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Muscle Activation in Individuals Who are Status-Post a Stroke during Over Ground, Treadmill, and Body Weight Supported Gait: A Comparative Study

Rhonda L. Breitbach
University of North Dakota

Kelly L. Malmin
University of North Dakota

Beth M. Nordmark
University of North Dakota

Jennifer A. Pederson
University of North Dakota

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by

Rhonda L. Breitbach
Bachelor of Science in Physical Therapy
University of North Dakota, 2004

Kelly L. Malmin
Bachelor of Science in Physical Therapy
University of North Dakota, 2004

Beth M. Nordmark
Bachelor of Science in Physical Therapy
University of North Dakota, 2004

Jennifer A. Pederson
Bachelor of Science in Microbiology
North Dakota State University, 2001

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This scholarly project, submitted by Rhonda L. Breitbach, Kelly L. Malmin, Beth M. Nordmark, and Jennifer A. Pederson in partial fulfillment of the requirements for the degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Graduate School Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

Cindy Ellom-Meland
(Graduate School Advisor)

(Chairperson, Physical Therapy)

PERMISSION

Title Muscle activation in individuals who are status-post a stroke during over ground, treadmill, and body weight supported gait: a comparative study.

Department Physical Therapy

Degree Doctor of Physical Therapy

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Signatures Rhonda L. Breitbach

Kelly A. Malmin

Beth M. Nordmark

Jay A. Pedersen

Date 12-15-05

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ABSTRACT

Purpose: The purpose of this study was to evaluate individuals who are status-post stroke during ambulation over ground, on a treadmill without support, and on a treadmill with partial body weight support (PBWS) to determine if there are any differences in muscle activation of major muscle groups in the lower extremity. **Subjects:** Two subjects were recruited for this study. Subjects were included if they were over the age of 50 years, could fulfill a two-hour time commitment, and walk independently with or without the use of an assistive device. Subjects were excluded if they have had surgery or an existing orthopedic involvement of the lower extremities. **Instrumentation:** Sensor surface electrodes were used to pick up electromyography (EMG) activity. EMG activity was collected and final data is presented as percent of normalized EMG activity as an average of four to five gait cycles for each of the support trials. **Procedure:** Consent forms were reviewed and signed by each participant. Electrodes and a heel switch were placed on the involved lower extremity. Subjects performed two trial walks over level ground. Subjects also performed three treadmill ambulation conditions in random order: ambulation on the treadmill without a harness (trm), ambulation on the treadmill with a harness and no body weight support (trmh), and ambulation on the treadmill with a harness and PBWS of 15% (trms). Subjects ambulated for two minutes and EMG activity was recorded for 30 seconds at the end of each minute during each trial condition. **Data Analysis:** The mean EMG activity of the second trial for all ambulation conditions was calculated for both stance and swing

phases of each subject. Descriptive statistics were then used to compare muscle activation across conditions, as well as rank EMG mean muscle activity for each trial condition from highest to lowest. **Results:** EMG rankings were inconsistent across conditions, but both subjects had the least gastrocnemius activity during the trms condition. **Conclusion and Clinical Implication:** There were no major findings or trends to suggest differences or similarities in muscle activation between any of the conditions for either subject. Therefore, further research is needed.

CHAPTER I

INTRODUCTION

Strokes affect an average of 750,000 Americans annually.[1] Individuals who suffer from a stroke often have residual neurological deficits, including motor weakness, poor motor control, and spasticity which negatively influence functional capacity.[2] A functional activity that is often affected is ambulation and many individuals are left non-ambulatory for a period of time. Therefore, gait training is a key component during rehabilitation.[3] Traditional approaches to gait training have included strengthening and coordination training through the use of component part practice.[3] More recent approaches focus on task-oriented repetitive strategies for gait training, including partial body weight support (PBWS) treadmill training.[3]

PBWS treadmill training uses a harness system to support a percentage of patients' body weight.[4-6] This decreases the load on the lower limbs and maintains an upright posture to allow performance of complex, repetitive ambulatory motions.[2,5] Current literature supports the use of 40% or less body weight support to maintain the appropriate gait kinematics during PBWS treadmill training.[4,6]

Problem Statement

Individuals often have difficulty with ambulation following a stroke. Gait training is a common focus of the rehabilitation process in order to enable these individuals to return to a functional level in society. PBWS treadmill training is an intervention that focuses on a task-specific approach to gait training. It is unknown

whether PBWS treadmill training facilitates appropriate muscle activation. Without appropriate muscle activation, it is more likely that compensations will develop during ambulation on steady ground.

Purpose of the Study

The purpose of this study was to evaluate individuals who are status-post stroke during ambulation over ground, on a treadmill without support, and on a treadmill with PBWS to determine if there are any differences in muscle activation of major muscle groups in the lower extremity.

Significance of the Study

The researchers' hypothesis was to find no differences between the ambulation conditions. Previous studies have been conducted validating the use of PBWS treadmill training in restoring functional ambulation. However, these studies have not included objectively measuring possible reasons for the improvement in function. The researchers focused on muscle activation to provide researchers and clinicians with possible theories behind the results of PBWS treadmill training.

Research Question

1. Is there a difference in muscle activation between ambulation over ground and on a treadmill and between ambulation over ground and on a treadmill with PBWS in individuals who are status-post a stroke?

Hypotheses

1a. HO = There is no difference in muscle activation between ambulation over ground and ambulation on a treadmill in individuals who are status-post a stroke.

HA = There is a difference in muscle activation between ambulation over ground

and ambulation on a treadmill in individuals who are status-post a stroke.

1b. HO = There is no difference in muscle activation between ambulation over ground and ambulation on a treadmill with 0% PBWS in individuals who are status-post a stroke.

HA = There is a difference in muscle activation between ambulation over ground and ambulation on a treadmill with 0% PBWS in individuals who are status-post a stroke.

1c. HO = There is no difference in muscle activation between ambulation over ground and ambulation on a treadmill with 15% PBWS in individuals who are status-post a stroke.

HA = There is a difference in muscle activation between ambulation over ground and ambulation on a treadmill with 15% PBWS in individuals who are status-post a stroke.

CHAPTER II

LITERATURE REVIEW

A stroke is a sudden onset of neurological dysfunction due to damaged blood vessels in the brain and an abnormality in cerebral circulation. Strokes are the third leading cause of death and the primary cause of disability in adults in the United States.[1] Strokes cause cognitive, sensory, and motor impairments that consequently lead to limitations in functions. Dysfunctions with gait are a key limitation that has a major influence on a person's ability to function in activities of daily living.

