Two Case Studies: Evaluation of Balance following Unilateral Total Knee Arthroplasty

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TWO CASE STUDIES: EVALUATION OF BALANCE FOLLOWING UNILATERAL TOTAL KNEE ARTHROPLASTY

by

Cathy Siegfried
Bachelor of Science in Physical Therapy
University of North Dakota, 1998

An Independent Study
Submitted to the Graduate Faculty of the
Department of Physical Therapy
School of Medicine
University of North Dakota
in partial fulfillment of the requirements
for the degree of
Master of Physical Therapy

Grand Forks, ND
May
1999
This Independent Study, submitted by Cathy L. Siegfried in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

(Signatures)

(Faculty Preceptor)

(Graduate School Advisor)

(Chairperson, Physical Therapy)
PERMISSION

Title  Two Case Studies: Evaluation of Balance Following Unilateral Total Knee Arthroplasty

Department  Physical Therapy

Degree  Master of Physical Therapy

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Signature  Cathy Sigfried

Date  December 17, 1998
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ACKNOWLEDGEMENTS

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ABSTRACT

The purpose of this case study was to evaluate balance of individuals following total knee arthroplasty between 12 and 16 weeks postoperatively using the NeuroCom Balance Master® 6.1 system. Two unilateral total knee arthroplasty (TKA) subjects and ten age-matched control subjects participated in the study. All subjects completed a series of five assessments including weight bearing, limits of stability, walk test, step up and over, and sit to stand on the NeuroCom Balance Master® system. Results showed differences in the sit to stand and weight bearing tests with TKA subjects bearing more weight on nonsurgical leg. TKA subjects also differed from the control group in the walk test demonstrating a decreased walking velocity.
CHAPTER 1
INTRODUCTION

Total knee arthroplasty (TKA) is one of the most common surgeries performed on the knee joint. Many people who undergo the technique are over 65 years old, suffering from degenerative joint disease, and excessive pain in the knee joint. The goal of the procedure is to relieve pain and restore normal function of the knee. Restoration of normal function has become the main goal of TKA.¹

There are many key elements that are involved in determining if normal function has been attained. Various areas such as gait, stair climbing abilities, joint proprioception, and patient subjective ratings have been examined postoperatively to determine functional outcomes of TKA. Another area of concern following total knee arthroplasty is balance. Balance skills following TKA are not discussed or described in the literature, and there is little documentation concerning this functional skill that provides the base for many movements of the body following TKA. Balance needs to be maintained during movement and is achieved by postural reflexes initiated by several key sensory systems including vision, vestibular, and somatosensory systems. Elements of the musculoskeletal system are also involved including muscle contractions at the hip, knee, and ankle joints, which are coordinated through a kinetic chain. Balance deficits can slow the return of normal function and increase risk of falls due to instability.
Consideration of balance in post operative TKA individuals can provide information regarding outcomes of surgery and rehabilitation processes. Many times balance is a forgotten area in the rehabilitation of orthopedic populations. More information about balance is helpful to the physical therapy profession in planning rehabilitation goals and treatment programs. Without this information it is difficult to make clinically sound decisions concerning the treatment of these patients. The purpose of this study is to examine balance following unilateral TKA using the NeuroCom Balance Master®.

The research questions being considered in this study are: 1) Does balance following unilateral TKA differ from the age-matched control group? 2) Is there a difference in balance skills between the two TKA case study subjects?

Most knee prosthesis used have advanced design that are focusing on restoring normal function. However, no implant design can exactly replicate the motions and sensations of the anatomical knee. The null hypothesis is that there is no difference in balance between the total knee arthroplasty subject and the age matched control group.
CHAPTER 2
LITERATURE REVIEW

Total knee arthroplasty

Total knee arthroplasty (TKA) is one of the most common surgical procedures performed on the knee joint. TKA is a common referral to physical therapy for rehabilitation of the joint flexibility and strength. Before an individual has this surgery performed, consideration needs to be given to the person’s level of function and the degree of knee joint dysfunction. Major indications for TKA include knee pain, instability of the knee joint, limited knee range of motion, and deformity of the joint. Generally, these complications result from degenerative joint changes due to osteoarthritis. Of these indications, relief of pain is the major concern for most individuals undergoing the surgery. Post operatively 90% of TKA patients report little or no pain and over 90% achieve adequate joint stability.¹

Even though pain relief is a major consideration in TKA, restoration of normal knee joint function is essential. If the proper knee biomechanics are not achieved, both the patient perceived outcomes and clinical outcomes of the surgery will be poor. Relief of pain is no longer the ultimate of the joint replacement.

The anatomical knee joint structure consists of the femoral condyles articulating with the concave tibial condyles. The knee joint is given its stability through various ligaments including the medial collateral ligament, lateral collateral ligament, anterior...
cruciate ligament (ACL), and posterior cruciate ligament (PCL). If these ligaments are resected or damaged, the implant used must compensate for the loss of stability that will occur in the knee.

The primary motions of the knee joint are flexion/extension and medial/lateral rotation. The axis of rotation for flexion and extension passes horizontally through the femoral condyles with the medial side lower than the lateral aspect of the joint, causing the axis to be slightly oblique. This is not a static axis of motion, but instead moves throughout the range of motion. To be a functional and effective prosthetic, an implant needs to replicate as close as possible these normal functions of the knee. However, an implant can never replace the normal biomechanics of the knee.

Many of the early TKA surgeries had poor outcomes resulting in a nonfunctional knee. TKA has evolved over the years through improved prosthetic design and surgical techniques that have concentrated not only on increasing function of the knee but also the longevity of the prosthesis. Initially, knee prostheses focused on pain relief without much consideration of knee kinematics or normal joint structure. The first knee implant designs were uniaxial that restricted knee motion to flexion-extension axis only and provided excessive restriction. These implants did not allow for the tibial rotation that occurs at the knee nor for the anterior and posterior translations of the tibia on the femur. The poor outcomes from these designs led to the evolution of the more current multiaxial prosthesis to allow for movement in multiple planes similar to the anatomical knee joint.1

Although many improvements have been made in prosthetic design, persons with total knee arthroplasty continue to experience functional limitations post operatively. In comparing individuals with TKA one year post operatively to normal age related...
individuals, Walsh and associates\textsuperscript{2} found that the TKA group had significant deficits in the areas of walking speed, stair climbing ability, and knee extensor strength when compared to normal control subjects. These functional limitations are often important in aspects of everyday living. Deficits in these areas result in the individuals having decreased ability to perform simple activities within the home or their chosen lifestyle.

Achieving a normal function of the knee joint does not appear to depend on the type of prosthetic design used. In an analysis of bilateral knee replacement with two different systems, one being a semiconstrained loose hinge prosthesis and the other an unconstrained low-contact-stress mobile bearing prosthesis, it was found that stride parameters were symmetrical but did not approach the normal gait parameters of stride length, gait velocity, and single limb stance duration in healthy elderly individuals.\textsuperscript{3} Other studies regarding gait following TKA have shown abnormalities in the gait pattern in the areas of stride length and stance time.\textsuperscript{2,4,5}

However, knee replacement does have a positive effect on the gait characteristics of individuals. Berman and coworkers\textsuperscript{6} looked at the functional results of TKA in individuals with osteoarthritis. Three groups were compared: unilateral knee replacement with no signs and symptoms of arthritis in the contralateral knee, unilateral knee replacement with asymptomatic arthritis in the contralateral knee, and bilateral knee replacements. Postoperatively, all groups showed improvement in the values of almost all parameters of gait including velocity, stride length, and step length, but these values did not approach the levels of normal healthy individuals.

Seen from these studies of TKAs, it is suggested that although gait does improve from the reduction of pain following knee arthroplasty, a normal gait pattern is not
achieved. Other factors such as prosthetic design, muscle weakness, and joint range of motion are playing a role in the attainment of normal gait. Perhaps balance and proprioception deficits are also playing a role in attainment of normal stride characteristics for TKA individuals.

