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

Jeremy St. Aubin
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TWO CASE STUDIES:
Evaluation of Balance Following Unilateral Total Knee Arthroplasty

by

Jeremy St. Aubin
Bachelor of Science in Physical Therapy
University of North Dakota, 1998

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

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

(Signature)
(Faculty Preceptor)

(Signature)
(Graduate School Advisor)

(Signature)
(Chairperson, Physical Therapy)
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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ABSTRACT

The purpose of this study was to compare total knee arthroplasties (TKA) to a group of control subjects to see if any balance deviations existed at 12-16 weeks post operatively. Ten normal and two TKA subjects (65-80 years of age) were evaluated with the NeuroCom Balance Master® 6.1 system. The evaluation consisted of five tests that measured endsway, reaction times and weight bearing characteristics. Ten normal subjects as well as two TKA's took place in this study. The results showed that the TKA's had a decreased reaction time, increased sway and abnormal weight bearing characteristics. In conclusion we see that at this time frame the TKA has a decreased level of balance compared to the normal group.
CHAPTER 1
INTRODUCTION

Balance and proprioception, just the concept brings to mind petite ballerinas prancing around on a beam three inches wide, but for most of the population balance is a far more important and difficult facet than this. For the elderly (those 65 and over) it is even more important, often determining when independence will be lost. Balance allows us to stand upright and move freely where we choose. It allows us to accomplish tasks of everyday living without the fear of injury. With these thoughts in mind it is plain to see why a study on balance is so relevant to PT.

Balance is an in-depth process utilizing sensory input, central processing, and neuromuscular responses.\(^1\) It is also a critical part of daily life allowing for self care and completion of activities of daily living. It is thought that knee mechano receptors are very important for balance because they communicate with the agonist and antagonist muscles through the sensory input.\(^2\) Since the knee joint is traumatized during surgery, many of these receptors are compromised and just how they are affected may correlate to how the subjects balance returns.

Balance and proprioception incorporate many of the same joint receptors and sensory feedback systems. Proprioception and position sense appears to falter as an
individual gets older.\textsuperscript{3} Mortality and morbidity are directly related to falls of those 65 and older.\textsuperscript{4} We as clinicians are also very aware that insult and injury to a joint decrease its position sense. If it were possible to identify where the problems were stemming from and treat them effectively perhaps we could lower both of these numbers.

Osteoarthritis is often the most prevalent cause leading to a total knee arthroplasty. In the United States over 100,000 of the TKA surgeries are performed yearly.\textsuperscript{5} It is also the case that osteoporosis, and the prevalence of osteoarthritis increase with age. Thus with an increase in age and an ever increasing chance of osteoarthritis with age we are sure to see the ever increasing chance of the TKA. The result of these restorative operations are like so many; to return normal function. However, few studies have solidified views that incorporated osteoarthritis, total knee arthroplasty and the elderly. With these key thoughts in mind it is easy to see why I chose a study to assess the difference in balance between a group of normative data and the group of TKA candidates. Assessment of the effects this surgery has on balance in the elderly TKA population is important and to obtain the most objectable data possible it is important to use appropriate tools.

One specific tool, an innovative piece of technology, that has started to identify balance problems is the NeuroCom Balance Master\textsuperscript{®} 6.0. Developed in 1989 this piece of technology has been used in past studies and is very useful in identifying balance deficits of numerous pathologies and ages and will be the major evaluative tool in this study.\textsuperscript{6}
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CHAPTER 2
REVIEW OF THE LITERATURE

The number one cause of death in humans sixty five and older are falls.\textsuperscript{4} Assuming however that a person does not die from a fall, then there is physical as well as psychological issues to deal with. This can in turn lead to large financial burdens to that person as well as sometimes the family. It may limit their activities of daily living; they’re working conditions, and generally makes living more difficult. Also, the communities financial burden is large as Medicare is involved in those clientele over the age of 65, the majority of this pathological community.

\textbf{Anatomy}

The knee joint consists of three bones the femur, tibia, and the patella. The femur and tibia articulate medially and laterally with the tibia gliding posteriorly during flexion. The patella is located in a frontal plane gliding superiorly during flexion. These are important considerations when knee replacement is contemplated, as both anatomical and biomechanical outcome is critical.\textsuperscript{17}

The knee joint is a hinge joint moving in only right angles to the bones involved. Movement consists mainly of flexion and extension as well as a little
rotation. Although there are only these few movements; they prove to be crucial in ambulation activities.

Menisci are simply shock absorbers between the femur and tibia plateau although they also help to increase the congruency between these bones. They are divided into two sections, the lateral menisci which is thought to look like a closed C shape, and the medial menisci, a more half moon appearance.

Collateral ligaments are located laterally and medially in the knee as well. The medial collateral ligament resists a valgus force and is attached to the medial distal femur and medial proximal tibia as well as the medial meniscus. The lateral collateral ligament resists varus and is located much the same except for no attachment to the meniscus.