Biomechanics of Gait

Gait is the propulsion of the body forward using coordinated, alternating, and rotatory movements of multiple body segments. Prior to considering the gait dysfunctions observed in a person who has suffered a stroke, it is necessary to review the biomechanics of a "normal" gait pattern. A gait cycle is the period of time during which one lower extremity strikes the ground twice. During one cycle of gait, the reference extremity travels through a stance phase and a swing phase. The stance phase begins when the reference extremity strikes the ground and ends when the toe leaves the ground. This phase comprises approximately 60% of the gait cycle. The swing phase begins when the toe leaves the ground and ends when the foot strikes the ground. This phase comprises approximately 40% of the gait cycle.[7]

The stance phase of gait consists of five events. The first event is initial contact (IC), which is the moment the lead extremity strikes the ground. IC occurs at 0% and

100% of the gait cycle. The second event is loading response (LR). LR begins immediately after IC and continues until the contralateral extremity lifts off the ground. LR occurs during 0%-12% of the gait cycle. The third event is midstance (MSt). MSt begins when the contralateral extremity lifts off the ground and continues until the body has progressed over and ahead of the supporting (reference) extremity. MSt occurs during 12%-31% of the gait cycle. The fourth event is terminal stance (TSt). TSt is the time period from the end of midstance to a point just before IC of the contralateral extremity. During TSt, there is progression of the body of the stance limb and weight is transferred onto the forefoot. TSt occurs during 31%-50% of the gait cycle. The fifth event is known as preswing (PSw). PSw begins just after the heel comes off the ground and ends the moment that the toes leave the ground. PSw occurs during 50%-62% of the gait cycle.[7]

The swing phase of gait consists of three events. The first event is initial swing (ISw). ISw begins when the toes of the reference leg leaves the ground and continues until maximum knee flexion occurs at 60^0. During ISw, the thigh is advanced forward as the foot comes off the ground. ISw occurs during 62%-75% of the gait cycle. The second event is midswing (MSw). MSw begins immediately after knee flexion to 60^0 and continues until the tibia is vertical. During MSw, the thigh continues to advance and the knee begins to extend. MSw occurs during 75%-87% of the gait cycle. The third event is called terminal swing (TSw). TSw is identified as the period of time from when the tibia is vertical to the point just before IC. TSw occurs during 87%-100% of the gait cycle.[7]

During the gait cycle, a period of time exists when the body is progressing over a single extremity. This is known as single limb support (SLS). A period of time also exists when both feet are in contact with the ground. This is known as double limb support (DLS). DLS occurs during 0%-12% and again during 50%-62% of the gait cycle. [7]

During the gait cycle, weight acceptance occurs when weight is rapidly loaded onto an outstretched extremity. This includes IC and LR. In addition, swing limb advancement occurs when the reference extremity is unloaded and advanced from behind to ahead of the body. Swing limb advancement includes PSw, ISw, MSw, and TSw and prepares the body to take the next step.[7]

Objective measurements are often taken to determine if the gait cycle is "normal." These measurements include stride length, stride duration, step length, step duration, cadence, walking velocity, stride width, and degree of toe out. Stride length is the linear distance between heel strikes of the same foot. Stride duration is the amount of time it takes for the reference extremity to accomplish one cycle of gait. Step length is the linear distance between the heel strike of the reference extremity to the heel strike of the contralateral extremity. Step duration is the amount of time required to take one step. Cadence is the number of steps taken per unit time, such as the number of steps per minute. Walking velocity is the rate of linear forward progression of the body; this is equal to step length times cadence. Stride width is the distance between the midpoint of the reference heel and the midpoint of the contralateral heel. Stride width normally ranges from one to five inches. The degree of toe out is the angle of foot placement.

This is measured by the angle between the line of forward progression and a line that bisects the midpoint of the heel and second metatarsal head.[7]

During the gait cycle, the body makes adjustments to help maintain the body's center of gravity (COG). The first adjustment is known as a lateral pelvic tilt and it occurs during MSw. At this time, the unsupported side of the pelvis drops in a frontal plane to help lower the COG while the contralateral extremity is in MSt. During MSt, knee flexion ranges from 0^0-15^0, the ankle plantarflexes, and the foot pronates in order to shorten the stance limb and help lower the COG. During the transition from MSt to TSt, the ankle remains plantarflexed, but the foot supinates to lengthen the stance limb and help raise the COG. During TSw and IC, the pelvis rotates forward on the advancing extremity and backward on the stance limb to help raise the COG and prevent excess dropping of the pelvis. The final adjustment is physiologic valgus at the knee of 170^0. This controls medial and lateral displacement of the COG during the gait cycle.[7]

In order to control advancement, provide stabilization, and propel the body and lower extremities during gait, appropriate muscle function must be present. During IC, the gluteus maximus and hamstrings contract concentrically and then isometrically in order to control the advancement of the lead extremity and aid in placement of the foot.[8] The quadriceps reach peak activity and contract concentrically to control the advancement of the limb.[8] The quadriceps initially contract concentrically to extend the knee. The quadriceps then contracts eccentrically to allow for heel strike and prevent the knee from buckling. The pretibials contract isometrically to prevent the toes from dragging.[7]

During LR, the pretibials reach peak activity.[9] The pretibials contract eccentrically to propel the body forward and allow for shock absorption. The hip is stabilized by an isometric contraction of the gluteus maximus and eccentric contraction of the abductors. The quadriceps continues to contract eccentrically to control the amount of knee flexion as the body prepares for MSt.[7]

During MSt, the abductors fire eccentrically in order to control pelvic drop. This is followed by an isometric contraction to maintain pelvic stability. The gastrocnemius and soleus perform an eccentric contraction to control tibial advancement. The quadriceps contract concentrically to prevent the knee from buckling and then become inactive as the body nears TSt.[8, 10] The momentum from MSt to TSt is primarily provided by the contralateral (swing) extremity.[7]

During TSt, there is no muscle activity at the pelvis, hip, or knee. However, the gastrocnemius and soleus reach peak activity and contract concentrically to lock the foot into supination.[8, 9] This creates a rigid lever for push off and transition into the swing phase of the gait cycle.[7]

During the swing phase of gait, adequate muscle function is necessary in order to control the range of motion at each joint, as well as allow for ground clearance. During PSw, the adductors contract eccentrically to control the position of the limb in space. The remaining motion during PSw is a result of momentum. The most important motion during this phase is passive knee flexion to 40^0.[7]

During ISw, the iliopsoas contracts concentrically to move the hip into 15^0 of flexion. The quadriceps contract eccentrically to help decelerate the extremity.[10] The hamstrings contract concentrically to flex the knee to 60^0, while the pretibials contract

concentrically to bring the ankle into neutral.[9] These motions allow for adequate toe clearance while the limb advances forward.[7]

During MSw, the iliopsoas contracts concentrically to further advance the degree of hip flexion to 25^0. The hamstrings contract eccentrically to control and decelerate the limb.[8] The pretibials now contract isometrically in order to maintain the ankle in a neutral position.[7]

During TSw, the gluteus maximus and hamstrings contract eccentrically and concentrically, respectively, in order to control the advancement of the limb forward and prepare the limb for placement at heel strike. The quadriceps contract concentrically to prevent the knee from buckling and maintain the knee in extension.[10] The pretibials contract isometrically and eccentrically to prepare for and make contact with the ground, respectively.[7, 9]