**Balance**

Balance is the body's ability to maintain the center of gravity (COG) over the base of support (BOS).\(^7\)\(^8\) The COG is located at the level of the second sacral vertebrae and slightly anterior to the joint axis of the ankle. The limits of stability (LOS), which are the maximum anterior, posterior, and lateral sway angles that keep the COG within the support area, are also important to consider in balance. If the limits are exceeded, postural corrections to reestablish equilibrium are needed or a fall will occur. These corrections made by the body are controlled through various systems involving both feed forward and feedback pathways.

Balance is a complex process that involves many sensory and musculoskeletal components responding through multiple afferent and efferent pathways. Sensory systems involved include vision, touch, proprioception, vibration sense, and vestibular sense. Muscle strength and neuromuscular control are the musculoskeletal components involved. Balance control is achieved through inputs from visual, vestibular, and somatosensory systems. The input is processed by central neural centers that result in a planned motor response to maintain the body's upright alignment in relation to the surroundings.\(^8\)
Many of the planned motor responses are in the form of automatic postural synergies. These motor patterns involve the ankle, hip, suspensory, and stepping strategies. The ankle strategy works well for small disturbances within the limits of stability by responding with small movements caused by muscle contraction sequence from distal to proximal. Larger disturbances require use of the hip strategy to restore alignment with the muscle contraction sequence from proximal to distal beginning with the hip musculature. The suspensory strategy occurs when the individual leans forward with flexion of the hips and knees to a slightly flexed position which lowers the COG and making balance control easier. When the limits of stability are surpassed, the stepping strategy is employed and a step is taken in any direction to prevent a fall. In this case the BOS is moving to get under the COG. The combined effect of these motor responses leads to postural control and maintenance within the limits of stability. A combination of the ankle, knee, and hip strategies is used to move the COG and maintain balance, but an injury to any of these joints or muscles can result in a loss of correct feedback for maintaining balance and possibly a fall.\textsuperscript{9}

Much of the input for the postural strategies comes from the proprioceptive senses. There are several types of proprioceptors present in the musculoskeletal system. In skeletal muscles there are muscle spindles, Golgi Tendon Organs (GTO), free nerve endings, and pacinian corpuscles. Ruffini’s endings, paciniform corpuscles, and free nerve endings are located in the joint capsule. Ruffini’s endings are responsible for the direction and velocity of joint movement, whereas paciniform endings monitor rapid joint movements. Golgi tendon-like organs, which detect the rate of joint movement, can be
found in the ligaments. These proprioceptors and mechanoreceptors are important in controlling postural sway and involved in an extensive feedback system.\textsuperscript{10}

The muscle spindle, which is sensitive to changes in muscle length and velocity of muscle stretch, contains two types of intrafusal fibers that are innervated by sensory fibers. Type Ia and type II sensory afferents are located in the intrafusal fibers. The muscle spindle fires when the muscle is stretched and type Ia fibers are activated and carry information to the spinal cord. Within the spinal cord, the axon branches to various synapses of the corresponding muscle and synergist motor neurons. The alpha motor neuron relays information to the muscles and results in a muscle contraction to prevent or control additional postural sway. This process is a type of stretch reflex and can function to restore stability after a positional disturbance. Rapid, prelearned postural adjustments such as motor strategies also function to maintain stability. Balance needs to be maintained during movement and is achieved by postural reflexes working separately or together.\textsuperscript{10}

Many studies have been done regarding the effect age has on balance and postural control.\textsuperscript{11-14} It has been shown that the elderly greater than 80 years of age have decreased balance skills when proprioceptive input is inaccurate compared to individuals younger than 80 years of age.\textsuperscript{8} Postural sway is found to increase with increasing age, leading to decreased stability in the elderly which is linked to the high incident of falls that are reported by the elderly.\textsuperscript{15}

Visual cues appear to have a substantial impact on postural control. Wolfson and associates\textsuperscript{13} found that when vision was distorted or absent, the elderly had increased difficulty maintaining their balance. Healthy adults use the somatosensory system as the
preferred sense for maintaining balance. If this system is unavailable, the body will attempt to use other systems such as vestibular and proprioceptive inputs.

Limited proprioceptive feedback has also been found to be detrimental in maintaining correct body alignment.\textsuperscript{11,13-16} Lack of the posterior and anterior cruciate ligament deprives the body of the necessary mechanoreceptors for determining joint position and thus proprioceptive feedback. Without adequate feedback for the CNS, the body is not sure which motor response is needed to maintain the COG over the BOS and a loss of balance can result. The delays associated with the increased time for processing to occur and the resultant motor response lead to decreased stability in the elderly. The lack of stability affects many aspects of activities of daily living and increases the risk of falling.

Even though age appears to be closely associated with declines in balance control, the link between gender and balance is not as clear. Hageman and colleagues\textsuperscript{14} found no difference in postural sway between gender when tested on the Neurocom Balance Master® equipment. However, some researchers have shown that gender differences in balance become evident in situations that highly stress balance strategies.\textsuperscript{17} It is reported that elderly women report more falls than their male counterparts, but it remains unclear whether that is due to lack of balance control or other unrelated factors such as strength.

**Proprioception**

Proprioception is the awareness and sensation of the body position and movements in relation to the body and space.\textsuperscript{7} Proprioception in the knee joint has been shown to decline with age.\textsuperscript{18,19} Barrett and associates\textsuperscript{18} found that joint position sense
slightly improved in replaced knees compared to osteoarthritic knees but did not achieve
the same level of awareness of a normal anatomical knee. Proprioception plays an
important role in balance control as the joint capsule and ligamentous structures of the
knee are key feedback routes for the body. Without awareness of where the body is
located, the proper motor strategy to correct imbalances cannot be used. Studies have
shown that a decreased proprioceptive input for the elderly greatly increases their
postural sway. Judge and associates\textsuperscript{19} found that decreased proprioception had a
four times greater effect on balance control than diminished vision did, implying that
proprioception plays an important role in balance.

Joint position sense following total knee arthroplasty is a gray area. It is clear that
total knee arthroplasty improves proprioception of the knee joint compared to its
preoperative level.\textsuperscript{20,21} A study that used the all the same implant designs in subjects
found that there was no difference in joint position sense regardless of PCL retention or
sacrificing, patellar resurfacing, or cement fixation.\textsuperscript{22} The same study also found no
difference between the TKA subjects and age matched control group in joint position
sense. Simmons and researchers\textsuperscript{20} compared individuals with a PCL retaining and
unconstrained knee implant to individuals with a cruciate substituting design with the
PCL excised. The retention of the PCL in that study did not have any significant
improvements on proprioception. The implications of these studies show that the PCL
does not have a significant role in proprioception in knee replacements.

Retention or sacrificing the posterior cruciate ligament is a debate that continues.
Some feel that retaining the PCL in TKA is optimal for various reasons.\textsuperscript{23} It is felt that
retaining the PCL is easy to do since most knees operated on have an intact PCL. The
retained PCL is also believed to enhance stairclimbing ability, give the knee added stability posteriorly, and provide necessary proprioceptive feedback to the neural processing centers. Proponents for resection of the PCL in TKA argue that this course allows for easier correction of alignment deformities, implantation of a system to reduce wear rates, and stability can be provided through the design of the knee implant. Some researchers have found that the sparing or sacrificing of the PCL does not have an effect post-operatively. In studying the effects of PCL retention in knee arthroplasty, Warren et al found the PCL retaining designs led to greater improvements in proprioception, but Skinner and associates have shown that TKA does not worsen nor improve a person’s joint position sense. The studies used different methods and a clear picture of the role the PCL plays in joint proprioception is unclear. In this study the subjects with total knee arthroplasty had the PCL sacrificed.

Balance is a very skilled and controlled activity of the body. It takes all of the many systems working together for one to maintain a upright position during dynamic movements. If an individual is lacking in any of the components of the sensory or musculoskeletal systems, balance abilities will be compromised.
Subjects

Ten healthy subjects and two subjects with unilateral total knee arthroplasties between the ages of 65 and 80 volunteered to participate in this study. Subjects who agreed to participate responded to signs posted at Altru Health Institute, local stores, and the Senior Citizen’s Center. All subjects provided written informed consent in accordance with guidelines established by Altru Health Systems and the University of North Dakota's Institutional Review Board prior to participating in this study (Appendix A).