The final piece of this anatomical puzzle is the cruciate ligaments. They are so named describing where they start on the tibia, as both are located inside the synovium. The anterior cruciate ligament begins anteriorly on the medial tibia and goes to the posterior lateral side of the femur. The posterior cruciate ligament goes posterior lateral tibia to the medial posterior femur. They are both considered very important in proprioception before and after total knee arthroplasty.

Joint Changes

Changes that take place in the knee joint and require some form of arthroplasty can be broken into three sections: loss of articular cartilage, breakdown of the bone and tibial lateral dislocation.
The first stage to be described is where loss of articular cartilage is evident, at this stage the bone has not been altered and very little change of range of motion or deformity presents itself. The ligamentous structures also present with very little change. No arthroplasty is usually indicated at this joint.\textsuperscript{9}

Breakdown of the bone and deformity presents itself in stage two. Collateral ligaments on the diseased side of the joint (medial for varus) often will present themselves as shortened. When this situation presents itself not only is bone taken from the knee but a release of the soft tissues is often mandated. A condylar replacement of joint is often suggested for this type of situation and breakdown.\textsuperscript{9}

Stage three can be described as tibial lateral dislocation. An assessment may reveal lengthened collaterals and cruciates. Often subscribed for this may be constrained prosthesis such as the type our patient received.\textsuperscript{9}

As is evident with all surgeries, the overlying goal is to take the least amount of bone while achieving the most joint integrity, secureness, and best alignment. This can be generalized into all reconstructive surgeries.

Often the goals of this surgery are relief or decrease of pain, increased ability to function in all capacitance, and return to as normal living as possible. Just how these goals are measured is varied throughout previous studies. Thoughts that are worth consideration before performing this joint replacement are age of the patient, how bad the knee is destroyed structurally, and the degree to which other joints have been insulted.\textsuperscript{9}
Pathology

Now let's talk about the pathology that most often presents to precipitate these sort of joint changes, osteoarthritis. Osteoarthritis, chronic breakdown of cartilage in the joints, takes different courses on different individuals but often pain and discomfort are present with diagnosis. Pain with movement can result in less movement and range of motion which weakens the surrounding musculature and is a circle effect making it even more difficult to move. With the decrease in movement, proprioceptive awareness is sure to show an effect.

Proprioception

Proprioception is described as information on position sense. There are receptors in the capsule and pericapsular tissues that respond to the central nervous system much like the postural responses and here you can find the “atoms”, or most basic element, of proprioception called joint receptors. Thus it easy to postulate that if there is a problem with position sense of an angle there will be problems with balance. The knee is also described as having many nerve endings located in the articular capsule. Those nerve endings are “relatives” of the nerves that supply the muscles moving the joint and skin area. This is an overview of Hiltons Law.

Proprioception can be severely affected if anything that is not normal to the joint is found there. Such is the case by McNair et al that studied knee joint effusion and proprioception in 29 year old healthy nonpathological individuals. It is common knowledge that joint fluid can often coagulate in excess in degenerative joint
conditions. McNair’s study reported that the knee lacked a maximal extension range and that the flexion could not be produced with the accuracy considered effective when there was the effusion. This shows the importance of minimizing joint fluid during proprioceptive tests.

In a study by Duncan et al they found that any shortcoming in functional mobility in the 65 and older age group without severe pathology may be controlled by an aggregate of sensory, effector, and central processing than by any specific deficit. There is also a study by Barrack et al that found a more pronounced degradation of daily living activities with those people with osteoarthritis and TKAs versus just TKAs. However, he also found that that there was no further damage with total knee arthroplasties if osteoarthritis was already present.

Skinner et al showed there was a direct correlation between decreased proprioception and age (20-82) increase. It is also thought this may be the reason for a widened base while walking that is often observed in those over 65.

Barrett et al compared joint proprioception in normal osteoarthritic and replaced knees and that study found that joint position sense was severely impaired in osteoarthritic knees. They also found that simply wearing an elastic bandage significantly improved those knees with fluid and those knees without fluid in accuracy of reproducing a specific degree of joint movement. Placing a joint in a specific angle and asking the patient to reproduce it on the other leg or returning the
test limb to the starting position and then asking the patient to reproduce it is an often used test for proprioceptive awareness.\textsuperscript{18}

Marks\textsuperscript{19} also conducted a similar study that displayed rematching angle testing significantly lower in the osteoarthritic subjects. Also, the osteoarthritic subjects provided increased error flexion magnitudes than the normative data.\textsuperscript{19}

**Knee Arthroplasty**

When describing a study on proprioceptive awareness in total knee arthroplasty, it may be important to first look at what is total knee arthroplasty itself. Simply broken apart arthro means joint and plasty means reconstruction, and in this instance, of the knee.\textsuperscript{10}

Universally there are four types of arthroplasty joints. They are the compartmental, condylar, semiconstrained, and constrained hinge. There is no definite type that is used most often and surgeon choice is the overlying factor. We will look singly at the type of joint which the subject presented with.

