	_____	_____
	Extension	_____	_____

APPENDIX H

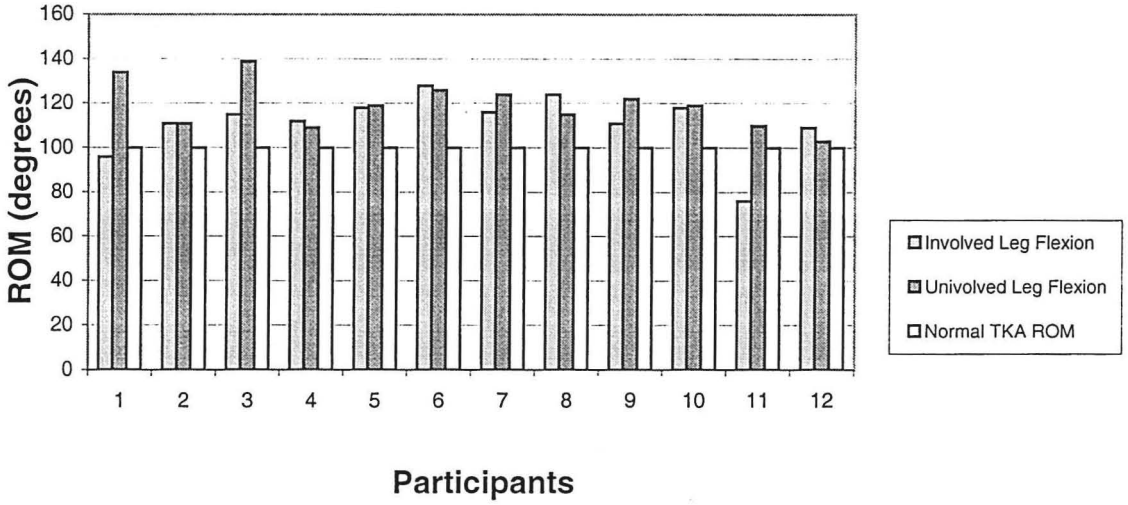


Figure 1. Flexion range of motion of the involved and uninvolved knee compared to normal TKA range of motion. Participants 7-10, and 12 have bilateral TKAs.

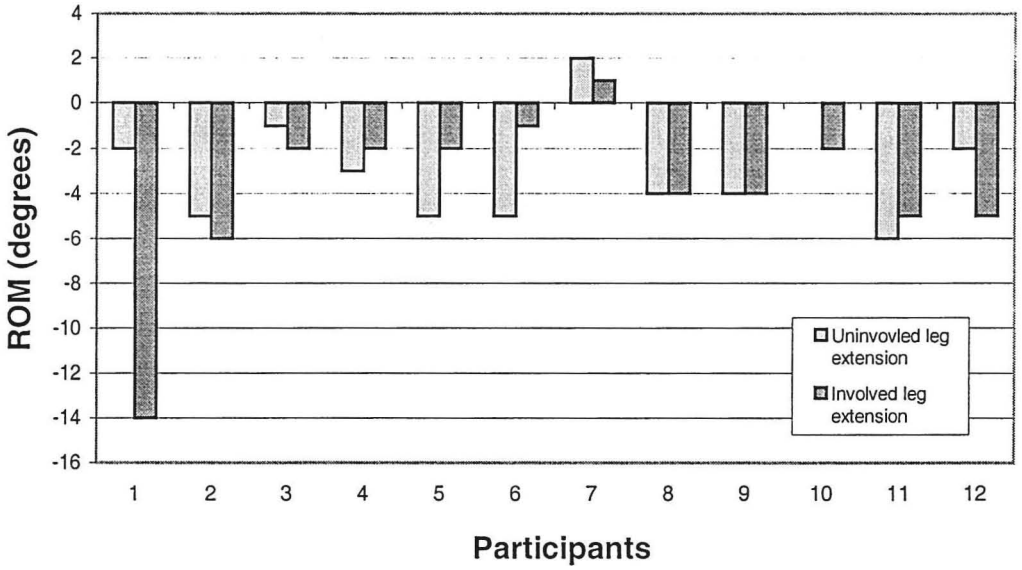


Figure 2. Extension range of motion of the involved and uninvolved knee. Negative numbers denote the number of degrees lacking full extension. Full extension = 0 degrees and is normal.