Pathological Gait

Deviations in gait often occur as a result of neurological insults, such as a stroke. Individuals who suffer from strokes often lack selective muscle control, which can lead to distorted patterns of muscle recruitment.[4, 9] In addition, muscle activity is prolonged and relaxation is delayed.[4, 9] The altered patterns of muscle activity cause differences in the "normal" proportions of stance and swing time during a gait cycle. Most often, stance time of the uninvolved limb is greater than that of the involved limb and there is more time spent in DLS than in SLS.[7, 9]

The weakness of specific muscles leads to characteristic gait patterns in individuals who have suffered a stroke. Weakness of the gluteus maximus causes a

characteristic sudden backward throw of the trunk and pelvis just after IC. At the same time, there is an apparent forward protrusion of the involved hip and utilization of the Y-ligament to stabilize the hip. In addition, full knee extension occurs during LR and in MSt. This results in a slight elevation of the pelvis on the involved side.[7]

Weakness of the gluteus medius results in a deviation known as a Trendelenburg gait. A Trendelenburg gait can be classified as either uncompensated or compensated. An uncompensated Trendelenburg gait is characterized by a drop of the pelvis on the uninvolved side during stance on the involved side. The pelvic drop is accompanied by an apparent lateral protrusion of the involved hip and a lateral shift of the entire trunk and pelvis toward the involved side. An increase in knee and hip flexion also occurs in the uninvolved limb to allow for adequate foot clearance. This often results in a steppage gait pattern. A compensated Trendelenburg gait is characterized by a drop of the pelvis on the uninvolved side during stance on the involved side. This drop is to a lesser degree than in an uncompensated pattern and is accompanied by an apparent medial protrusion of the involved hip. In addition, there is a marked dipping of the shoulder on the involved side combined with bending of the entire trunk downward and laterally over the involved hip. The erector spinae and quadratus lumborum on the uninvolved side are used to elevate the pelvis. A twisting of the trunk to bring the pelvis forward on the opposite side may still occur and the steppage gait pattern may be present; however, it is less pronounced in the compensated pattern.[7]

A weakness in the hip flexors will result in lower extremity circumduction, which includes hip hiking and hip abduction on the involved side during the swing phase. The abdominal muscles will contract to produce a posterior pelvic tilt to help advance the

thigh at ISw. In order to aid in producing hip flexion, excessive knee flexion may occur. Vaulting and a lateral trunk lean to the uninvolved side will help to achieve adequate foot clearance on the involved side. An individual with a hip flexor gait will ambulate slower with a decreased step length on the involved side.[7]

A weakness of the quadriceps results in a gait that is characterized by trunk flexion at IC and trunk extension during PSw. This is characteristic if only one side is affected. When both quadriceps muscles are affected, the trunk will remain flexed throughout the gait cycle. A forward flexed posture causes the COG to shift forward, which results in an external extension moment at the knee. Further stabilization of the knee is gained when a person places a hand on the involved anterior thigh. The knee is kept in this hyperextended position during the stance phase. This is sometimes due to hip extensor contractions that forcibly "snap" the thigh back.[7]

A gastrocnemius and soleus weakness is characterized by an increased knee flexion at TSt due to a lack of the ability to raise the heel. Excessive dorsiflexion is evident throughout the stance phase and causes the forefoot to be higher off the floor than normal. The uncontrolled dorsiflexion results in instability during single limb support. In addition, there is an insufficient push-off and the entire foot lifts off the floor as one unit. The ultimate result is an overall decrease in forward velocity.[7]

A weakness in dorsiflexor muscles results in a gait pattern characterized by foot drop during the swing phase. Consequently, there is excessive hip and knee flexion to allow for adequate foot clearance. Dorsiflexor weakness may also result in a steppage gait pattern. At IC, a foot slap may be heard due to the unrestrained plantarflexion that is occurring. During the gait cycle, a loss in forward velocity, a shortened stride and step

length, and instability in stance may be observed. Due to the loss of forward velocity, tibial advancement is restricted. In order to compensate, premature heel off on the unaffected limb, excessive knee extension on the affected limb, and/or a forward trunk lean during stance on the involved limb may occur.[7]

Gait Interventions

The dysfunctions that occur with gait make gait training an essential part of the rehabilitation process. Traditional approaches have focused on retraining components of gait, such as weight bearing, weight shifting, and balance.[3, 9] The training is initiated in static positions, which is followed by task performed with dynamic movements.[9] Other conventional approaches are based on neurofacilitation techniques, which includes Brunnstrom's synergistic movements, proprioceptive neuromuscular facilitation, and Bobath's neurodevelopmental therapy (NDT).[3] Most traditional approaches have focused on techniques that inhibit tone, as well as gait preparatory tasks. However, current approaches are based on a task-specific strategy that uses dynamic activities in combination and repetition.[3] Partial body weight support (PBWS) treadmill training is an intervention based on the task-specific strategy.[2 - 3]

PBWS treadmill training is a system that relieves a percentage of a person's body weight through use of an overhead suspension and parachute harness. It provides external support for balance control and trunk stabilization by accommodating movements of the body during ambulation on a treadmill.[6, 8, 11] Utilization of the treadmill allows for repetitive, rhythmic cueing while the PBWS unloads the lower extremity. The PBWS allows the patient to maintain an upright position while weight bearing, as able, through the lower extremities.[2] According to Hesse et al,[12] initial

parameters recommended for PBWS treadmill training include body weight support beginning at 30% to 40% and an introduction speed of .25 m/s.

The rationale behind the effectiveness of PBWS treadmill training is based on two prominent theories. The first theory is the Central Pattern Generators (CPG) Theory. It suggests that CPG's are a "network of hardwired, stereotyped neural connections for low-level motor programs capable of producing a rhythmical output" for activities such as ambulation.[9 p 142] CPG connections are at the spinal cord level and are said to be triggered by external forces or stimuli, such as the treadmill movement during PBWS treadmill training.[9] Through this external stimulation, afferent receptors generate the essential sensory response required to train CPGs in the spinal cord thought to bring about ambulation.[13] However, CPG's are unable to produce "normal" gait by themselves and they do not explain the voluntary movements associated with gait.[9]

Therefore, PBWS is supported by a second theory, known as the Dynamic Systems Theory. According to this theory, "movement control is organized around goal-directed behavior."[9 p 142] The focus is aimed toward the underlying impairments with the intention to restore functional tasks, such as gait.[9] The Dynamic Systems Theory relies on an external force to trigger its effects, which is consistent with PBWS.[6] PBWS treadmill training removes weight from the lower extremities in a balanced way in order to increase weight bearing on the involved extremity, promote symmetry, and facilitate weight shifting all while maintaining an upright posture. The constant rate of the treadmill's movement allows multiple repetitions of the gait cycle to be practiced, which follows the Dynamic Systems Theory, as well as the task-oriented approach.[9]

PBWS treadmill training has recently gained use as an intervention due to its potential advantages for gait rehabilitation. PBWS permits patients who are wheel-chair bound, as well as other patients with neurological gait deficits, to perform compound repeated gait cycles rather than single preparatory tasks early in the rehabilitation process.[3] In addition, PBWS provides as much weight support as is needed in order for patients to assume an upright posture and perform rhythmic stepping patterns.[6] Additional advantages for PBWS treadmill training include providing balance and safety during the gait cycle, preventing falls, increasing training time duration, promoting a repetitive task-specific approach, and allowing patients to practice a more natural gait cycle.[13]

A number of studies have been conducted to evaluate the effectiveness of PBWS treadmill training as an intervention for gait rehabilitation in the stroke population. Conclusions have been positive and have supported the use of PBWS due to its promotion of symmetry, balance, and over ground walking abilities.[4-6, 9] To the best of the researchers' knowledge, a limited number of studies have been conducted to substantiate the rationale for the effectiveness of PBWS.[8, 14] Therefore, the purpose of this study was to evaluate individuals who are status-post stroke during ambulation over ground, on a treadmill without support, and on a treadmill with PBWS to determine if there are any differences in muscle activation of major muscle groups in the lower extremity.