The type that the doctor used, a Posterior Cruciate Ligament (PCL) sacrificing approach, was a unilateral compartmental. This type has a femoral component that has a single stud and the flat tibial component has a flange for fixation.\textsuperscript{9} The tibial and femoral pieces are both cemented in position. What makes this type original is that it has a mobile meniscal polyethylene bearing which is placed between the femoral and tibial instruments. These make shift menisci allow rotation and will allow the remaining ligaments to choose their path of travel in the synovium.
PCL Importance

It is critical to consider the importance of the posterior cruciate ligament and proprioception as this is a topic of great debate. Replacements can be done resecting the posterior cruciate ligament and replacing it with a central cam. It can also simply be left in the joint. In a study by Cash et al.\textsuperscript{20} no difference was found in proprioceptive awareness between those deficient of the ligament and those spared. However in many other reports, the feeling is quite the contrary. Such is the case report by Attfield\textsuperscript{21}, where he found that semiconstrained knees, where the PCL is spared, tested significantly higher than hinge joint knees, where the PCL is sacrificed, suggesting the importance of ligaments and the capsule.

Total knee replacement protocols either spare or sacrifice the posterior cruciate ligament. There are advocates for both sides. Those who feel it should be spared believe that it decreases stress to the bone prosthesis site and that it also helps in the stress bearing function. It also leads to questioning the ability of the surgeon to balance the posterior cruciate so that normal kinematics can occur. Proponents for the resection feel that there are excellent clinical results and the much better fit of the polyethylene component which thus decreases the polyethylene stress.\textsuperscript{25}

Balance Components

The sensorimotor system is very important in movement. Interaction of sensory and motor systems occurs throughout the CNS and makes up this system.\textsuperscript{12} Any changes in tactile, proprioceptive awareness, vision problems or vestibular
systems can severely alter a subjects ability to ambulate or produce any sort of motion.

Not only is the knee critical during movement and mobility activities, the knee is critical in supporting the body while movement and nonmovement activities are occurring. With the foot on the ground the knee and hip work together as well as the ankle to support the body in erect posture. Dynamically the body helps transfer body weight during all activities of motion. Whether we squat, run, or walk, it is active in locomotor activities.

Balance is a three way system involving congruency between motor, sensory, and biomechanical components. Although our study looks at the knee, hip and ankle are equally important in the lower extremity proprioception. These systems all must work together to achieve the balance that is so important in our daily lives. Let us now break down the three important components and the result expected due to aging.

Problems

As one ages, especially over 65, there are many changes that occur to the individual sensory system that affect balance. If a situation is void of somatasensory and visual feedback increased balance problems can result due to the void. Dizziness and degenerative processes due to aging otoliths can often set problems off here. This may result in positional vertigo and imbalance during ambulatory activities.

In the somatasensory system (touch) thresholds are thought to increase according to a study that reported inability of the subjects to feel a vibratory
sensation. This could due to sensory neuropathies or other diseases that affect the relay of sensory information.

Vision is simply how well you see your surroundings using the retina, stimulating the rods and cones, and nerve impulses to the brain. Vision can also have a direct correlation on the balance an elderly patient presents with. It is postulated that due to less light reaching the retina and decreases in visual contrast sensitivity there are increasing problems with defining contours and depth perception. This also can be due to age related effects such as macular degeneration, cataracts and loss of peripheral vision.

The vestibular system, which is mainly used for hearing, is equally important for balance. It involves using the specialized hair cells called mechanoreceptors that trigger nerves which are eventually perceived as balance. The vestibular system steadily declines with a loss of 40% of the hair and nerve cells by the time the subject attains an age of 70.

With this information presented there needs to be no major problems with any of the three systems so that the emphasis of any study is not focusing on these problems, but the knee joint pathology itself.

**NeuroCom Balance Master® 6.1**

The Balance Master® 6.1 is one of a host of evaluative tools used to assess balance. It has shown its effectiveness in many other studies incorporating mild head injuries and stroke. The use of it however to test the orthopedic population is still
very underdeveloped. It has been used often across age ranges and genders establishing normative data and used to compare in other studies. One of these studies by Hageman\textsuperscript{25}, took into account the effects of age and gender on postural control. An interesting fact that offers more validity to this literature review is that he did indeed find that those over 65 had a decreased balance ability than those of a younger age with no effect on gender.\textsuperscript{25}

**Outcomes**

The outcomes of total knees are improving each year and there seems to be a direct correlation between younger patients and total knee arthroplasty. There is also a push toward younger and more mobile patients.\textsuperscript{7} This will definitely envelop a larger population and lead to a healthier happier individual. The idea behind not allowing the younger patients this surgery before was that the joints would last a maximum of ten years. Now that the materials and techniques are changing to accommodate for more active individuals, and the techniques have improved as well as the materials to last longer this is an option. This will surely be the case as there are already 100,000 TKA’s yearly.\textsuperscript{5}

As we move toward more patient evaluation of their health and health related quality of life, as well as the population trying to be more active and function moderately in society, ie working, we shall see this type of surgery remain prevalent. In a study by Rissanen, he found that the subjects reported a significant increase in their quality of life after the TKA compared to prearthroplasty.\textsuperscript{26}
CHAPTER 3

METHODOLOGY

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. 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, and range 65-71). 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’® (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 the rehabilitation hospital where the NeuroCom Balance Master® equipment was set up. Once at the facility, subjects completed a pre-screening medical questionnaire (see Appendix B) 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. All subjects provided written informed consent in accordance with guidelines established by Altru Health System’s and the University of North Dakota’s Institutional Review Board, prior to participating in this study (Appendix A).