The control group consisted of ten healthy older adults (6 males and 4 females). The mean age for the control group was 69.9 (SD ±3.63, range 65-71) years. The two case study participants were referred from a participating physician. Both subjects had a total knee replacement secondary to osteoarthritis within the last 16 weeks and reported no other lower extremity joint replacements. Subject A was a 71 year-old female who was 16 weeks post-op right TKA. Subject B was a 74 year-old female who was 15 weeks post-op left TKA. The referring physician used Osteonics’s® (Osteonics Corp, Allendale, NJ) Scorpio™ total knee system as the knee component. The surgical procedure involved complete removal of the posterior cruciate ligament.
After subjects agreed to participate, they were asked to go to Altru Health Institute where the NeuroCom Balance Master® equipment was set up. Once at the facility, subjects completed a pre-screening medical questionnaire (Appendix A) regarding previous falls, history of dizziness, joint problems, previous surgeries and possible medications that may adversely affect balance. To participate in this study, all subjects had to be able to stand independently for two minutes, ambulate independently with no assistive device, achieve at least ninety degrees of knee flexion, and report no history of falls in the last six months. Subjects also needed to have adequate visual ability to allow for viewing the commands on the computer screen.

**Instrumentation**

The NeuroCom Balance Master® (NeuroCom International, Clackamas, OR) with 6.1 version software was used in this study. This system is designed to assess balance and mobility skills in individuals with a variety of diagnoses and provide objective information regarding balance ability. The NeuroCom Balance Master® operates on a forceplace that consists of two 9 inch by 60 inch footplates. Underneath each footplate are two force transducers with the axis orientated vertically. These transducers are located along the front to back center of each footplate and measure the horizontal and vertical forces. The NeuroCom Balance Master® utilizes complex equations to calculate body sway angles and stability limits. Results can be summarized and depicted in charts and graphs. A computer monitor is positioned at eye-level at one end of the forceplates to provide written commands and relay visual feedback regarding center of gravity displacement.25
The system has an internal calibration system and self-calibrates upon start up when no weight is on the forceplates. Many studies evaluating the validity and reliability of the NeuroCom Balance Master® have been done. The results of these studies show that the limits of stability, sit-to-stand, and step up and over have moderate to high reliability for the normal adult and elderly population. The weight bearing test demonstrates high reliability on the same population while the walk test showed poor to moderate reliability. Hageman et al. reported that the test-retest reliability for sway measurements and movement time was high in 12 normal subjects. Clark et al. concluded that the limits of stability test is a reliable test of dynamic balance ability in healthy older adults. The NeuroCom Balance Master® also has a high learning curve with some improvements resulting from increased repetition and learning how to control the cursor.

Procedure

Following completion of the pre-screening questionnaire (Appendix B), height measurements were taken and a pre-test assessment (Appendix B) was done. Range of motion measurements were taken for ankle plantar flexion and dorsiflexion, knee flexion and extension, and hip flexion, extension, abduction and adduction. All measurements were taken with subjects in the position recommended by Norken and White, except for hip extension, which was measured in the side-lying position. This position was used to avoid any discomfort in prone or inability to tolerate the prone position. Circumferential measurements were taken at the joint line, as well as the suprapatellar and infrapatellar borders. Subjects also completed a visual analogue scale regarding the current level of
pain in their knees. MCCormack et al.\textsuperscript{29} reported retest reliability of the visual analogue scale to be .94.

Testors, who had received instruction in the NeuroCom Balance Master\textsuperscript{®} and performed reliability studies prior to this research, provided verbal instructions to subjects. Study participants were given a brief warm up period to familiarize them with the NeuroCom Balance Master\textsuperscript{®} system. This allowed individuals to see the relationship between the movement of the cursor and the alteration in the body's center of gravity. To help compensate for the high learning curve, subjects were taken through the assessment twice, with only the second trial being used for scoring purposes and data analysis. A standardized script (Appendix B) was used for each subject to explain and guide the assessment procedures and prevent bias due to possible researcher cueing. For safety reasons, each subject wore a gait belt during evaluation on the NeuroCom Balance Master\textsuperscript{®}, and although the participant was allowed some balance disturbances, a spotter was present to help prevent a possible fall. Individuals needed to be challenged by the tests completed to allow for an accurate picture of balance skills, so mild balance disturbances were allowed. The entire testing procedure including the pre-screening questionnaire and pre-test measurements took approximately 45 minutes to complete.

Five tests were chosen to assess balance. These tests were chosen due to their functional nature and incorporation into daily living activities. The five tests were bilateral weight bearing, limits of stability (LOS), walk test, step up and over, and sit-to-stand. The sit-to-stand and walk test address balance and motor control. The step up and over test and the weight bearing test are used to look at weakness and proprioception while the LOS measures voluntary center of gravity control.\textsuperscript{30} The sit-to-stand test is
found in the level one assessment, while the other four tests are found in level two, which is considered to be a moderate level in the NeuroCom Balance Master® system.²⁵

Prior to each test, the subject's feet were placed in the appropriate position on the forceplate. Foot position was carefully monitored by the tester and readjusted if deviation occurred from the pre-set position. For each assessment test, the NeuroCom Balance Master® 6.1 software system calculated specific parameters (i.e. movement velocity, end sway, etc.) from the forceplate data. Each parameter is reported as the average of the three trial scores.

Weight Bearing/Squat Test

The weight bearing test measured the percentage of weight borne by each leg with the patient standing erect, with knees flexed to 30 degree, and finally with knees flexed to 60 degrees. The subject was instructed to squat down until the desired angle was reached and then asked to hold that position until the system assessed the weight bearing percentages. Two goniometers, one fixed at 30 degrees and the other at 60 degrees, were used to assure that the patient was in the appropriate amount of knee flexion.

Limits of Stability Test

Because the ability to control the center of gravity within the base of support is essential for normal balance, the limits of stability (LOS) test was used to provide information about the subject's balance ability and degree of control. The LOS test measures the subject's ability to move towards eight peripheral targets, represented by visual square targets displayed on the computer monitor. The targets are positioned in a circle and the subject attempts to move toward them in eight directions; forward, right forward, right, right back, back, left back, left, and left front. Continuous visual feedback
was provided by a cursor representing the subject’s center of gravity. Subjects were instructed to control the cursor by weight shifting and leaning while keeping arms relaxed by sides. The subject was instructed to begin in the center target and move towards the highlighted outer target as soon as the visual cue (a blue circle) appeared. Subjects were instructed to move towards the target as quickly and accurately as possible and hold the attained position until the blue circle disappeared. If the subject was unable to reach the outside target, he was told to move as close to the target as possible. This test measured reaction time, movement velocity (average COG movement), maximum excursion (furthest distance traveled by COG), and directional control (comparison of amount of movement in intended direction to the amount of extra movements).

Sit-to-Stand Test

The sit to stand test is a functional test that measures the mean weight transfer, rising index, and COG sway velocity. It also evaluates right and left symmetry, which is the difference in weight borne on each leg when coming to stand. The subject was positioned on a bench in a seated position with the knees bent to approximately 90 degrees and toes slightly behind the knees. The feet were positioned at equal distances from the midline of the forceplates. The subject was instructed to sit erect with good posture, stand up quickly when the “go” sign appeared, and then maintain the standing position as steadily as possible until the “hold steady” sign disappeared from the screen. This was repeated three times with the mean values for the three trials being reported.
Walk Test

The walk test was used to identify several gait characteristics including step length, step width, cadence velocity, and mean end sway. The subject was positioned at the end of the forceplate opposite of the monitor with both feet on the forceplates. The patient was instructed to stand in that position until the “go” sign appeared and then walk quickly to the opposite end of the forceplate and stand motionless until the “hold steady” cue disappeared from the screen. For the first trial the subject was told to begin with either foot. For subsequent trials the subject was instructed to begin with the same foot that was used for the first trial.