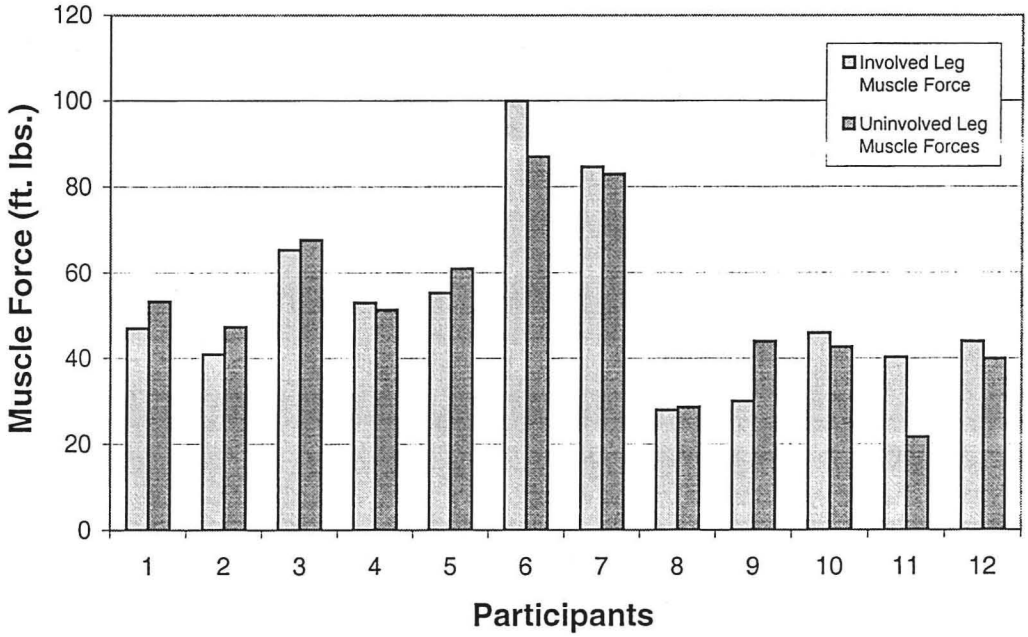


Figure 3. The amount of knee extension muscle force of the involved compared to the uninvolved lower extremity.

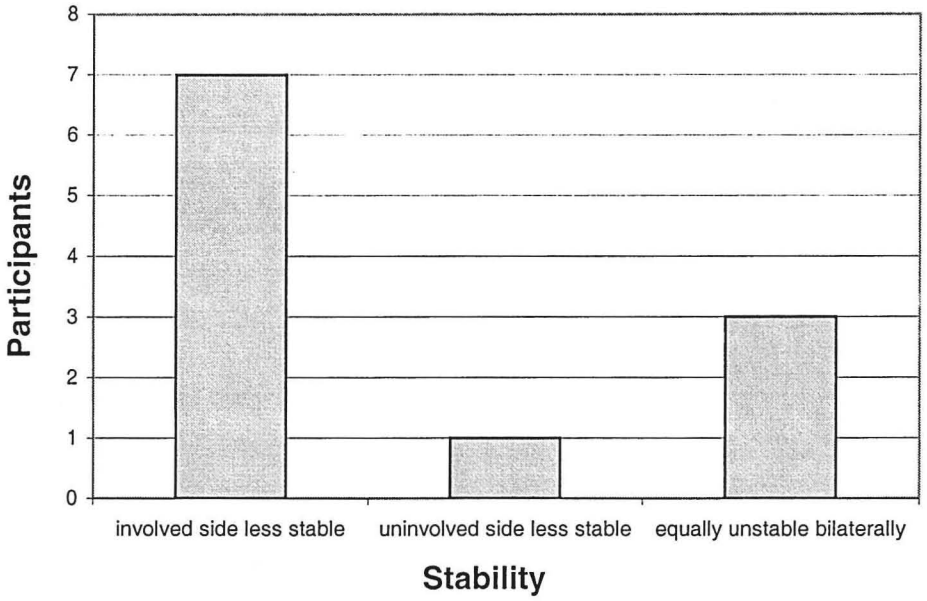


Figure 4. The lower extremity that the participant is less stable on during the US.