**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 patients with a variety of diagnosis and provide objective information regarding balance ability. The NeuroCom Balance Master® operates on a forceplate 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 (Appendix B).

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.6 Hageman et al.28 reported that the test-retest reliability for sway measurements and movement time was high in 12 normal subjects. Clarke et al.29 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 sidelying position.30 This was done because we thought that the TKA case study subjects would find the prone position uncomfortable. 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.31 McCormack et al.31 reported retest reliability of the visual analogue scale to be .94.
Subjects were given instructions and a brief warm up period to familiarize them with the NeuroCom Balance Master® system. This allowed them to see the relationship of how to move the cursor on the screen by altering their 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 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®, and although the participant was allowed some balance disturbances, a spotter was present to help prevent a possible fall. Individuals should 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. Both testers took a class about the NeuroCom Balance Master® and performed reliability studies prior to this research.

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, 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. 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.  

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, specific parameters (i.e. movement velocity, end sway, etc.) were calculated from the forceplate data. Each parameter is reported as the average of the three trial scores.

**Weight Bearing**

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**

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**

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

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

The final performance test was the step up and over test using an eight-inch curb. 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 a 8 inch curb. Subject B used a 4 inch curb due to fear and apprehension with used 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 SPSS computer program (SPSS Inc: Chicago IL) 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 for the control group (n=10) collected and calculating means and standard deviations. The data of each TKA subject was compared against each other as well as the normative data of the control group. These numbers were also compared against the age normative data of the Neurocom BalanceMaster® 6.1 to determine if any balance differences between any of the groups were apparent. There were no subjects, TKA or control, that needed to be excluded from this study.

In the following section each test considered 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 right TKA will be described as "A" and the left will be described as "B". The scores of each TKA will be compared to the Neurocom Balancemaster® 6.1 normative data in the final section of this chapter. Please refer to the tables provided if any further numbers are desired.

Range of Motion

There were no noticeable pretest differences between the normative group and the group of TKA’s that would elicit any deviations that would place the TKA’s in a position that would hinder them from completing the assessment and presenting with comparative results to the norm group.
Visual Analogue Scale

The visual analogue scale results showed no noticeable difference as all participants, including the TKA's, marked at the “no pain” end of the scale.

Weight Bearing Squat Test

The weight bearing squat test for our normative data showed a mean of 53.7% SD=±3.7133 (Range 48-60) of the weight being borne on the left and 46.3% SD=±3.7133(Range 40-52) of the weight being borne on the right with the knees in 0° of flexion. The results show at 30° of flexion were a mean at 51.7% SD=±7.0875 (Range 35-62) of the weight being borne on the left and 48.3% SD=±7.085 (Range 38-65) being borne on the right. Finally at 60° of flexion, the results were 53.2% SD=±6.0882 (Range 42-62) being borne on the left and 46.8 SD=±6.0882 (Range 38-58) being borne on the right.

The normative data is not noticeably different in comparison to the 2 TKA subjects. Subject A showed 52% of the weight being borne on the left and 48% of the weight being borne on the right at 0° compared to subject B who showed 43% of the weight being borne on the left and 57% on the right. The results at 30° were 58% of the weight being borne on the left and 42% on the right for A compared to B who demonstrated 40% of the weight being borne on the left and 60% on the right. The final measurement at 60° exhibited A with 56% of the weight being borne on the left and 44% on the right compared to B with 43% of the weight being borne on the left and 57% on the right. This showing that the involved leg is still not accepting half of the subjects body weight. Please refer to table 1 and figure 1.
Table 1. -- Weight Bearing test

<table>
<thead>
<tr>
<th>Subject</th>
<th>Knees extended</th>
<th></th>
<th>Knees Bent 30°</th>
<th></th>
<th>Knees Bent 60°</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Right Left</td>
<td>Right Left</td>
<td>Right Left</td>
<td>Right Left</td>
<td>Right Left</td>
<td>Right Left</td>
</tr>
<tr>
<td>Subject A</td>
<td>48 52</td>
<td>42 58</td>
<td>44 56</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subject B</td>
<td>57 43</td>
<td>60 40</td>
<td>43 57</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control Group</td>
<td>46 54</td>
<td>48 52</td>
<td>47 53</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* numbers expressed as a percentage of body weight