CHAPTER III

METHODOLOGY

Review and approval was obtained from the University of North Dakota Institutional Review Board before the initiation of this study (see Appendix A). The methods used in this study are described below.

Subjects

Two subjects were recruited for this study at the School of Medicine and Health Sciences Department of Physical Therapy. Subjects were included if they were over the age of 50 years and could fulfill a two-hour time commitment. They were also required to walk independently with or without the use of an assistive device. Furthermore, subjects were excluded if they have had surgery or have existing orthopedic involvement of the lower extremities. These impairments could lead to additional compensation of their gait pattern, which potentially could change the data collected.

Before beginning participation in this study, each subject was issued a copy of an information and consent form (Appendix B). Each subject was asked to read and sign the consent form to indicate his understanding of the study and its purpose. Subjects were given a copy of the consent form to take with them, for use if further questions or concerns arose. Subjects were also asked to fill out a patient history intake form to obtain demographic information (Appendix C).

Instrumentation

Sensor surface electrodes (Model M-00-S, Ambu, Denmark) were used to pick up EMG activity. EMG activity was collected with a Noraxon Telemyo8 telemetry unit (Noraxon USA, 13430 North Scottsdale Rd., Scottsdale, AZ 85254) and transmitted to a Noraxon Telemyo8 receiver. Data was then digitized by an analog digital interface board in Peak Analog Module. The Peak Motus5 system (Peak Performance, Englewood, CO) was used to store and analyze the EMG data. Final data are presented as percent of normalized EMG activity as an average of four to five gait cycles for each of the support trials.

The GAITRite electronic walkway (CIR systems, Inc.) was used to collect data through sensors during ambulation over level ground. Data was then sent to a computer where the GAITRite software analyzed and computed step length, velocity, cadence, and other gait parameters.

Procedure

After the consent form was reviewed and signed by each subject they were prepared for participation in the study by the following methods. EMG electrode sites were determined according to EMG standards from Cram et al.[15] Electrodes were placed on the following selected lower extremity muscles: adductor longus, rectus femoris, vastus lateralis, biceps femoris, gastrocnemius, and anterior tibialis. Placement sites for the electrodes were marked using a permanent marker on the involved lower extremity of each subject. Self adhesive electrodes were placed on the skin of each participant after the area was shaved and cleaned with rubbing alcohol. Two electrodes were placed at each of six locations. The inter-electrode distance of 3.3 centimeters was maintained

between electrodes. A ground electrode was placed on the fibular head. A heel switch was placed in the shoe of the involved lower extremity of each subject to determine when initial contact occurred. The heel switch was moved to outside the shoe for the second subject due to interference from an ankle foot orthosis.

The subjects were then weighed without harness using a standard medical scale to determine the appropriate amount of support to be used during conditions with body weight support. Subjects' leg length was measured in standing from the greater trochanter of each leg to the floor. The order of body weight support conditions for ambulation was then determined by having the subjects draw pieces of paper out of a hat.

Electrodes were hooked up to the analyzing equipment and each subjects' EMG activity was measured in relaxed standing on level ground to determine a baseline. A receiver picked up EMG signals and then sent them to a computer for data recording and display. Next, each subject ambulated over ground on the GAITRite system (gtrt) for approximately 16 feet to determine velocity and EMG measurements. Subjects were allowed one practice walk over the GAITRite system. Subjects then performed two trial walks and EMG activity was recorded for 30 seconds during each trial. Subjects were allowed to rest between trials for at least three minutes but no longer than five minutes.

Prior to performing the treadmill conditions, subjects ambulated on the treadmill without a harness to determine their self selected speed and adapt to walking with electrodes on. The subjects were then allowed to rest for one to two minutes before completing the treadmill trials. Data collection for the treadmill conditions were as follows.

For the treadmill conditions, subjects ambulated on the treadmill at their self selected speed for two minutes. EMG activity was recorded for 30 seconds at the end of the first and second minutes. The treadmill conditions consisted of ambulation on the treadmill without a harness (trm), ambulation on the treadmill with a harness and no body weight support (trmh), and ambulation on the treadmill with a harness and partial body weight support of 15% (trms). For the trmh and trms ambulation conditions, the harness was donned using the greater trochanters as a reference for standard placement. A rest period of three to five minutes was allowed between each ambulation condition.
All randomized ambulation conditions were performed by each subject. Subject one completed the trials in the following order: gtrt, trm, trmh, trms. Subject two completed the trials in the following order: gtrt, trms, trmh, trm. See Appendix D for participant and equipment set-up.

Statistical Analysis

The EMG files imported from the Peak Performance system were analyzed using Myoresearch XP (Noraxon, USA) software program. The EMG data was integrated, smoothed, filtered, and rectified. The data was normalized to an overground (gtrt) walking trial for each subject. Final data are presented as percent of normalized EMG activity as an average of four to five gait cycles at each of the support trials. The EMG data was analyzed using MyoResearch software package to make comparisons between muscle activity and weight bearing support levels.

The EMG data was processed and the data was then smoothed and rectified. The mean EMG activity of the second trial for all ambulation conditions was calculated for both stance and swing phases of each subject. Descriptive statistics were then used to

compare muscle activation across conditions as well as rank EMG mean muscle activity for each trial condition from highest to lowest.

CHAPTER IV

RESULTS

The purpose of this study was to evaluate individuals who are status-post stroke during ambulation over ground, on a treadmill without support, and on a treadmill with PBWS to determine if there are any differences in muscle activation of major muscle groups in the lower extremity. The research question looked at whether there was a difference in muscle activation between ambulation over ground and on a treadmill. Furthermore, it looked at ambulation over ground and on a treadmill with PBWS in individuals who are status-post a stroke.

For stance phase of subject one, the adductor muscles were ranked first in the trms and gtrt conditions. The rectus femoris and vastus lateralis were most active during the trms condition. The biceps femoris was most active during the trmh condition; however, it was only slightly more active than in the gtrt and trm conditions. The anterior tibialis ranked fifth for gtrt and trmh conditions, sixth for trm and trms conditions, and was most active during the trmh condition. The gastrocnemius muscle was most active during the gtrt condition. Complete results are located in Table 1 and Figure 1.