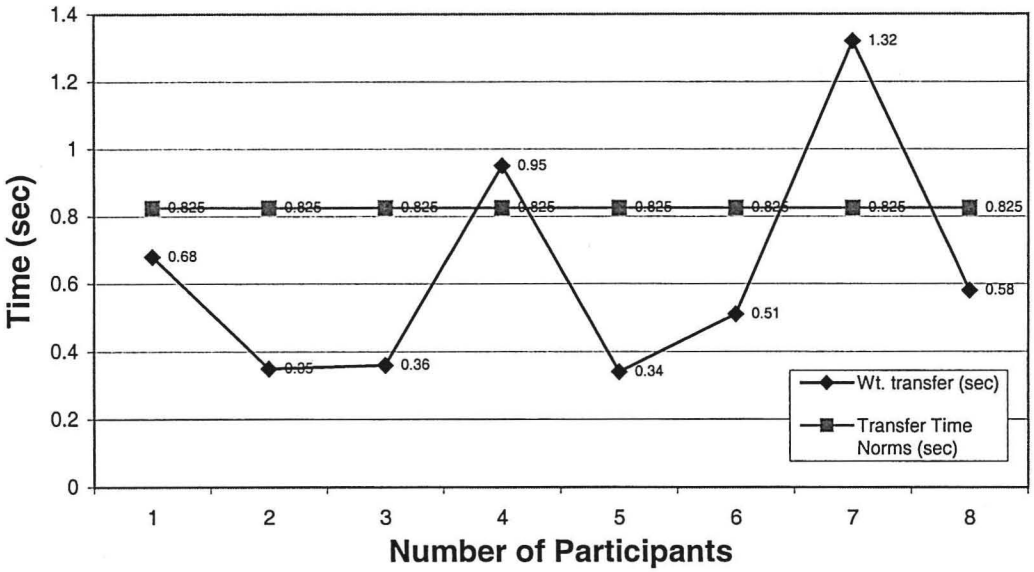


Figure 5. Weight transfer times for the STS for age groups 40-59 and 60-69. A score below 0.825 is considered normal for these age groups.