Figure 1. Body Weight being borne with knees extended

Walk Test

The normative data results showed an endsway mean of 4.24 deg/sec SD=±1.6015 (Range 2.3-6.4) and a mean speed of 69.27cm/sec SD=±13.4751 (Range 45.3-84.9). Also, the step length mean was 47.33 cm SD=±15.6484 (Range 30.1-77.8) with the mean step width 19.94cm SD=±2.3871 (Range 16.1-23.4).
The numbers for the TKA's showed some difference secondary to the patients taking shorter and more controlled steps. The step width for A was 18.9 cm and 37.4 cm for the step length. B showed results of 18.5 cm for the step width and 32 cm for the step length. The final results for endsway were 2.9 deg/sec and speed of 50.8 cm/sec for subject A. Subject B exhibited results of endsway of 2.5 deg/sec and speed of 34.5 cm/sec. Please refer to table 2.

<table>
<thead>
<tr>
<th>Walk Test</th>
<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>Subject A</td>
<td>2.9</td>
<td>50.8</td>
<td>37.4</td>
<td>18.9</td>
<td></td>
</tr>
<tr>
<td>Subject B</td>
<td>2.5</td>
<td>34.5</td>
<td>32</td>
<td>18.5</td>
<td></td>
</tr>
<tr>
<td>Control Group</td>
<td>4.24</td>
<td>69.27</td>
<td>47.33</td>
<td>19.94</td>
<td></td>
</tr>
</tbody>
</table>

**Sit To Stand Test**

The normative data presented with an average of 5% more than the 50% desired weight being borne on either the left or right lower extremity during this test. This can be further broken down into 6 controls bearing more weight on the left with a mean of 5.2% SD=±1.1081 and 4 controls bearing more weight on the right with a mean difference of 4.7% SD=±1.25. The comparison by the TKA's is significantly different as subject A displayed 13% more than the desired 50% of the weight on the left and subject B displayed 15% more on the right. Please refer to table 3 and figure 2.
Table 3. Sit to stand average results

<table>
<thead>
<tr>
<th></th>
<th>Weight Transfer*</th>
<th>Rising Index†</th>
<th>COG Sway Velocity‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject A</td>
<td>0.51</td>
<td>14</td>
<td>4</td>
</tr>
<tr>
<td>Subject bilat.</td>
<td>0.4</td>
<td>10</td>
<td>5.5</td>
</tr>
<tr>
<td>Control Group</td>
<td>0.4930</td>
<td>16.2</td>
<td>3.8</td>
</tr>
</tbody>
</table>

*: reported in seconds  
†: reported as percent body weight  
‡: reported as degrees/seconds

Figure 2. Weight symmetry of all participants on coming to stand
Step Up and Over

The normative data collected resulted in a mean impact index of 11.9% SD=±5.3219 (Range 3-19) which was different from the 50% expected. This number can be further broken down into 6 subjects with a greater left impact mean of 10.83 SD=±4.12 (Range 6-16) and the right impact mean at 13.5 SD=±7.14 (Range 3-19). All subjects had to do three trials leading with the right leg and three trials with the left leg. The movement time for the controls was 5.5% SD=±7.0119 (Range 0-21) difference between the right and left legs. These numbers can be further broken down into 4 controls left movement time dominant with a mean of 7.75 SD=±9.43 (Range 1-21) and the other 5 controls with the right dominant and a mean of 4.8 SD=±5.54 (Range 1-14). There was one control that showed no noticable difference bilaterally. The final reported mean for the lift up index was at 9.3% SD=±7.1032 (Range 0-21) difference from the 50% of equal weightbearing expected on each lower extremity. These numbers can be divided like the previous and 3 controls dominant on the left at a mean of 12.67 SD=±8.5 (Range 3-19) and 6 controls dominant on the right with a mean of 9.2 SD=±6.1455 (Range 4-21). It should be mentioned that the Neuro Com Balance Master® 6.1 will interpret the direction to which the difference is occurring such as in the impact difference if the right has a larger percent of body weight coming down than when the trial is run on the left, but for descriptive statistical analysis we will run only true percentage differences and further discuss the directional differences in the following chapter.

The impact index reported for each of the TKA's was 6% difference on the right for control A compared to 15% for control B. The movement time for control A is 6%
difference for subject A compared to 4% for subject B. The final interpretative data for the TKA’s was the lift up index. Subject A had an 8% difference while subject B showed no percent difference. It should be noted that subject A used an 8 inch curb while subject B used a 4 inch curb as she was unsteady at the 8 inch height. Please refer to table 4.