Table 1. Stance Phase Subject One: Mean Amplitude EMG and Ranking of Muscle From High to Low EMG Activation.

Condition		Adductors	Rectus Femoris	Vastus Lateralis	Biceps Femoris	Anterior Tibialis	Gastroc
gtrt	Mean	118.7	72.2	101.6	106.8	74.9	106.8
	Rank	1	6	4	2	5	2
trm	Mean	63.2	122.5	129.83	105.1	58.8	92.2
	Rank	5	2	1	3	6	4
trmh	Mean	111.1	59	172.8	112.1	80.2	96.9
	Rank	3	6	1	2	5	4
trms	Mean	205	129.1	188.9	64.9	35	58.8
	Rank	1	3	2	4	6	5

gtrt = over ground, trm = treadmill without harness, trmh = treadmill with harness, trms = treadmill with 15% BWS

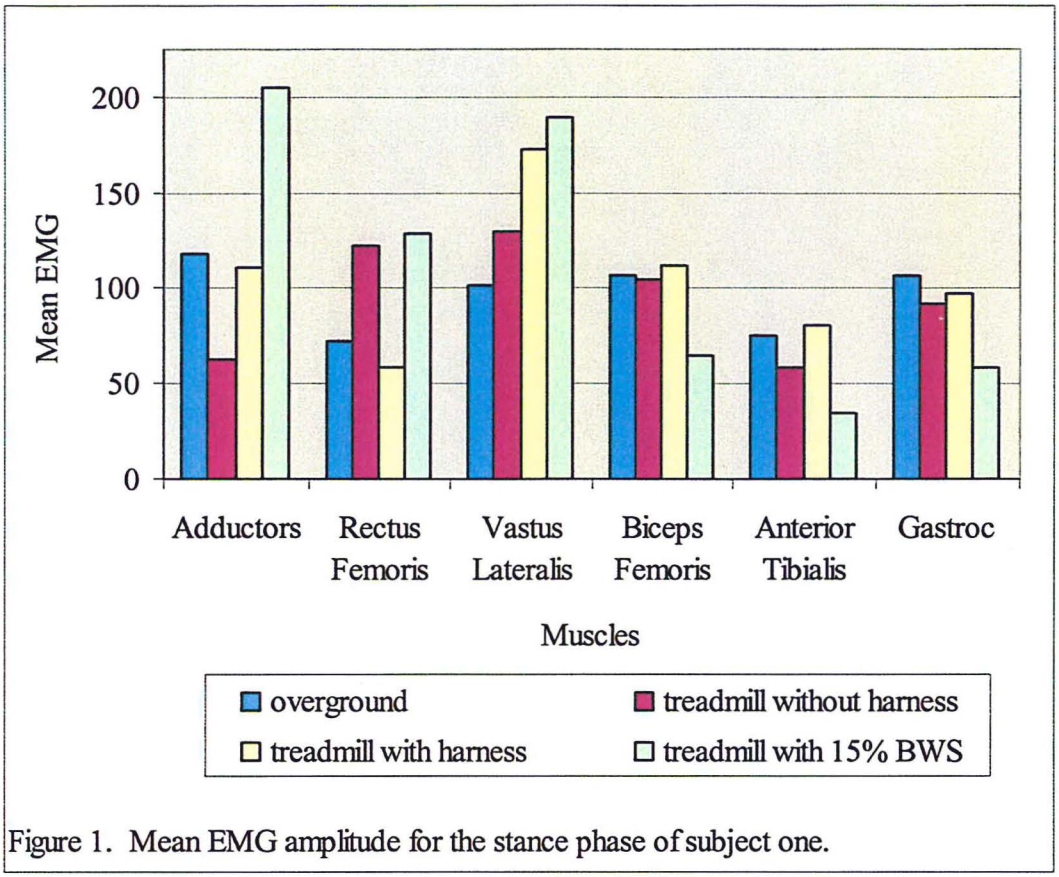

Figure 1. Mean EMG amplitude for the stance phase of subject one.

For swing phase of subject one, the adductor muscle group ranked sixth throughout all conditions and was most active during the trm condition. The rectus femoris was most active during the trm condition. The vastus lateralis was most active during the trmh condition. The biceps femoris was most active during the trm condition. The anterior tibialis was most active during the gtrt condition. The gastrocnemius was most active during the trmh condition. Complete results are located in Table 2 and Figure 2.

Table 2. Swing Phase Subject One: Mean Amplitude EMG and Ranking of Muscle From High to Low EMG Activation.

Condition		Adductors	Rectus Femoris	Vastus Lateralis	Biceps Femoris	Anterior Tibialis	Gastroc
gtrt	Mean	34.8	81.2	66.2	77.6	130.6	67.1
	Rank	6	2	5	3	1	4
trm	Mean	63.6	148.2	80.8	91.73	122.3	70.6
	Rank	6	1	4	3	2	5
trmh	Mean	48.1	93.1	95.1	57.6	92.5	122.9
	Rank	6	3	2	5	4	1
trms	Mean	45.6	67.1	49.7	59.1	79.6	64.1
	Rank	6	2	5	4	1	3

gtrt = over ground, trm = treadmill without harness, trmh = treadmill with harness, trms = treadmill with 15% BWS

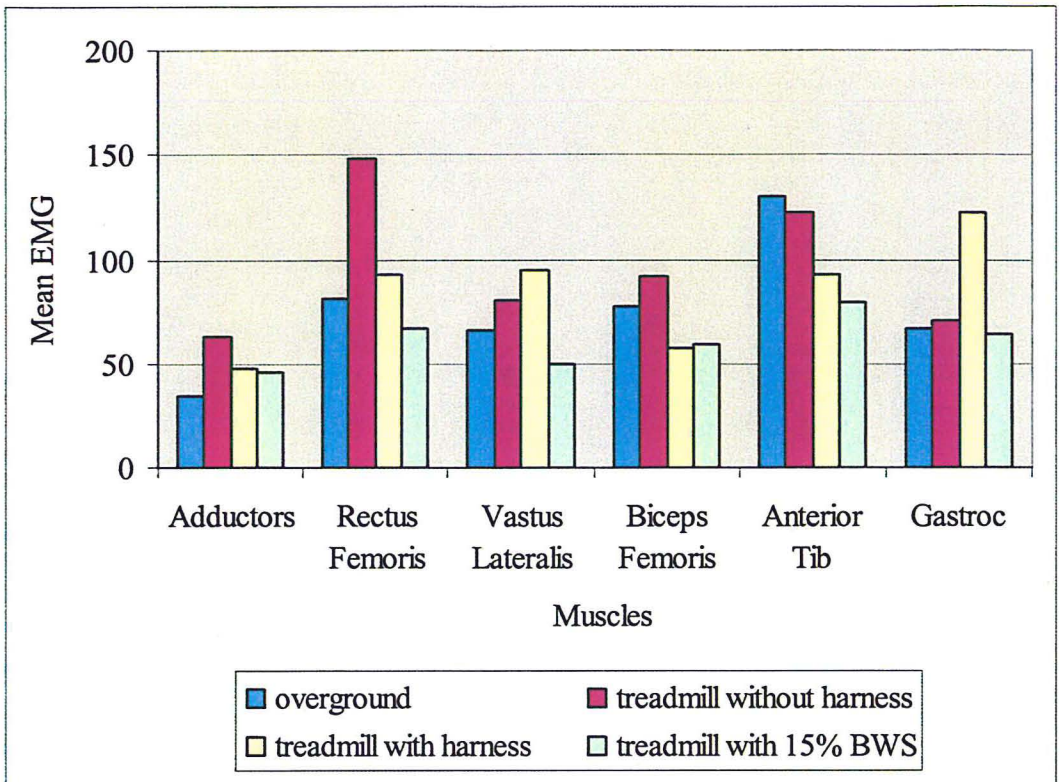

Figure 2. Mean EMG amplitude for the swing phase of subject one.