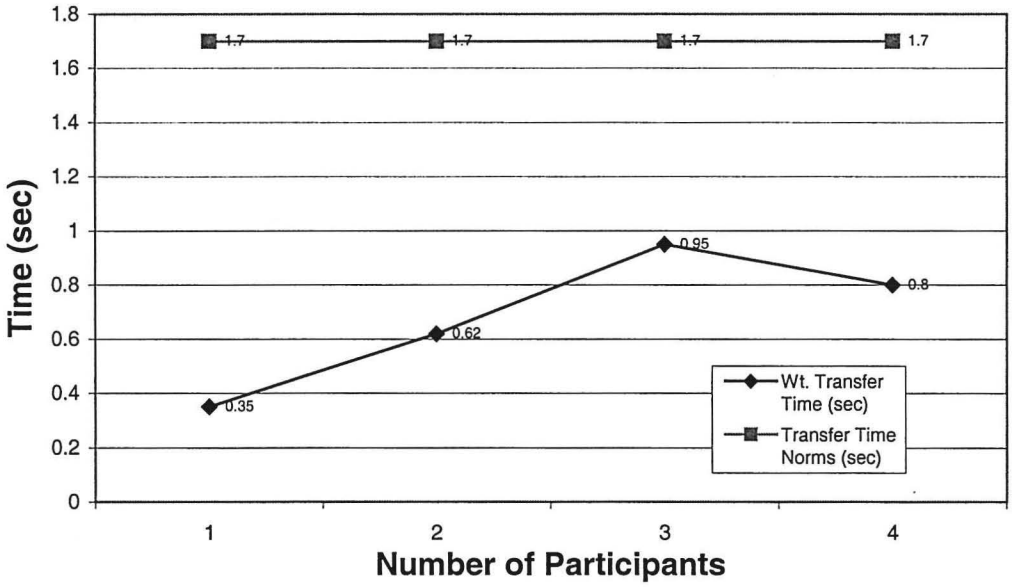


Figure 6. Weight transfer times for the STS for the age group of 70-79. A score below 1.7 is considered normal for this age group.

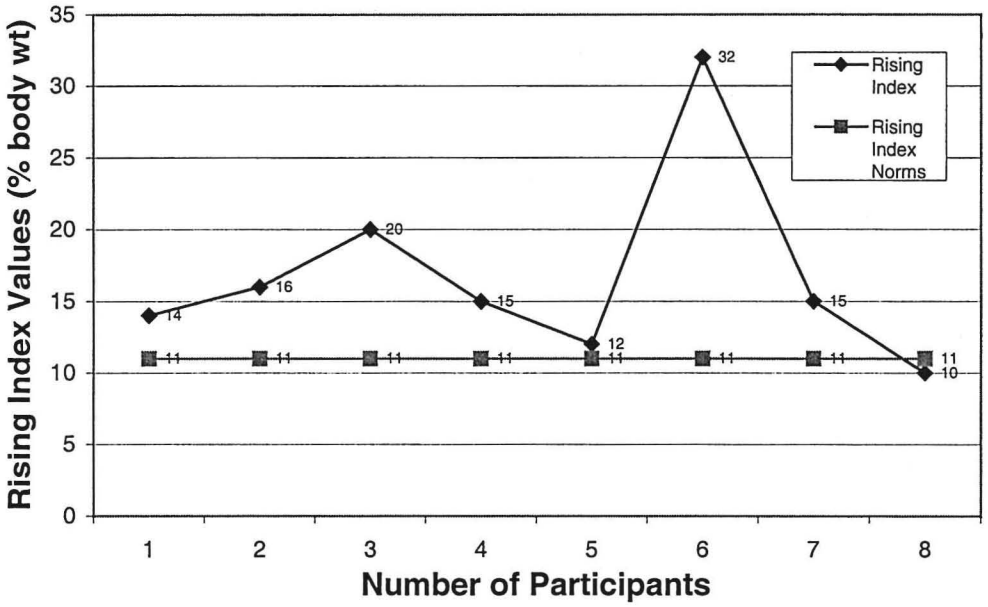


Figure 7. Rising index for the STS for the age groups of 40-59 and 60-69. A score above 11 is considered normal for these age groups.