**Table 4.** Step up and over averages.

<table>
<thead>
<tr>
<th></th>
<th>Lift Up Index</th>
<th>Movement Time</th>
<th>Impact Index</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</td>
<td>40.1</td>
<td>39.5</td>
<td>1.446</td>
</tr>
</tbody>
</table>

* 1: body weight borne on each leg reported in percentages
† 2: reported in seconds
‡ 3: body weight on each leg reported in percentages
§ performed test using 4” curb

**Limits of Stability**

The limits of stability normative data is very inclusive and for all results please refer to the table provided. The following normative data will be reported in the order as follows: front, right, back, and left. Directional control (movement toward the intended target) values were 84.8% SD=±3.3066 (Range 85-95), 79.44% SD=±14.7181 (Range 44-91), 59.33% SD=±5.348 (Range 39-89), and 80.2% SD=±4.8546 (Range 77-94). Movement velocity normative values were 4.26 deg/sec SD=±1.1225 (Range 1.4-4.9), 4.17 deg/sec SD=±2.4748 (Range 2.2-8.8), 2.38 deg/sec SD=±2.52 (Range .6-6.3), and 4.00 deg/sec SD=±.83 (Range 1.4-10.4). Reaction times were .82 sec SD=±.5969 (Range
.27-2.28), 1.03 sec SD=±.1641 (Range .3-1.93), .91 sec SD=±.1257 (Range .21-1.21),
and .61 sec SD=±.1528 (Range .46-2.07). Maximal excursions to the front were 99.5% 
SD=±7.5638 (Range 83-106), 96.44% SD=±3.7655 (Range 64-105), 81.33% 
SD=±25.1189 (Range 30-314), and 96.8% SD=±3.8072 (Range 71-108).

The TKA results were different from each other and also different from the 
normative data collected. Subject A directional control was (using the previous system of 
reporting) 58%, 62%, 70%, and 90%. Subject B’s results were 79%, 70%, 94%, and 74%.
The numbers for movement velocity of subject A were 2.1 deg/sec, 2.3 deg/sec, 2.0 
deg/sec, and 3.3 deg/sec. The comparative numbers for B were 1.5 deg/sec, 2.5 deg/sec, 
1.3 deg/sec, and 1.7 deg/sec. The reaction times for A were .99 sec, 1.04 sec, .85 sec, and 
1.79 sec. The correlative numbers for B are 1.36 sec, 1.1 sec, .69 sec, and 1.13 sec. The 
last numbers to be observed were the maximum excursions and the results for A were 
71%, 71%, 68%, and 107%. These numbers for subject B were 80%, 101%, 76%, and 
80%. Please refer to tables 5-9.

Limits of Stability sectioned tables.

<table>
<thead>
<tr>
<th>Table 5. Reaction time averages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>Subject A</td>
</tr>
<tr>
<td>Subject B</td>
</tr>
<tr>
<td>Controls</td>
</tr>
</tbody>
</table>

* (seconds)
Table 6. Movement velocity averages

<table>
<thead>
<tr>
<th>Subject</th>
<th>Front</th>
<th>Right Front</th>
<th>Right</th>
<th>Right Back</th>
<th>Back</th>
<th>Left Back</th>
<th>Left</th>
<th>Left Front</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject A</td>
<td>2.4</td>
<td>1.8</td>
<td>3.2</td>
<td>2.1</td>
<td>2.4</td>
<td>2.6</td>
<td>3.5</td>
<td>2.7</td>
</tr>
<tr>
<td>Subject B</td>
<td>1.5</td>
<td>1.9</td>
<td>3.4</td>
<td>1.5</td>
<td>1.4</td>
<td>1.2</td>
<td>2.5</td>
<td>1.6</td>
</tr>
<tr>
<td>Controls</td>
<td>3.1</td>
<td>4.5</td>
<td>4.7</td>
<td>2.8</td>
<td>2.5</td>
<td>3.1</td>
<td>4.0</td>
<td>1.2</td>
</tr>
</tbody>
</table>

* (degrees/second)

Table 7. Endpoint excursion averages

<table>
<thead>
<tr>
<th>Subject</th>
<th>Front</th>
<th>Right Front</th>
<th>Right</th>
<th>Right Back</th>
<th>Back</th>
<th>Left Back</th>
<th>Left</th>
<th>Left Front</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject A</td>
<td>41</td>
<td>32</td>
<td>68</td>
<td>63</td>
<td>29</td>
<td>57</td>
<td>76</td>
<td>63</td>
</tr>
<tr>
<td>Subject B</td>
<td>35</td>
<td>99</td>
<td>56</td>
<td>44</td>
<td>50</td>
<td>30</td>
<td>68</td>
<td>70</td>
</tr>
<tr>
<td>Controls</td>
<td>73</td>
<td>82</td>
<td>74</td>
<td>65</td>
<td>54</td>
<td>61</td>
<td>87</td>
<td>81</td>
</tr>
</tbody>
</table>

* (%)