For stance phase of subject two, the adductor muscles were most active during gtrt and trms conditions with subtle differences between conditions. The rectus femoris muscle was most active during the gtrt condition. The vastus lateralis was most active during the gtrt condition. The biceps femoris was most active during the trm condition. The anterior tibialis was most active during the trmh condition and was ranked first for all conditions. The gastrocnemius was most active during trm condition and only slightly lower during the trmh condition. The complete results are located in Table 3 and Figure 3.

Table 3. Stance Phase Subject Two: Mean Amplitude EMG and Ranking of Muscle From High to Low EMG Activation.

Condition		Adductors	Rectus Femoris	Vastus Lateralis	Biceps Femoris	Anterior Tibialis	Gastroc
gtrt	Mean	62.3	83.2	76.3	71	84.3	52.5
	Rank	5	2	3	4	1	6
trm	Mean	36.9	38.8	44.2	76.8	74.9	57.9
	Rank	6	5	4	1	2	3
trmh	Mean	37.5	57.2	53.3	62	94.2	57.1
	Rank	6	3	5	2	1	4
trms	Mean	61.1	58.8	63.7	48.3	76.4	41.9
	Rank	3	4	2	5	1	6

gtrt = over ground, trm = treadmill without harness, trmh = treadmill with harness, trms = treadmill with 15% BWS

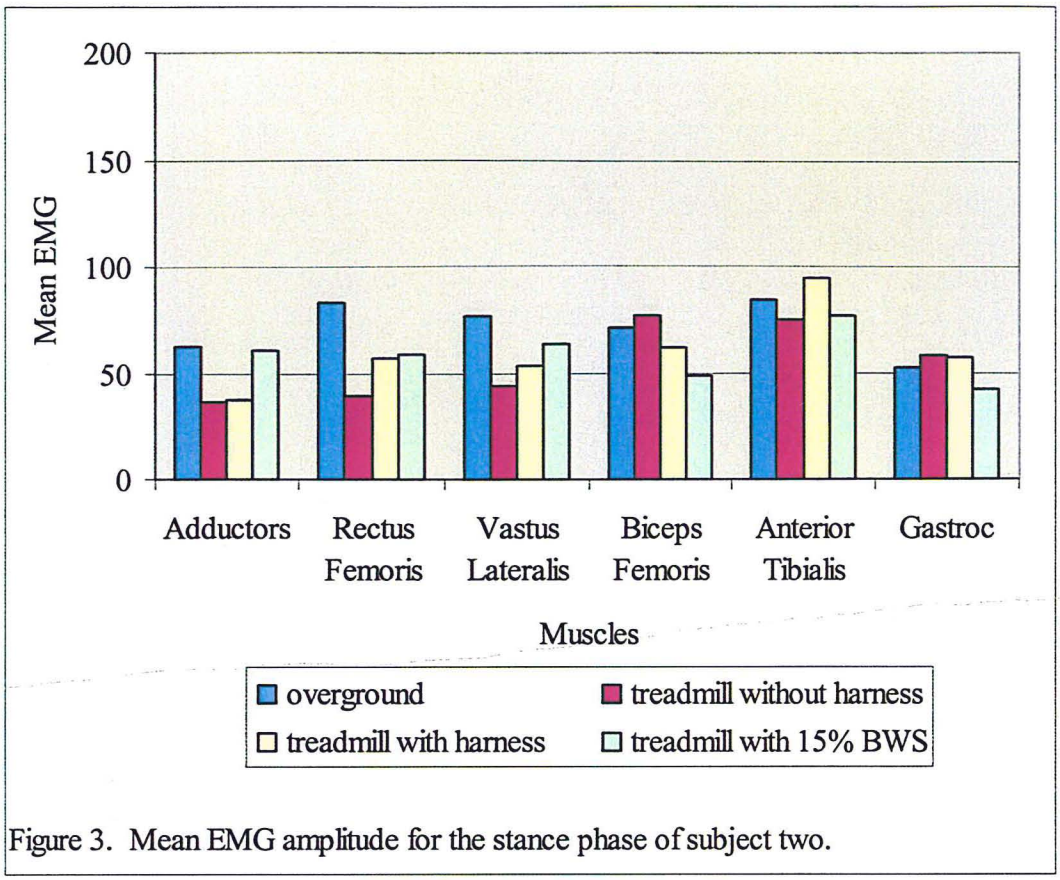

Figure 3. Mean EMG amplitude for the stance phase of subject two.

For swing phase of subject two, the adductor muscles were most active during trmh. The rectus femoris was third for gtrt and trms, fourth for trm, trmh conditions, and was most active for gtrt condition with trms was only slightly lower. The vastus lateralis ranked sixth through all conditions and was most active during the trm condition. The biceps femoris ranked fifth for all conditions and was most active during the trm condition. The anterior tibialis ranked first for gtrt, trm, and trmh conditions and second for trms condition. The anterior tibialis was most active during the trmh condition. The gastrocnemius was most active during gtrt condition. Complete results are located Table 4 and Figure 4.

Table 4 Swing Phase Subject Two: Mean Amplitude EMG and Ranking of Muscle From High to Low EMG Activation.