Step Up and Over Test

The final performance test was the step up and over test using an eight-inch curb. The height of the curb can be adjusted if needed. Measured parameters of this assessment include rising index, movement time, and impact index. These characteristics are measured as the individual steps up onto the curb with one foot, swings the other foot over the curb and down to the forceplates and then down with the curb foot to a level, erect standing posture. The height of the curb can be adjusted. All of the control subjects and subject A used an eight-inch curb. Subject B used a four-inch curb due to fear and apprehension with use of the higher curb. This test includes three trials with the right foot leading and three with the left foot leading. Subjects were instructed to wait for the “go” cue, perform the movement and remain still after the movement until the “hold steady” cue disappeared from the screen.
Data Analysis

The Statistical Package for the Social Sciences (SPSS Inc.; Chicago, IL) computer program was used to calculate results. Using the SPSS computer program, descriptive statistics of means and standard deviations were calculated for the control group and the case study participants. Means of the various tests for the control group were compared to the scores of the TKA case study subjects.
CHAPTER 4
RESULTS

The results of this study were calculated by taking the data collected for the control group (n=10) and calculating means and standard deviations. The data for each TKA subject was compared to the data of the control group. The two case study subjects were also compared to each other. There were no subjects, TKA or control, that needed to be excluded from this study. Subjects were tested one time, and all subjects were able to complete all of the tests.

In the following section each test will be highlighted. The data collected for the control group will be presented and will be followed by a comparison to the TKA's. For ease of reading, the case study subject with the right TKA will be identified as "A" and the case study subject with the left TKA will be identified as "B". Please refer to the tables provided in Appendix C if additional numbers are desired.

Sit to Stand Test

For this test, several variables including mean weight transfer, rising index, center of gravity sway velocity, and right/left weight symmetry were recorded by the NeuroCom Balance Master® 6.1 software. The largest difference between groups was found in the left/right weight symmetry. It was expected that equal body weight would be borne on
each leg when coming to a stand. In the control group, six subjects had more weight on
the left leg with a mean difference of 5.2% (SD ±1.11), and the remaining four had more
weight on the right with a mean difference of 4.7% (SD ±1.25). For subject A 13% more
than expected body weight was on the left, while subject B displayed 15% more body
weight on the right. A graphic representation of the results is found in Figure 1.

![Figure 1: Left/Right Symmetry When Coming to a Stand](image)

The rising index is the average amount of force exerted by the legs during the
rising phase expressed as a percentage of body weight. Both TKA case study subjects
demonstrated less rising force than the control group. Subject A had a force of 14% body
weight while subject B demonstrated 10%. The control group had a mean force of 16.2% (SD ±1.78, range 7-24). The case study subjects also displayed a greater center of gravity (COG) than the control group. Subject A and B averaged 4 and 5.5 degrees per second respectively while the control group demonstrated a COG sway velocity of 3.8 degrees per second (SD ±0.31, range 1.30-4.70).

**Weight Bearing/Squat Test**

The weight bearing test assessed the percent of body weight on each leg. There were greater differences in this test with the knees flexed to 30 degrees and flexed to 60 degrees. Table 1 contains the results of this test. Subject A showed only a four percent difference between right and left weight bearing with the knees extended. At 30 and 60 degrees of knee flexion, there was greater asymmetry as evidenced by a 16% and 12% difference respectively. Subject B showed a 14% difference between left and right weight bearing with knees extended and a 20% difference at 30 degrees of knee flexion. At 60 degrees knee flexion, there was a 14% difference between right and left weight bearing.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Knees extended</th>
<th>Knees Flexed 30°</th>
<th>Knees Flexed 60°</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Right</td>
<td>Left</td>
<td>Right</td>
</tr>
<tr>
<td>Subject A</td>
<td>48%</td>
<td>52%</td>
<td>42%</td>
</tr>
<tr>
<td>Subject B</td>
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<td>43%</td>
<td>60%</td>
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<tr>
<td>Control Group</td>
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<td>54%</td>
<td>48%</td>
</tr>
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</table>
Walk Test

The control group data was first complied together in aggregate, but with closer examination there were large ranges with some of the parameters. For this reason the control group was divided according to gender, and the mean for step length changed. The results are reported in Table 2. Subject A and subject B showed noticeable deficits in walk speed compared to the control group. Step length, step width, and endsway were comparable between subjects and the control group.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Endsway (deg/sec)</th>
<th>Speed (cm/sec)</th>
<th>Step Length (cm)</th>
<th>Step Width (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control Group</td>
<td>4.2</td>
<td>69.3</td>
<td>47.3</td>
<td>19.9</td>
</tr>
<tr>
<td>Males</td>
<td>3.5</td>
<td>69.6</td>
<td>56.3</td>
<td>21.3</td>
</tr>
<tr>
<td>Females</td>
<td>5.3</td>
<td>68.8</td>
<td>33.9</td>
<td>17.9</td>
</tr>
<tr>
<td>Subject A</td>
<td>2.9</td>
<td>50.8</td>
<td>37.4</td>
<td>18.9</td>
</tr>
<tr>
<td>Subject B</td>
<td>2.5</td>
<td>34.5</td>
<td>32</td>
<td>18.5</td>
</tr>
</tbody>
</table>

Step Up and Over

The results for the control group and the case study subjects were similar for most aspects of this test. The lift up index, which is the average maximum force exerted by the step leg expressed as a percentage of body weight, for the TKA subjects was lower than the control group. Subject A showed 26% body weight on the left and 22% on the right. Subject B displayed values of 16% body weight on both the left and right. These values compare to a control group lift up index of 39.5% (SD ±3.48, range 23-62) on the left and 40.1% (SD ±2.76, range 28-57) on the right. Subject B had impact index values of 17%
on the left and 23% on the right while the control group displayed mean indexes of
40.5% (SD=4.0366, range 23-60) on the left and 40.9% (SD ±4.43, range 24-64). It
should be noted that subject A and the control group used an eight inch curb, while
subject B used a four inch curb. Due to this variation, an accurate comparison cannot be
made with subject B’s results.

**Limits of Stability**

Several parameters were recorded for this test and these results are reported in
appendix C. The only difference reportable was in the maximum excursions for the TKA
subjects. Subject A had a value of 107% to the left while the control group had a mean
value of 96.8% (SD ±4.69, range 78-127). Subject B had a value of 101% to the right
while the control group displayed mean excursion of 96.4% (SD ±3.32, range 85-114).

**Preassessment Tests**

There were no noticeable differences between the control group and the TKA
subjects for the lower extremity range of motion measurements taken. The visual
analogue scale showed no noticeable difference between the control group and the case
study subjects. All subjects marked towards the no pain end of the scale. Since subjects
were tested in normal attire, some of the clothing worn restricted the ability to take
accurate knee joint circumferential measurements. For this reason, it was felt that the
girth measurements taken were not accurate, but no gross abnormalities of the knee joint
were noted in the control subjects. The two case study subjects were both measured and
showed no major girth differences between the right and left knee joint.
CHAPTER 5
DISCUSSION

The results of data from this study showed some differences between the TKA subjects and the control group. This discussion will consider the results of the control group compared to the TKA case study subjects as well as a comparison between the case study participants themselves.

Discussion of Results

The sit to stand test completed was a very functional test that normal individuals perform several times daily. Ideally, when coming to a stand, midline orientation should be preserved with only small deviations occurring to either side. Any large differences can be seen as a bias towards one side and signify a problem with maintaining midline orientation. This test was very demanding, and, if a deficit existed between sides, it would likely be identified by the test. The results of the TKA subjects demonstrated deficits in this area. Subject A showed a deviation toward favoring the left (non-surgical) side while subject B had more body weight on the right (non-surgical) side when rising. The control group asymmetry between sides closely agreed with the study by Engardt and Olsson\textsuperscript{32} who determined 5\% asymmetry was normal in the elderly populations.
Both TKA subjects displayed more than this 5% asymmetry between sides. The asymmetry between sides represented by the TKA subjects can lead to a loss of balance when rising due to excessive weight on one leg. When too much weight is on one leg, an individual leans that way and tends to move beyond their limits of stability resulting in a loss of balance.