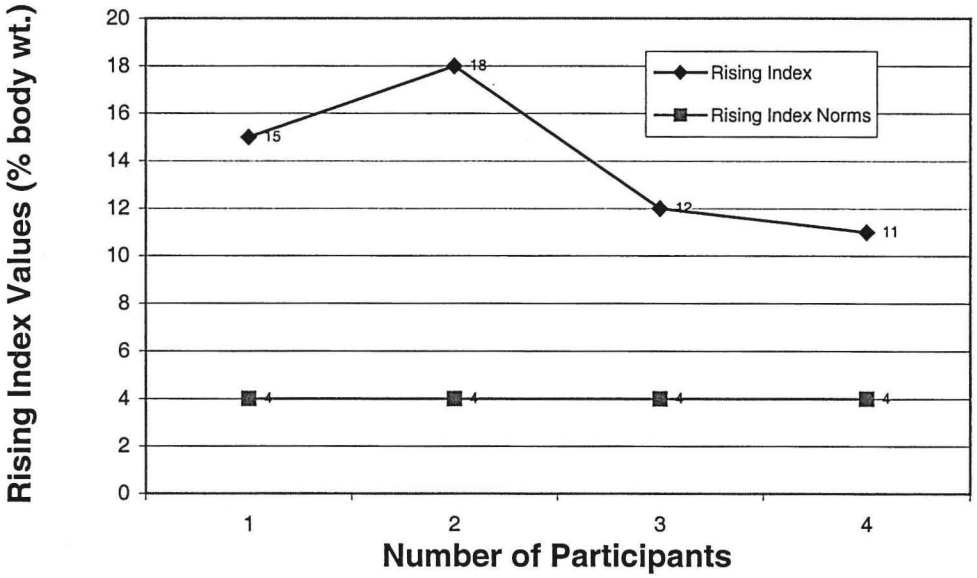


Figure 8. Rising index for the STS for the age group of 70-79. A score above 4 is considered normal for this age group.

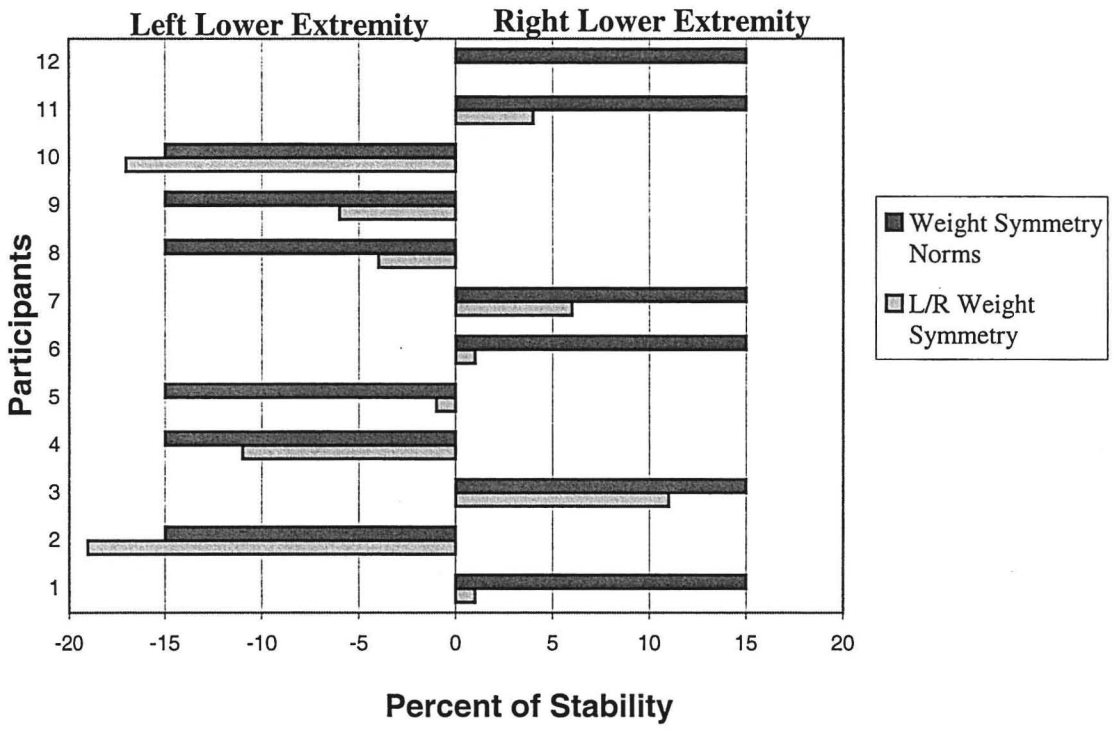


Figure 9. Left to right weight symmetry for the STS compared to a weight symmetry norm.