Table 8. Maximum excursion averages

<table>
<thead>
<tr>
<th>Subject</th>
<th>Front</th>
<th>Right Front</th>
<th>Right</th>
<th>Right Back</th>
<th>Back</th>
<th>Left Back</th>
<th>Left</th>
<th>Left Front</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject A</td>
<td>60</td>
<td>81</td>
<td>80</td>
<td>77</td>
<td>68</td>
<td>111</td>
<td>87</td>
<td>89</td>
</tr>
<tr>
<td>Subject B</td>
<td>79</td>
<td>103</td>
<td>99</td>
<td>78</td>
<td>74</td>
<td>77</td>
<td>97</td>
<td>90</td>
</tr>
<tr>
<td>Controls</td>
<td>96</td>
<td>100</td>
<td>90</td>
<td>88</td>
<td>95</td>
<td>85</td>
<td>95</td>
<td>104</td>
</tr>
</tbody>
</table>

* (%)
**Table 9. Directional Control averages**

<table>
<thead>
<tr>
<th>Subjects</th>
<th>Front</th>
<th>Right Front</th>
<th>Right</th>
<th>Right Back</th>
<th>Back</th>
<th>Left Back</th>
<th>Left</th>
<th>Left Front</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject A</td>
<td>43</td>
<td>71</td>
<td>81</td>
<td>77</td>
<td>78</td>
<td>67</td>
<td>91</td>
<td>80</td>
</tr>
<tr>
<td>Subject B</td>
<td>88</td>
<td>88</td>
<td>90</td>
<td>81</td>
<td>69</td>
<td>65</td>
<td>90</td>
<td>87</td>
</tr>
<tr>
<td>Controls</td>
<td>87</td>
<td>83</td>
<td>80</td>
<td>65</td>
<td>63</td>
<td>66</td>
<td>86</td>
<td>83</td>
</tr>
</tbody>
</table>

* (%)
CHAPTER 5
DISCUSSION

The results of this study show that there is a balance difference between the TKA subjects and the normative data. This is most apparent when looking at the endsway mean of the TKA’s at 2.7 deg/sec and the norm group at 4.24 deg/sec. There are further differences throughout the numbers and I believe explanations of why some of the outcomes are apparent. I did not say deficit for the fact that the TKA’s outcome numbers were inside the average for that age group described by NeuroCom Balance Master® 6.1.

The first test described in the results was the weight bearing and squat test. This test showed that for the normative group about 50% of the persons weight was borne on each side. The TKA subject on the other hand showed that with increasing angular flexion they were less likely to bear that 50% expected. In fact at 30° the two TKAs demonstrated only about 40% of their body weight on their affected leg. This could be due to an array of things such as pain or decreased strength. It could also be largely due to the psychological effect of knowing the leg has had pathology (a preoporatory habit) and the decreased use that accompanies the idea of over using it or the pain that often accompanies the arthroplasty following surgery. Subject A showed an improved percentage at 0° and this may be due to a host of things as well such as type of weight bearing allowed post surgery, previous condition, the therapy received in the hospital, and how compliant the patient is with her home program.
The second test was more of a functional test and this was the walk test. As stated earlier there was a large discrepancy with endsway with the norms at 4.24 deg/sec and the TKA’s at 2.7 deg/sec. I believe a further look into these numbers is warranted. As you can see the TKA subjects took much shorter steps at 37.4 cm and 32 cm than the norms at a mean of 47.33. Also, their speed 50.8 cm/sec and 34.5 cm/sec was much slower than the norms mean of 69.27 cm/sec. The TKA subjects were taking shorter and much slower controlled steps resulting in the decreased endsway. I believe if they would have taken larger steps at a similar pace to the controls this would have altered the results considerably. This is a wonderful concept to understand however, in knowing that a TKA will take shorter more controlled steps it may be an integral part of therapy to keep this concept in mind while administering or setting up treatment plans for these arthroplasties.

A study that incorporates these ideas is by Hageman\textsuperscript{25} who found that when the conditions were normalized that the older population (60-75) exhibited longer movement times and larger areas of sway.

The sit to stand is another very functional test as this is involved in many transfers per day. Our results were quite apparent as the norm group showed slight variation in rising with only 5% more weight being borne on one side versus the other. The TKAs' had more weight being borne on the uninvolved side such as the left leg for subject A at 13% and 15% on the right leg for subject B. This is correlative to our weight bearing test when the uninvolved leg supported much more weight than the involved. Since the sit test starts at approximately 90\(^\circ\) of knee flexion it must come through varying degrees to come to a stand. Those same degrees we measured in the weight bearing and squat test.
With this in mind it is obvious to understand why the uninvolved leg was used at a greater capacitance.

The step up and over test showed little variance and this surprised me. Subject B however used only a 4 inch curb compared to subject A. This results in less demand being placed on the varying degrees of knee joint flexion. This subject also circumducted her involved leg, hiking her hip, while completing this task. This resulted in less flexion being required to come to stand on top of the curb. This could be why when comparing the subjects between themselves subject A had an 8% difference and subject B a no percent difference. There is also a eccentric contraction of the quadriceps femoris happening as the right leg is brought forward in the test and we notice also that even though the operation was on the right knee, for subject A, the impact index is slightly higher for the right side when compared to her left. Their was very little difference otherwise between the norms and the TKA subjects. I would also be interested to know what leg they used dominantly before the surgery to ascend and descend stairs. Perhaps they were placing demands on the leg that did not support the weight previously so that their was not such a difference. Such as if they previously ascended stairs with the right and now had to do it with the left, the right would be more prepared to do the activity even if it did not have the strength or ROM.