The rising index parameter of this assessment also identified some differences between groups. This variable measured the maximum vertical force exerted by legs during rising to a stand. Both of the TKA subjects produced less rising force than the control group did.

Another consideration in the sit to stand test was the COG sway velocity, which is a measurement of the movement of the COG over the base of support during rising and five seconds after that phase. In this area both case study individuals were found to have less control of the COG. Deficits found in the case study subjects could be attributed to a lack of knee joint control due to decreased proprioception. Other studies\textsuperscript{18,22} have documented that proprioception following TKA does improve, but does not attain the level of a normal, anatomical knee.

The weight bearing test was expected to produce equal body weight borne on each leg within 7% which was closely replicated by the control group in this research. For the TKA subjects, the limit of equal body weight on each leg was exceeded. Both case study participants stood with more weight on the non-surgical side consistently for all conditions of this test. The differences between sides were greater with the knees flexed than when standing erect which can be expected since it has been postulated that the more the knee is required to flex, the greater the chance of identifying a difference
between sides. A large difference between sides can lead to instability for the individual. This instability can diminish an individual’s ability to react to disturbances in the center of gravity. The loss of the ability to quickly react to disturbances through postural reflexes and motor strategies can result in the center of gravity exceeding the limits of stability, resulting in a fall.

In the walk test, both of the TKA subjects showed a decreased step length in comparison to the entire control group mean. However, when examining the variance and range within the control group it was observed to be rather large. For this reason the control group was separated based on gender. Other studies as well have separated gait characteristics according to gender due to shorter step length and slower speeds for females. Using the mean step length values for the female controls, the difference was diminished when compared to the TKA case study subjects. This was a fair and justifiable comparison to take since both of the TKA subjects were female. The velocity of walking for both TKA subjects was slower compared to the control group. Subject B’s walking speed was substantially decreased in comparison to subject A as well. The difference between the control group and TKA subjects could be due to a decreased ability to advance the surgical side as quickly due to stiffness or an avoidance of discomfort in the knee caused by walking too quickly. The difference between case study subjects in regard to walking speed could be attributed to the degree of osteoarthritis in other joints or the individual’s pre-operative status, which is unknown.

Step up and over was another functional test completed in this study. This test required balance, strength, and coordination to complete. Forces exerted for the lift up index were less for both TKA subjects compared to the control group. The lift up index
measured the maximum lifting force exerted by the leg leading the movement. This force might have been decreased in the TKA subjects due to uncertainty of control of the movement or decreased confidence in one’s ability to complete the task without assistance. Subject B also had a decreased impact index in comparison to subject A and the control group. This could be attributed to the use of a lower four-inch curb for subject B as compared to an eight-inch high curb for subject A and the control group. Fear and unsteadiness may have been the underlying cause for this need.

In the limits of stability test the only difference was in the maximum excursion (MXE) for the TKA subjects. The lack of differences in this test was very important since it has been concluded that this is a reliable test of dynamic balance abilities. Both subjects had higher percentages when shifting toward the uninvolved side. The differences from the control group are not large, but it is interesting to note that they were the only values that varied. MXE was the farthest distance the subject moved their COG in attempting to reach the target. This similarity could be coincidence or be related to the TKA status of the subject. Perhaps since the subjects already tend to bear more weight on the nonsurgical side, it would be possible to misjudge the balance point of movement for their body in order to reach the target.

Limitations

There were several limitations in this study. One limitation was reliability of the assessments used in this study. The walk test has poor reliability compared to high reliability of the weight-bearing test. The remaining three assessments used were reported to have moderate to high reliability. Also it was observed by the researchers
that between the three trials of each test there were some high coefficients of variance signifying a variable performance by the individual. Since some the tests performed, namely the step up and over and the sit to stand test, are routinely performed activities of daily life, submaximal effort is used which results in greater variability than those tasks that require maximum effort.³⁴

Some discrepancies between the testers were also considered to be a limitation. Even with the use of a standardized script, there were differences in the administration of the assessments. Environmental factors such as the degree of peripheral noise and traffic of individuals through the testing area varied with each subject. Occasionally, conversations occurred between the subject and the tester or spotter during the scoring of a trial.

A third area to consider was the lack of TKA participants in this study. The low number of subjects limits the conclusions that can be made from the research. Some areas of possible discrepancy can be identified but further research is needed to provide more concrete information regarding deficits following TKA. Higher numbers in the control group would also improve the validity of the results for them. With increased numbers of age matched control individuals, a comparison between this group and the NeuroCom Balance Maser® would be possible.

Lack of knowledge regarding the TKA case study participants’ prior level of function also was a limiting factor. TKA subjects’ activity level prior to surgery may have been decreased due to knee joint pain and dysfunction. If the activity level was low, it could have a detrimental effect on the individual’s strength and performance abilities before the joint replacement was done. A longitudinal designed study may have been
useful in this aspect to compare individuals before and after TKA to examine the degree of improvement in their skills.

Related to the prior level of activity is the degree of osteoarthritis (OA) in other joints especially the lower extremity joints. This was not included in the pre-assessment screening or on the questionnaire. Degree of OA in other joints was also not a criteria used for defining individuals able to participate in this study. Severe OA would limit the motion of the joint and cause pain with movement. The combined effect of these factors would have a detrimental effect on the individual’s performance on the tests.

**Conclusions and Recommendations**

Deficits identified in this study appear to point more toward TKA individuals having proprioceptive and muscle control deficits than balance difficulties following the surgery. This was demonstrated by the differences between the TKA case study subjects and the control group in the tests of step up and over, sit to stand, and the weight bearing test identify difficulties in the area proprioception. The limits of stability test, which is a dynamic balance assessment, did not identify any major differences between the control group and the case study participants. However, lacking in the areas of muscle control and proprioception can have a large impact on balance. Both of these systems are instrumental in relying information to the body for the proper movements to correct any loss of balance. Without the entire feedback system in place, balance skills would be diminished in these individuals.

Implications of the study are in the area of dynamic movement retraining. Most of the differences identified in this study are from a lack of control and proprioceptive
sense which needs to be incorporated into a rehabilitation program for all orthopedic patients. Further studies need to be completed regarding TKA individual's performance in the performance tests of step up and over and the sit to stand test. Research comparing the preoperative skills to the post operative level would give researchers a clearer understanding of the improvement or comparison of the individual who has a TKA to an age matched control group.
APPENDIX A
Grand Forks Medical Park

Institutional Review Board

Human Subjects Review Form

For new projects or procedural revisions to approved projects involving human subjects.

Cathy Siegfried
Principal Investigator: Michelle Overbo, Jeremy St. Aubin Phone #: (701)777-2831 Date: 5/18/98
Institution: University of North Dakota Department: Physical Therapy
Research Coordinator: Schawnn Decker Phone #: (701)777-6389
Project Title: Evaluation of Balance Following Unilateral Total Knee Arthroplasty

Funding Agencies (if applicable): none

Type of Project: □ New Project □ Continuation □ Renewal □ Student Research Project
□ Dissertation or Thesis Research □ Completed Project
□ Reports (Adverse events, deaths, complications)
□ Amendments or change in project

Dissertation/Thesis Adviser, or Student Advisor: Schawnn Decker

Proposed Project: □ Involves New Drugs (IND) □ Involves Non-Approved Use of Drug □ Involves a Cooperating
Institution □ None of the Above

If any of your subjects fall in any of the following classifications, please indicate the classification:
□ Minors (< 18 Years) □ Pregnant Women □ Mentally Disabled □ Fetuses □ Mentally Retarded
□ Prisoners □ Students □ Abortuses □ Control Group

If your project involves any human tissue, body fluids, pathological specimens, donated organs, fetal material, or placental materials, check here __.

☐ Expedited Review requested under item (number) of HHS Regulations (see attached explanation)
☐ Exempt Review requested under item (number) of HHS Regulations (see attached explanation)

1: ABSTRACT (Limit to 200 words or less and include justification or necessity for using human subjects. Attach additional sheet if necessary.)