Condition		Adductors	Rectus Femoris	Vastus Lateralis	Biceps Femoris	Anterior Tibialis	Gastroc
gtrt	Mean	71.8	72.5	20.3	26.7	75.3	74.8
	Rank	4	3	6	5	1	2
trm	Mean	50.6	40.8	22.8	39.9	66.2	47.2
	Rank	2	4	6	5	1	3
trmh	Mean	75.2	61.1	20.9	32.3	84.8	70.8
	Rank	2	4	6	5	1	3
trms	Mean	70.3	66.8	14.7	22.7	69.8	36.5
	Rank	1	3	6	5	2	4

gtrt = over ground, trm = treadmill without harness, trmh = treadmill with harness, trms = treadmill with 15% BWS

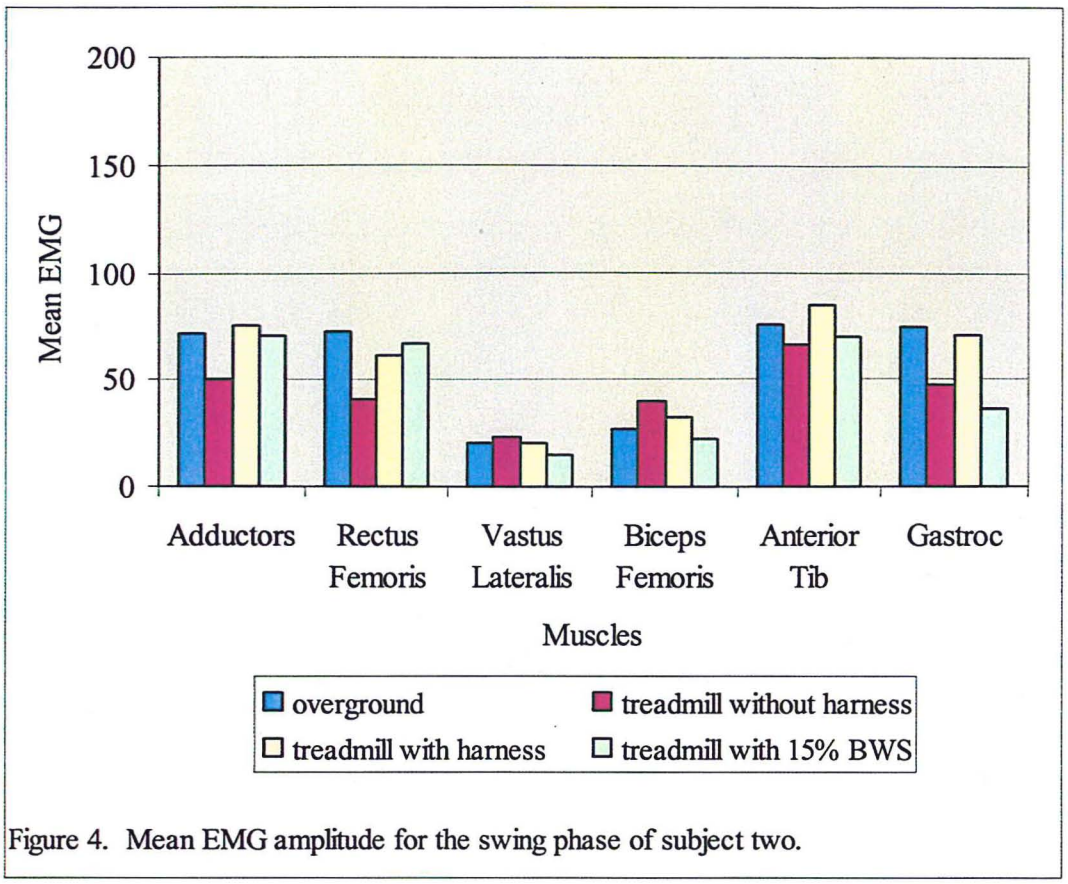

Figure 4. Mean EMG amplitude for the swing phase of subject two.

CHAPTER V

DISCUSSION

Individuals who suffer from a stroke often have residual neurological deficits, including motor weakness, poor motor control, and spasticity which negatively influence functional capacity.[2] A functional activity that is often affected is ambulation and many individuals are left non-ambulatory for a period of time. Therefore, gait training is a key component during rehabilitation.[3] PBWS treadmill training is an intervention that focuses on a task-specific approach to gait training. Studies have not included objective measurements or possible reasons for the improvement in function from PBWS interventions. The purpose of this study was to evaluate individuals who are status-post stroke during ambulation over ground, on a treadmill without support, and on a treadmill with PBWS to determine if there are any differences in muscle activation of major muscle groups in the lower extremity.

Our research question looked at whether there was a difference in muscle activation between ambulation over ground and on a treadmill. We also looked at ambulation over ground and on a treadmill with PBWS. There were no major findings or trends to suggest differences or similarities in muscle activation between any of the conditions for either subject.

Hesse et al[3] found gastrocnemius activity to be diminished with increasing body weight support on the treadmill and was significantly reduced compared to over ground ambulation. In addition, less plantar flexor spasticity and decreased tibialis anterior

activity was found with EMG during ambulation on a treadmill. For our study, both subjects had the least gastrocnemius activity during the treadmill with 15% BWS condition. Only subject one had decreased EMG activity with ambulation on treadmill as compared to over ground. Subject two ambulated with use of an ankle foot orthosis (AFO) on his hemiplegic side and therefore this may have affected his gastrocnemius and tibialis anterior muscle activity.

We only had two subjects for our study and each subject was analyzed independently. Based on the rankings of the EMG activity, neither subject demonstrated a trend. Consequently, we cannot make generalizations or significant conclusions based on this data.

Limitations

A major limitation of our study was the number of participants. We were only able to recruit two subjects that met our inclusion criteria. In addition, we were unable to identify trends secondary to intra-subject variability. One subject was more affected by his stroke and required the use of an AFO during ambulation which may have affected EMG results.

Fatigue, comfort level with the environment and equipment, and the effect of learning curve are also possible limitations of our study. Subjects may have been fatigued due to length of time to place electrodes, don the LITEGait harness, and complete all four ambulation conditions. Although there was a required rest between conditions, the total time necessary to ambulate for all conditions exceeded one hour. Each subject had previously used a treadmill, but not in the last two to four years. Only one subject had previous experience ambulating with the LITEGait. The length of time

since using a treadmill and lack of familiarity with the LITEGait system may have affected performance. A small learning curve may have altered muscle activation by the final condition on the treadmill.

Electromyography limitations may have included placement of electrodes, muscle fiber type, the amount of subcutaneous tissue, volume conduction from other muscles, and contraction type.[15] In addition, Hogrel[16] identified environmental conditions and physiological characteristics of the neuromuscular systems, such as muscular coordination, fatigue, and motor unit recruitment as other limitations. In an attempt to control for some of these limitations, we used a standardized protocol for electrode placement. After electrode placement we performed manual muscle tests to verify that each electrode was over the correct muscle and to verify the equipment was functioning properly. In addition, to improve validity, we normalized the EMG data to each subject's second trial for the overground ambulation condition.

In order to differentiate between stance and swing phase of subject one, manual timing was required to digitize the data. The foot switch was faulty at the beginning of subject one's ambulation during the overground condition. During the latter portion of the trial, the foot switch was functioning normally. Therefore, we timed each phase of the gait cycle for the beginning of the trial using objective data from the end of the trial. We did not compare the beginning and end of the other ambulation conditions to ensure that the subject's phases were consistent throughout each trial. Consequently, the subjective timing may have altered the results. After ambulation of the overground conditions we moved the foot switch to the outside of subject one's shoe which eliminated the need for manual timing in the remaining conditions.

Recommendations

In conclusion, we were not able to determine any trends between or within subjects for EMG muscle activity. Therefore, further research is needed. A recommendation for future studies would be to repeat the study with more subjects. This would increase the power of the study and allow for inferential statistical analysis. In addition, a motion analysis component could be included to look at gait kinematics along with muscle activation. Motion analysis would be beneficial to determine timing of the gait cycle phases, assessment of gait symmetry, and presence or absence of a favorable gait pattern. Another recommendation would be to compare persons post stroke with healthy subjects of similar demographics. This would provide a reference for a non-pathological gait cycle.