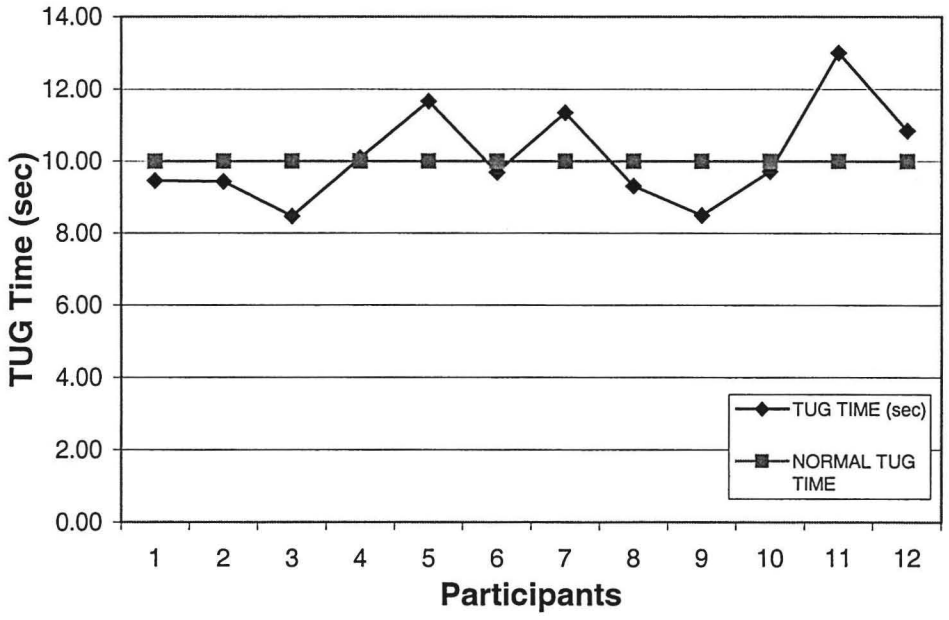


Figure 10. The participants' TUG time scores compared to a normal TUG time of 10 seconds.

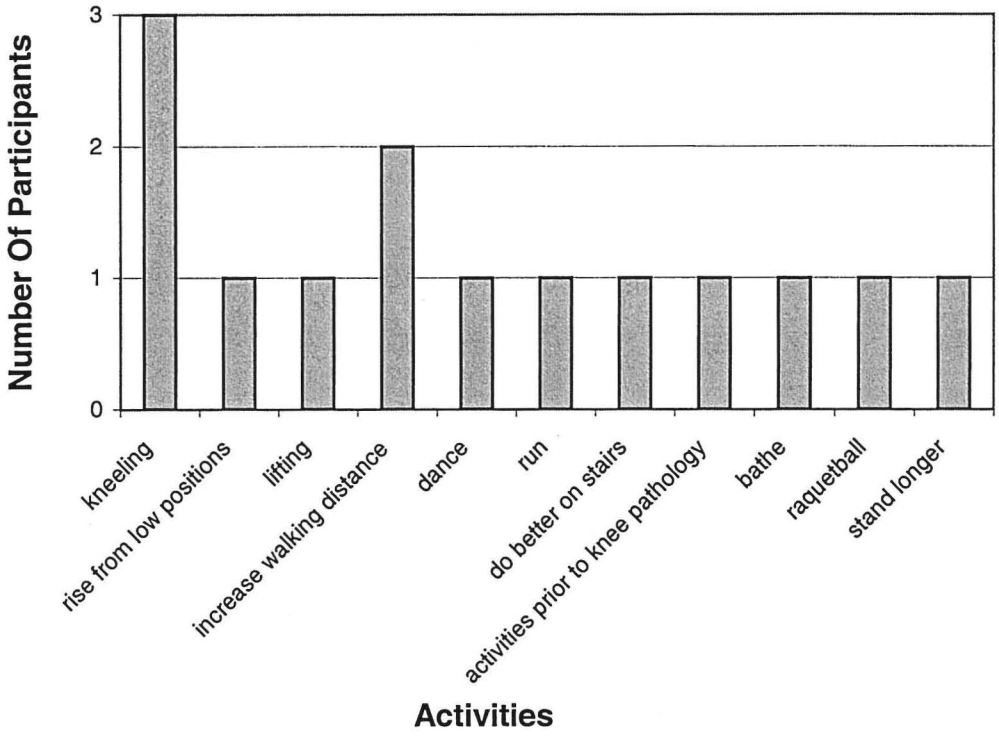


Figure 11. Activities participants reported they would like to be able to perform.