Total knee arthroplasty is a common procedure often used to relieve pain in the knee joint. The individual's painful knee leads to a decrease in functional abilities. Few studies have been done documenting balance skills following TKA. Balance is a necessary component of daily life for ambulation, mobility and personal care tasks. Without proper balance and proprioception, the risks of falls and resulting injury will increase. The purpose of this study is to examine balance skills of elderly subjects following TKA using the NeuroCom Balance Master™ 6.1 system. This equipment is a computer system that is commonly used in physical therapy clinics to assess balance and for balance training programs. Individuals who are 12-16 weeks post operative from the arthroplasty will be utilized in this study to gain knowledge of their current balance status. Normal, healthy age-related individuals will also be tested for the establishment of normals. A comparison of the balance skills between the control group and the TKA group will increase the knowledge of static and dynamic aspects of balance and identify any deficits in balance that may exist following unilateral TKA.
PLEASE NOTE:

Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate attach sections from your proposal including data collection instruments where applicable.

2. PROTOCOL: (Describe procedures to which humans will be subjected.)

SUBJECTS

Thirty subjects who have undergone unilateral TKA and are between the ages of 65 and 80 will be tested for this study. Subjects will be selected by referral from the participating physician (currently Dr. Brian Briggs). To be included in this study, subjects must be able to stand independently for two minutes and be able to achieve 90 degrees of knee flexion bilaterally. Subjects will be given a questionnaire regarding their prior fall and medical history for the purposes of attaining suitable subjects without balance deficits secondary to other causes. Please see the attached questionnaire. Each subject will be required to sign a consent form and complete a questionnaire prior to participating in this study. A control group (n=30) consisting of community dwelling, age-related normal subjects will be utilized for the comparison of scores on the assessments. The first ten subjects will be retested within three days to establish reliability for the testers.

METHODS

We will use the NeuroCom Balance Master™ 6.1 system to assess balance skills of TKA subjects. The equipment is a computer system that is designed to provide objective measurements of balance. This process is achieved through the use of two force plates that interpret balance skills by challenging an individual's ability to maintain their center of gravity within normal limits.

TKA subjects will be tested between twelve and sixteen weeks post-op. The referring physician and his staff will pre-screen potential participants for history of balance related medical disorders, medications, and other lower extremity joint replacements. A pre-assessment will be completed for each subject including joint range of motion measurements, current pain levels, and joint effusion measurements. Before any scores are recorded, subjects will be given a brief warm-up period to familiarize them to the machine and will be taken through each assessment test to acquaint them with the procedure and account for the high learning curve associated with the Balance Master. The testing session will consist of a series of five tests including bilateral weight bearing, limits of stability, walk test, sit to stand, and step up and over. The control group will also be taken through the same assessment procedure.

Subjects will allowed a break as needed between the familiarization session and the scoring session. There will also be a break between tests to allow for positioning of subject's feet. During the assessments, two spotters will be present on either side of the subject and a gait belt will be placed around the subject's waist. The tester will operate the computer and position the subject's feet properly on the force plates.

Traditional descriptive and analytical statistics characterizing the TKA subjects' balance skills in comparison with the age-related normal group's balance skills. Results will be reported in aggregate.
3. BENEFITS: (Describe the benefits to the individual or society.)

The individuals participating in this study will benefit by knowing the degree their balance was affected by TKA. If any significant balance deficits are determined for subject this information will be forwarded to the referring physician for possible implementation of a balance training program. There will also be knowledge gained of how balance after TKA compares to the age-related control group and to other studies concerning functional outcomes of TKA. Data concerning balance assessment will also be useful to physicians, physical therapists, and other healthcare professionals in providing an objective and repeatable measure of balance following TKA. Increasing knowledge of balance can lead to improvements in rehabilitation, functional outcomes, and decrease the risk of falls.

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

During this study there is only minimal risk to the individual. The assessments the subjects will be performing are part of everyday activities and will provide challenges to the subjects' dynamic balance control. Subjects will be allowed to experience some instability, but safety and prevention of falls will be a primary concern. To minimize the risk of falls during testing, subjects will wear a gait belt and two assistants will be standing close enough to the force plates to guard the subject from falling if loss of balance does occur.

All subjects in this study will be voluntary participants who will be chosen based on referral from the participating physician and willingness to participate in the study indicated by signing the consent form. Subjects will be allowed to halt testing or withdraw from the study at any time. Data will be assigned a number corresponding to the subject so no subject can be identified and anonymity will be preserved. All data will be stored on 3.5" diskettes and kept by Schawn Decker to ensure confidentiality and the data remains untampered.
5. **CONSENT FORM:** A copy of the CONSENT FORM to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no CONSENT FORM is to be used, document the procedures to be used to assure that infringement upon the subject's rights will not occur.

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

The consent forms will be kept by Schawn Decker at the University of North Dakota, Department of Physical Therapy, room 2542, Medical Science North building for a period of two years. A copy of the consent form is attached.

6. For FULL IRB REVIEW, forward the signed original of this completed form and, copies as outlined in the attached instructions to:

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

Eleanor Tveit, IRB Secretary  
1000 South Columbia Road  
Grand Forks, ND 58201  
701-780-6161

The policies and procedures on Use of Human Subjects in Medical Park Institutions apply to all activities involving use of Human Subjects performed by personnel conducting such activities. No activities are to be initiated without prior review and approval of the Medical Park Institutional Review Board.

Signatures:

Principal Investigator:  
[Signature]  
Date: 5/27/98

Project Director:  
[Signature]  
Date: 5/27/98

Student Advisor  
(where applicable):  
[Signature]  
Date: 5/27/98
Research Project Action Report

Date:       June 4, 1998            IRB#:     PT-007
Principal Investigator: Cathy Siegfried, Michelle Overbo Department: Physical Therapy Phone #: 777-2831
Research Coordinator: Schawnn Decker Phone #: 777-6389

Project Title: Evaluation of Balance Following Unilateral Total Knee Arthroplasty

The above referenced project protocol and Informed consent was reviewed by the Medical Park Institutional Review Board on and the following action was taken:

☐ Project approved. Next Scheduled review is on ____________________

If no date is given, then review will be required in 12 months. (See REMARKS SECTION for any special condition.)

☐ Project approved. EXPEDITED REVIEW NO. ________________________________________________

Next scheduled review 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 denied. (See REMARKS SECTION for further information.)

☐ Amendment approved

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

Medical Park Institutional Review Board

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 IRB office to obtain the required documents.
INFORMATION AND CONSENT FORM

TITLE: Evaluation of Balance Following Unilateral Total Knee Arthroplasty using the NeuroCom Balance Master®

You are being invited to participate as a normal age-related control subject in a study conducted by Michelle Overbo, Jeremy St. Aubin, and Cathy Siegfried, physical therapy students at the University of North Dakota. The purpose of this study is to examine the effects of one-sided knee arthroplasty on balance using a specialized computer analysis program and equipment developed for evaluating balance. We hope to evaluate balance skills of persons with a total knee replacement and compare them to persons with normal knees. Community dwelling subjects without previous joint replacements, balance deficits, or medical diagnosis affecting balance will be asked to participate in this study for establishing baseline balance skill levels.

You will be evaluated on the Balance Master® equipment using five (5) different tasks. You will be asked to complete two trials on the equipment. The first trial will be used to familiarize you with the tests and using the Balance Master®. The second trial will be the same tasks and results will be recorded for further analysis.

The study will take approximately an hour of your time for each trial. Testing will be done at the Physical Therapy department at Altru Rehabilitation Institute at an assigned time. You will be asked to fill out a short questionnaire concerning your past medical history and previous balance problems. We will first record age, sex, and height and assign a number for your results. A pre-assessment will be completed by the tester consisting of joint range of motion, joint swelling, and pain levels. During the trials, we will be recording balance components utilizing the Balance Master® equipment and program.

Although the process of physical performance testing always involves some degree of risk, the investigators in this study feel the risk of injury or discomfort is minimal. To assess balance, you will be asked to stand on a platform without a walker or cane for assistance. Due to the risk of losing balance, you will wear a gait belt and two spotters will be present during testing to assist in the event that loss of balance does occur.