The final test was the limits of stability and I believe this test showed some interesting findings as well. Directional control would be largely related to proprioception and balance as the demand is placed on the joint to reach those specific targets located in the various directions. The norm group averaged in the 80’s for all directions required,
while the TKA subjects were often much less than that especially in the direction of the arthroplasty. The movement velocity was also faster toward the intended target in the norm group 3.07 deg/sec versus the TKA’s average of 2.09deg/sec. This could leave many questions such as is the difference a result of the receptors in the joint, is it the cutaneous nerves around the joint that are compromised, is this a result of the aging, (such as the study by Skinner et al\textsuperscript{14}) we discussed earlier, taking more of an effect. There was also a large difference between the TKA subjects themselves as the average for directional control for subject A was 1.75 deg/sec and for subject B 2.45deg/sec a 28.57% difference between the subjects.

A further look into the numbers shows a norm mean of well above 90% in all maximal excursions while those with arthroplasties were only above 90% when going to their uninvolved side. This is very consistent with our other observations and I feel further validates this study.

When comparing this studies normative data to that of the Balance Master\textsuperscript{®} 6.0 normative data we see that ours across the tests appear comparable and have no noticeable difference. However, it is very difficult to compare these numbers with validity not only due to the fact there are less than 30 subjects in both of our groups, but Also, the Balance Master\textsuperscript{®} 6.0 data is divided between age ranges of 60-69 and 70-79, while ours was from 65-71.

The largest limitation was the low population of TKA subjects. All attempts were made to insure reliable and valid findings between all groups of subjects such as limited joint swelling and adequate ROM for the activities required. The largest limitation was
the low population of TKA subjects. Intertester reliability was preestablished, but subject A and subject B did receive instructions from different testers. We were fortunate enough to use the same doctor and type of arthroplasty but the previous level of function, rehab intervention and compliance with their home program was not obtained and this should be considered in prescreen if any further studies of this type are performed. It is true that there is no way to match any two subjects. Those that continue to do the exercises are sure to be stronger and realize what that joint can or cannot handle as far as balance situations. Also, the goals the patient sets after the surgery would have a large part to do with whether they were continually striving for more function.
CHAPTER 6

CONCLUSION

The purpose of this study was to see if there were any differences in the balance of TKA’s and normative data. This was found to be the case in both the left and right TKAs’ however validity was not proven with such a limited number of subjects.

Also to test the inter and intratester reliabilities the numbers were compared with the Balance Master® 6.1. Although these numbers can not be compared validly I feel there is a strong correlation and once intertester and intratester reliability has been established the machine can provide very strong objectable data and results. This will help to identify any differences or problems in balance that may present themselves.

I also wanted to find out if there were a difference in outcomes between the TKA’s. These numbers for the most part were similar with some variances in tests however I realized that their were too many independent variables in the treatments and interactions throughout the arthroplasty time frame for any sort of educational statement about the results to be made. However it was the case that both of these subjects fell into their respective norms for their age groups.

I also feel that the similar results of tests show there is validity in this study. This is a very functional study because it puts forth the overlying question what is the balance of the patient at this time frame and should we expect to see balance problems.
There is very little research that compares the entities that this study compares however to make any kind of inference, a larger group of subjects needs to be obtained. Finding educated answers to these questions will not only allow the therapist to relay better and more effective treatment but allow third party payers more insight to where their dollars are most effective and to provide a better scope of care to their members.
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
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 □

X Expedited Review requested under item 3 (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 be 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 every day 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 Schawnn 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.
ID#: 
Sex: 
Age: 
Height: 
Involved side: 

PRE-ASSESSMENT

Hip flex(supine) right left
Hip ext(sidelying) right left
Hip abd(supine) right left
Hip add(supine) right left
Knee flex(supine) right left
Knee ext(supine) right left
Dorsiflexion right left
Plantarflexion right left

Knee circumferential measurements

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Pain Scale Rating

PAIN AS BAD
AS IT COULD BE

50
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?

2. Have you had any symptoms of unexplained dizziness or lightheadedness in the past six (6) months?

3. Have you experienced any blackouts in the past six (6) months?

4. Are you currently taking any medications that make you feel dizzy or lightheaded or that you know can cause dizziness and lightheadedness?

5. Do you have any hip/knee/ankle diseases?
   If yes, please explain:

6. Have you had any hip/knee/ankle surgeries?
   If yes, please explain:

7. Have you had any lower extremity joint (knee or hip) replacements?
   If yes, Which joint/joints?

8. Are you currently using any crutches, canes or walker for assistance in walking in home or out of home?

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