Table 4. SF-36 Health Status Survey

SF-36 Physical Function (PF) and Physical Component Summary PCS)				
Subjects	PF	PF NORM	PCS	PCS NORM
45-54 years old				
1	48.62	49.72	51.65	49.62
2	36.00	49.72	34.23	49.62
55-64 years old				
3	40.20	47.25	47.75	47.44
5	38.10	47.25	46.57	47.44
6	42.30	47.25	49.61	47.44
10	31.78	47.25	38.76	47.44
12	46.51	47.25	54.37	47.44
65-74 years old				
4	48.62	43.60	50.43	44.70
7	57.03	43.60	59.01	44.70
8	33.88	43.60	38.03	44.70
9	27.57	43.60	32.16	44.70
75 & older				
11	23.36	39.68	25.08	40.00

REFERENCES

1. Wallmann HW. Balance and postoperative lower extremity joint replacement. *Orthop Phys Ther Clin North Am.* 2002:101-108.
2. Kurosaka M, Yoshiya S, Mizuno K, Yamamoto T. Maximizing flexion after total knee arthroplasty: the need and the pitfalls. *J Arthroplasty.* 2002; 17(4):59-62.
3. Itokazu M, Uemura S, Aoki T, Takatsu T. Analysis of rising from a chair after total knee arthroplasty. *Bull Hosp Jt Dis.* 1998;57(2):88-92.
4. Roach KE, Miles TP. Normal hip and knee active range of motion: The relationship to age. *Phys Ther.* 1991;71(9):656-65.
5. Maxey L, Magnusson J. *Rehabilitation for the postsurgical orthopedic patient.* St Louis, Mo: Mosby, Inc; 2001:268-86.
6. Walsh M, Woodhouse LJ, Thomas SG, Finch E. Physical impairments and functional limitations: a comparison of individuals 1 year after total knee arthroplasty with control subjects. *Phys Ther.* 1998;78(3):248-58.
7. Oldmeadow LB, McBurney H, Robertson VJ. Hospital stay and discharge outcomes after knee arthroplasty. *J Qual Clin Pract.* 2001;21(3):56-60.
8. Skinner HB, Barrack RL, Cook SD, Haddad RJ Jr. Joint position sense in total knee arthroplasty. *J Orthop Res.* 1984;1(3):276-83.
9. Fernandez F. Balance Rehabilitation Using the Balance Master. 1997.

10. Daubney ME, Culham EG. Lower-extremity muscle force and balance performance in adults aged 65 years and older. *Phys Ther.* 1999;79(12):1177-85.
11. Bartolo C, Miller K, Seals R, Stotesbery C. *Examination of Tester Reliability Utilizing the Limits of Stability on the NeuroCom Balance Master for Assessing Balance in Healthy Individuals* [master's thesis]. Grand Forks, ND: University of North Dakota; 2001.
12. Nashner LM. Sensory, Neuromuscular, and Biomechanical Contributions to Human Balance. NeuroCom International Inc., Clackamas, Ore.
13. Liston RAL, Brouwer BJ. Reliability and validity of measures obtained from stroke patients using the balance master. *Arch Phys Med Rehbail.* 1996;77(5):425-30.
14. Daubney ME, Culham EG. Lower-extremity muscle force and balance performance in adults aged 65 years and older. *Phys Ther.* 1999;79(12):1177-1185.
15. Nashner LM. The need for balance centers. Clackamas, Ore: NeuroCom International Inc.
16. Hageman PA, Leibowitz M, Blanke D. Age and gender effects on postural control measures. *Arch Phys Med Rehabil.* 1995;76(10):961-5.
17. Allison L. Identifying and Managing Elderly Fallers. Clackamas, Ore: NeuroCom International Inc.
18. Su FC, Lai KA, Hong WH. Rising from chair after total knee arthroplasty. *Clin Biomech.* 1998;13(3):176-181.