Your name will not be used in any reports of the results of this study. Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission. The data will be identified by a number known only by the investigators. The investigator or participant may stop the experiment at any time if the participant is experiencing discomfort, pain, fatigue, or any other symptoms that may be detrimental to his/her health. Your decision whether or not to participate will not prejudice your future relationship with the Physical Therapy Department or the University of North Dakota. If you decide to participate, you are free to discontinue participation at any time without prejudice.
The investigators involved are available to answer any questions you have concerning this study. In addition, you are encouraged to ask any questions concerning this study that you may have in the future. Questions may be asked by calling Michelle Overbo at 772-7170 or Cathy Siegfried at 777-9170. If you have any questions regarding your rights as a research subject, call the chairperson of Institutional Review Board, Altru Health Systems at 780-6161. A copy of this consent form is available to all participants in the study.

In the even that this research activity which will be conducted at Altru Health Institute results in a physical injury, medical treatment will be made available, including first aid, emergency treatment and follow up care as it is to member of the general public in similar circumstances. Payment for any such treatment must be provided by you and your third party payment, if any.

ALL OF MY QUESTIONS HAVE BEEN ANSWERED AND I AM ENCOURAGED TO ASK ANY QUESTIONS THAT I MAY HAVE CONCERNING THIS STUDY IN THE FUTURE. MY SIGNATURE INDICATES THAT, HAVING READ THE ABOVE INFORMATION, I HAVE DECIDED TO PARTICIPATE IN THE RESEARCH PROJECT.

I have read all of the above and willingly agree to participate in this study explained to me by Michelle Overbo, Jeremy St. Aubin or Cathy Siegfried.

Participant's Signature __________________________ Date __________________________

Witness (not the scientist) __________________________ Date __________________________
INFORMATION AND CONSENT FORM

TITLE: Evaluation of Balance Following Unilateral Total Knee Arthroplasty using the NeuroCom Balance Master®

You are being invited to participate as a post total knee replacement subject in a study conducted by Michelle Overbo, Jeremy St. Aubin, and Cathy Siegfried, physical therapy students at the University of North Dakota. The purpose of this study is to examine the effects of one-sided knee arthroplasty on balance using a specialized computer analysis program and equipment developed for evaluating balance. We hope to evaluate balance skills of persons with a total knee replacement and compare them to persons with normal knees. Only subjects with total knee replacements on one side and no history of balance or vestibular problems will be asked to participate in this study.

You will be evaluated on the Balance Master® equipment using five (5) different tasks. You will be asked to complete two trials on the equipment. The first trial will be used to familiarize you with the tests and using the Balance Master®. The second trial will be the same tasks and results will be recorded for further analysis.

The study will take approximately an hour of your time for each trial. Testing will be done at the Physical Therapy department at Altru Rehabilitation Institute at an assigned time. You will be asked to fill out a short questionnaire concerning your past medical history and previous balance problems. We will first record age, sex, and height and assign a number for your results. A pre-assessment will be completed by the tester consisting of joint range of motion, joint swelling, and pain levels. During the trials, we will be recording balance components utilizing the Balance Master® equipment and program.

Although the process of physical performance testing always involves some degree of risk, the investigators in this study feel the risk of injury or discomfort is minimal. To assess balance, you will be asked to stand on a platform without a walker or cane for assistance. Due to the risk of losing balance, you will wear a gait belt and two spotters will be present during testing to assist in the event that loss of balance does occur.

Your name will not be used in any reports of the results of this study. Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission. The data will be identified by a number known only by the investigators. The investigator or participant may stop the experiment at any time if the participant is experiencing discomfort, pain, fatigue, or any other symptoms that may be detrimental to his/her health. Your decision whether or not to participate will not prejudice your future relationship with the Physical Therapy Department or the University of North Dakota. If you decide to participate, you are free to discontinue participation at any time without prejudice.
The investigators involved are available to answer any questions you have concerning this study. In addition, you are encouraged to ask any questions concerning this study that you may have in the future. Questions may be asked by calling Michelle Overbo at 772-7170 or Cathy Siegfried at 777-9170. If you have any questions regarding your rights as a research subject, call the chairperson of Institutional Review Board, Altru Health Systems at 780-6161. A copy of this consent form is available to all participants in the study.

In the even that this research activity which will be conducted at Altru Health Institute results in a physical injury, medical treatment will be made available, including first aid, emergency treatment and follow up care as it is to member of the general public in similar circumstances. Payment for any such treatment must be provided by you and your third party payment, if any.

ALL OF MY QUESTIONS HAVE BEEN ANSWERED AND I AM ENCOURAGED TO ASK ANY QUESTIONS THAT I MAY HAVE CONCERNING THIS STUDY IN THE FUTURE. MY SIGNATURE INDICATES THAT, HAVING READ THE ABOVE INFORMATION, I HAVE DECIDED TO PARTICIPATE IN THE RESEARCH PROJECT.

I have read all of the above and willingly agree to participate in this study explained to me by Michelle Overbo, Jeremy St. Aubin or Cathy Siegfried.

________________________________________
Participant's Signature  Date

________________________________________
Witness (not the scientist)  Date
PRE-ASSESSMENT

ID#: ________
Sex: ________
Age: ________
Height: ________
Involved side: ________

ROM

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Knee circumferential measurements

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Pain Scale Rating

PAIN AS BAD
AS IT COULD BE

43
SCREENING QUESTIONNAIRE

Please answer these questions to the best of your knowledge.

1. Have you had two or more unexplained falls in the past six months?  Yes  No

2. Have you had any symptoms of unexplained dizziness or lightheadedness in the past six (6) months?  Yes  No

3. Have you experienced any blackouts in the past six (6) months?  Yes  No

4. Are you currently taking any medications that make you feel dizzy or lightheaded or that you know can cause dizziness and lightheadedness?  Yes  No

5. Do you have any hip/knee/ankle diseases?  If yes, please explain:  Yes  No

6. Have you had any hip/knee/ankle surgeries?  If yes, please explain:  Yes  No

7. Have you had any lower extremity joint (knee or hip) replacements?  If yes, Which joint/joints?  Yes  No

8. Are you currently using any crutches, canes or walker for assistance in walking in home or out of home?  Yes  No

9. Please list any disease processes or medical problems:
SCRIPT

Remember to introduce self to subject and to refer them as Mr. or Ms. as appropriate.

**Bilateral Weight Bearing**
(position subject on forceplates with feet positioned parallel and align each medial malleolus with wide blue line, and the center of each heel with the M line)

The first test we are going to complete is bilateral standing which will have you stand on the forceplates. This will measure the percentage of body weight on each leg. There will be three trials.

I am going to position your feet on the forceplates.

**Erect**
Please look forward and stand erect with your knees straight. I am starting scoring now.
Relax.
For 30 degree squat:
(check foot position)
Now bend both your knees and squat down until I say to hold. *(measure 30 degree angle with goniometer)* Hold position and look forward. Starting scoring now. *(push mouse button)* Relax.
For 60 degree squat:
(check foot position)
Bend both knees and squat slightly until I say to hold. *(measure 60 degree angle with goniometer)* Hold position and look forward. Starting scoring now. *(push mouse button)* Relax.

**Limits of Stability**
The next test is limits of stability. This test will measure your ability to voluntarily sway to different positions and hold them. To do this test you need to shift your weight to move the cursor representing you on the screen. Keep your cursor in the center target. When the blue circle appears in the yellow outer target move your cursor as quickly and accurately as you can to the yellow target with the blue circle in it and hold steady there. There will be eight trials, one for each target. Before we start, I need to position your feet. *(position feet)* We are starting trial one now. *(push mouse button)*
After each trial:
I need to recheck the position of your feet. *(check foot position)* Starting the next trial now.