19. Nashner L. Comprehensive Management of Balance and Mobility Disorders. Available at: http://www.onbalance.com/main.cfm?action=medical. Accessed on August 22,2000.

20. NeuroCom International, Inc. Setting the Standard in Balance and Mobility. Available at: http://www.onbalance.com/index.ctm?action=balancemaster. Accessed on September 14, 2002.

21. Balance Master Version 7.1 Operator's Manual. Clackmas, Ore: NeuroCom International, Inc.;1998.

22. Janssen WG, Bussmann HB, Stam HJ. Determinants of the sit-to-stand movements: A review. *Phys Ther.* 2002;82(9):866-977.

23. Lewek M, Stevens J, Snyder-Mackler L. The use of electrical stimulation to increase quadriceps femoris muscle force in an elderly patient following a total knee arthroplasty. *Phys Ther.* 2001;81(9):1565-71.

24. Walsh M, Woodhouse LJ, Thomas SG, Finch E. Physical impairments and functional limitations: A comparison of individuals one year after total knee arthroplasty with control subjects. *Phys Ther.* 1998;78(3):248-58.

25. Rossi MD, Brown LE, Whitehurst M, Charni C, Hankins J, Taylor CL. Comparison of knee extensor strength between limbs in individuals with bilateral total knee replacement. *Arch Phys Med Rehabil.* 2002;83(4):523-6.

26. Riddle DL, Stratford PW. Interpreting validity indexes for diagnostic tests: An illustration using the Berg Balance Test. *Phys Ther.* 1999;79(10):939-948.

27. Shumway-Cook A, Woollacott M. *Motor Control: Theory and Practical Applications*. 2nd ed. Philadelphia, Pa: Lippincott Williams and Wilkins; 2001:272,274,364-630.

28. Albright BH. Functional assessments: For the geriatric client. Rocky Mountain University. 2001.

29. Steffen TM, Hacker TA, Mollinger L. Age- and gender-related test performance in community-dwelling elderly people: Six-minute walk test, Berg Balance scale, Timed Up and Go test, and gait speeds. *Phys Ther.* 2002;82(2):130-135.

30. Wall JC, Bell C, Campbell S, Davis J. The Timed Get-Up-and-Go test revisited: Measurement of the component tasks. *J Rehabil Res Dev.* 2000;37(1):109-113.

31. SF-36 General Health Status Survey to Determine Patient Satisfaction at Short-term Follow-up after Total Hip and Knee Arthroplasty. Available at: http://www.smaserviceinc.com/soa/jsoafl97/3text.htm. Accessed September 20, 2002.

32. Kiebzak GM, Vain PA, Gregory AM, Mokris JG, Mauerhan DR. SF-36 general health status survey to determine patient satisfaction at short-term follow-up after total hip and knee arthroplasty. *J South Orthop Assoc.* 1997;6(3):169-72.

33. Ware JE, Kosinski M, Dewey JE. *How to Score: Version 2 of the SF-36® Health Survey*. Lincoln, RI: Quality Metric Incorporated:2000.

34. Dunbar MJ. Subjective outcomes after knee arthroplasty. *Acta Orthop Scand.* 2001; 72 (301):1-63.

35. Kendall F, McCreary E, Provance P. *Muscles: Testing and Function.* 4th ed. Philadelphia, Pa: Lippicott Williams and Wilkins;1993:412.

36. Berg K, Wood-Dauphinne S, Williams JI, Gayton D. Measuring balance in the elderly: Preliminary development of an instrument. *Physiother Can.* 1989; 41(6): 304-11.

37. Norkin CC, White DJ. *Measurement of Joint Motion: A Guide to Goniometry.* 1995; Philadelphia, Pa; F.A. Davis company:137-141.

38. Gay LR. *Educational Research: Competencies for Analysis and Application.* 5th ed. Columbus, Ohio: Prentice-Hall, Inc.;1996:260-61.

39. McMillan JH, Schumacher S. *Research in Education: A Conceptual Introduction.* 2nd ed. United States of America: Harper Collins Publishers;1989:160-161.