**Walk**
The third test is the walk test. You will be asked to walk the length of the forceplates. There will be three trials of this test. To complete this test, you need to stand on the far...
end of the forceplates. *(show subject where to stand)* When the test starts you will see the
"HOLD STEADY" sign on the screen. Stand upright and as steadily as possible. When
the “GO” sign appears on the screen, walk quickly to the end of the forceplates. Then
remain still while the “HOLD STEADY” sign stays on the screen. I am starting the
assessment now. *(note which foot the subject leads with)*

After each trial:
Please return to the starting position at the end of the forceplates and the same process
will be repeated. Follow the cues on the computer monitor. Please start the test with the
same foot, your _____ foot. Starting the test now.

**Step up and over**
The step up and over test will have you step up onto this curb *(point out the curb)* with
one foot, swing the other foot over the curb and down onto the floor and then step down
with the curb foot. *(demonstrate move to them)* There will be six trials—three with the
right foot leading and three with the left foot leading. When the test starts you’ll see the
“HOLD STEADY” sign on the screen. Stand upright as steadily as possible. When you
see the “GO” sign, quickly step up onto the curb with your _____ foot, swing over the
curb and step down with your _____ foot, and then step down with your _____ foot.
Stand as steadily as possible until the test is done. Starting scoring now.

After 1st, 2nd, & 4th trials:
Please return to the starting position and begin with your_____ foot. Follow the cues on
the screen. Starting scoring now.

After 3rd trial:
Now you will lead with your_____ foot. The same move will be used for stepping over
the curb. Step up onto the curb with your _____ foot, swing over the curb and step down
with your _____ foot, and then step down with your _____ foot. Follow the cues on the
screen. Starting scoring now.

**Sit to Stand**
The last test is the sit to stand test. There will be three trials. You will be seated on the
bench on the forceplates. When the test starts you will see the “HOLD STEADY” sign
on the screen. Sit as erect as possible. When you see the “GO” sign, stand up quickly
and stand as steadily as possible until the scoring is done. *(seat subject on the bench with
each foot equidistant from the center line, hips and buttocks forward away from the back
of the chair, and knees bent so feet are slightly behind knees)* We will start the test now.

After each trial:
Please sit down again and we will repeat the test. *(reposition according to guidelines
above)* Starting the test now.
### Table 1: Results of Sit to Stand

<table>
<thead>
<tr>
<th></th>
<th>Weight Transfer (seconds)</th>
<th>Rising Index (% body weight)</th>
<th>COG Sway Velocity (degrees/second)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject A</td>
<td>0.51</td>
<td>14</td>
<td>4</td>
</tr>
<tr>
<td>Subject B</td>
<td>0.4</td>
<td>10</td>
<td>5.5</td>
</tr>
<tr>
<td>Control Group*(n=10)</td>
<td>0.49 ± .092</td>
<td>16.2 ± 1.78</td>
<td>3.8 ± .31</td>
</tr>
</tbody>
</table>

* reported as means ± SD

### Table 2: Results of Step Up and Over Test

<table>
<thead>
<tr>
<th></th>
<th>Lift Up Index (% body weight)</th>
<th>Movement Time (seconds)</th>
<th>Impact Index (% body weight)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Right</td>
<td>Left</td>
<td>Right</td>
</tr>
<tr>
<td>Subject A</td>
<td>22</td>
<td>26</td>
<td>1.81</td>
</tr>
<tr>
<td>Subject B*</td>
<td>16</td>
<td>16</td>
<td>2.13</td>
</tr>
<tr>
<td>Control Group(n=10)</td>
<td>Mean</td>
<td>40.1</td>
<td>39.5</td>
</tr>
<tr>
<td></td>
<td>SD</td>
<td>±2.76</td>
<td>±3.48</td>
</tr>
</tbody>
</table>

* Subject used a four inch curb height

### Table 3: Circumferential Measurements for TKA Case Study Subjects

<table>
<thead>
<tr>
<th></th>
<th>Subject A</th>
<th></th>
<th>Subject B</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Right</td>
<td>Left</td>
<td>Right</td>
<td>Left</td>
</tr>
<tr>
<td>Suprapatellar (cm)</td>
<td>45.3</td>
<td>44.1</td>
<td>64.0</td>
<td>64.5</td>
</tr>
<tr>
<td>Knee Joint Line (cm)</td>
<td>43.5</td>
<td>42.0</td>
<td>60.0</td>
<td>61.0</td>
</tr>
<tr>
<td>Infrapatellar (cm)</td>
<td>39.9</td>
<td>38.0</td>
<td>55.0</td>
<td>57.0</td>
</tr>
</tbody>
</table>
Table 3: Results of Limits of Stability: control group reported as means and standard deviations

<table>
<thead>
<tr>
<th></th>
<th>Control Group (n= 10)</th>
<th>Subject A</th>
<th>Subject B</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reaction Times (secs)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Front</td>
<td>0.82 (±0.074)</td>
<td>0.99</td>
<td>1.36</td>
</tr>
<tr>
<td>Right</td>
<td>1.03 (±0.13)</td>
<td>1.04</td>
<td>1.10</td>
</tr>
<tr>
<td>Back</td>
<td>0.61 (± 0.063)</td>
<td>0.85</td>
<td>0.69</td>
</tr>
<tr>
<td>Left</td>
<td>0.91 (±0.094)</td>
<td>1.79</td>
<td>1.13</td>
</tr>
<tr>
<td>Comprehensive</td>
<td>0.85 (±0.062)</td>
<td>1.17</td>
<td>1.07</td>
</tr>
<tr>
<td><strong>Movement Velocity (degs/sec)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Front</td>
<td>4.26 (±0.73)</td>
<td>2.10</td>
<td>1.50</td>
</tr>
<tr>
<td>Right</td>
<td>4.17 (± 0.056)</td>
<td>2.30</td>
<td>2.50</td>
</tr>
<tr>
<td>Back</td>
<td>2.38 (±0.33)</td>
<td>2.00</td>
<td>1.30</td>
</tr>
<tr>
<td>Left</td>
<td>4.00 (±0.82)</td>
<td>3.30</td>
<td>1.70</td>
</tr>
<tr>
<td>Comprehensive</td>
<td>3.65 (±0.52)</td>
<td>2.40</td>
<td>1.80</td>
</tr>
<tr>
<td><strong>Endpoint Excursion (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Front</td>
<td>77.40 (±3.85)</td>
<td>40</td>
<td>57</td>
</tr>
<tr>
<td>Right</td>
<td>77.33 (±3.68)</td>
<td>54</td>
<td>70</td>
</tr>
<tr>
<td>Back</td>
<td>52.00 (±4.15)</td>
<td>38</td>
<td>41</td>
</tr>
<tr>
<td>Left</td>
<td>80.30 (±4.42)</td>
<td>74</td>
<td>56</td>
</tr>
<tr>
<td>Comprehensive</td>
<td>72.50 (±1.94)</td>
<td>52</td>
<td>56</td>
</tr>
<tr>
<td><strong>Maximum Excursion (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Front</td>
<td>99.50 (±3.85)</td>
<td>71</td>
<td>80</td>
</tr>
<tr>
<td>Right</td>
<td>96.44 (±3.32)</td>
<td>71</td>
<td>76</td>
</tr>
<tr>
<td>Back</td>
<td>81.33 (±9.81)</td>
<td>68</td>
<td>101</td>
</tr>
<tr>
<td>Left</td>
<td>96.80 (±4.69)</td>
<td>107</td>
<td>80</td>
</tr>
<tr>
<td>Comprehensive</td>
<td>93.60 (±2.73)</td>
<td>79</td>
<td>84</td>
</tr>
<tr>
<td><strong>Directional Control (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Front</td>
<td>84.80 (±1.90)</td>
<td>58</td>
<td>79</td>
</tr>
<tr>
<td>Right</td>
<td>79.44 (±3.76)</td>
<td>62</td>
<td>70</td>
</tr>
<tr>
<td>Back</td>
<td>59.33 (±5.68)</td>
<td>70</td>
<td>94</td>
</tr>
<tr>
<td>Left</td>
<td>80.20 (±2.31)</td>
<td>90</td>
<td>74</td>
</tr>
<tr>
<td>Comprehensive</td>
<td>76.10 (±2.33)</td>
<td>70</td>
<td>79</td>
</tr>
</tbody>
</table>
REFERENCES