APPENDIX A

REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW

University of North Dakota Institutional Review Board

Date: 5/19/2005 **Project Number:** IRB-200505-390

Principal Investigator: Flom-Meland, Cindy; Malmin, Kelly; Breitbach, Rhonda; Pederson, Jennifer A.; Nordmark, Beth

Department: Physical Therapy

Project Title: Muscle Activation in Individuals who are Status-Post a Stroke During over Ground, Treadmill, and Body Weight Supported Gait: A Comparative Study

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on May 24, 2005 and the following action was taken:

☒ Project approved. **Expedited Review** Category No. 3
Next scheduled review must be before: May 23, 2006

☑ **Copies of the attached consent form with the IRB approval stamp dated May 24, 2005 must be used in obtaining consent for this study.**

☐ Project approved. **Exempt Review** Category No. _____
This approval is valid until _____ as long as approved procedures are followed. No periodic review scheduled unless so stated in the Remarks Section.

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

☐ Minor modifications required. The required corrections/additions must be submitted to RDC for review and approval. **This study may NOT be started UNTIL final IRB approval has been received.**
(See Remarks Section for further information.)

☐ Project approval **deferred. This study may not be started until final IRB approval has been received.**
(See Remarks Section for further information.)

REMARKS: Any unanticipated problem or adverse occurrence in the course of the research project must be reported within 72 hours to the IRB Chairperson or RDC by submitting an Unanticipated Problem/Adverse Event Form.

Any changes in protocol or Consent Forms must receive IRB approval prior to being implemented. You must submit a Protocol Change Form with all revised research documents to include changes to protocol, consent forms, or supportive materials, with the appropriate signatures, to Research Development and Compliance for review and approval.

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

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

cc: Chair, Physical Therapy; Dean, School of Medicine

Signature of Designated IRB Member
UND's Institutional Review Board

5/24/05
Date

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 310 Form may be required. Contact RDC to obtain the required documents.

(Revised 07/2004)

University of North Dakota Human Subjects Review Form

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

Please provide the information requested below:

Principal Investigator: Cindy Flom-Meland, Kelly Malmin, Rhonda Breitbach, Jennifer A. Pederson, Beth Nordmark

Telephone: 777-4130 E-mail Address: cfmeland@medicine.nodak.edu

Complete Mailing Address: PO Box 9037 PT

School/College: School of Medicine and Health Sciences Department: Physical Therapy

Student Adviser (if applicable): Cindy Flom-Meland

Telephone: 777-4130 E-mail Address: cfmeland@medicine.nodak.edu

Address or Box #: PO Box 9037 PT

School/College: School of Medicine and Health Sciences Department: Physical Therapy

Project Title: Muscle activation in individuals who are status-post a stroke during over ground, treadmill, and body weight supported gait: a comparative study.

Proposed Project Dates: Beginning Date: 05/01/05 Completion Date: 05/01/06 (Including data analysis)

Funding agencies supporting this research: N/A

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

___ YES or _X_ NO Does the Principal Investigator or any researcher associated with this project have a financial interest in the results of this project? If yes, please submit, on a separate piece of paper, an additional explanation of the financial interest (other than receipt of a grant)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

_____ Date submitted: _____ Status: ___ Approved ___ Pending

_____ Date submitted: _____ Status: ___ Approved ___ Pending

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

_X_ YES or ___ NO New Project

___ YES or _X_ NO Dissertation/Thesis

___ YES or _X_ NO Continuation/Renewal

_X_ YES or ___ NO Student Research Project

___ YES or _X_ NO Is this a Protocol Change for previously approved project? If yes, submit a signed copy of this form with the changes bolded or highlighted.

___ YES or _X_ NO Does your project involve medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form.

___ YES or _X_ NO Does your project include Genetic Research? If yes, refer to Chapter 3 of the Researcher Handbook for additional guidelines regarding your topic.

___ YES or _X_ NO Does your project include Internet Research? If yes, refer to Chapter 3 of the Researcher Handbook for additional guidelines regarding your topic.

___ YES or _X_ NO Will subjects or data be provided by Altru Health Systems? If yes, submit two copies of the proposal. A copy of the proposal will be provided to Altru.

___ YES or _X_ NO Will research subjects be recruited at another organization (e.g., hospitals, schools, YMCA) or will assistance with the data collection be obtained from another organization?

If yes, list all institutions: _____

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

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

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

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

This study will involve: Check all that apply.

_____ Deception
_____ Radiation
_____ New Drugs (IND)
_____ Non-approved Use of Drug(s)
_____ Recombinant DNA
__X__ None of the above will be involved in this study
_____ Stem Cells
_____ Discarded Tissue
_____ Fetal Tissue
_____ Human Blood or Fluids
Other _____

I. Project Overview

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

Strokes affect an average of 750,000 Americans annually. Individuals who suffer from a stroke often have residual neurological deficits, including motor weakness, poor motor control, and spasticity which negatively influence functional capacity. A functional activity that is often affected is ambulation and many individuals are left non-ambulatory for a period of time. Therefore, gait training is a key component during rehabilitation. Traditional approaches to gait training have included strengthening and coordination training through the use of component part practice. More recent approaches focus on task-oriented repetitive strategies for gait training, including partial body weight support (PBWS) treadmill training.

PBWS treadmill training uses a harness system to support a percentage of patients' body weight. This decreases the load on the lower limbs and maintains an upright posture to allow performance of complex, repetitive ambulatory motions. Current literature supports the use of 40% or less body weight support to maintain the appropriate gait kinematics during PBWS treadmill training. With the use of EMG, we will compare muscle activation in patients who are status-post stroke while ambulating over ground, on a treadmill, and on a treadmill with PBWS. We believe there will not be significant EMG differences between conditions during ambulation.

II. Protocol Description

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

1. **Subject Selection.**
   a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects. If incentive payments will be made to anyone for enrolling participants, describe the incentive package.

      Subjects will be recruited from the city of Grand Forks by the researchers. This will be done by calling possible subjects, which will be provided by Cindy Flom-Meland. Each subject will complete a one-time 2-hour obligation. There will be 30 subjects who are status-post stroke recruited.

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

      All the subjects will be over the age of 50 and will complete one session lasting 2 hours. Subject will be allowed to participate if they are able to walk independently either with or without the use of canes, crutches, and/or a walker.

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

Subjects will be excluded if they have not had a stroke, if they have orthopedic involvement of the lower extremities, including surgery. Subjects who have had surgery or have existing orthopedic involvement may have compensational gait patterns. These patterns could potentially change the data collected.

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

This study will be comprised of 30 subjects status-post stroke in order to have an adequate number of subjects for statistical analysis.

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

EMG has been proven to be a valid and useful tool.

2. Description of Methodology.

a) Describe the procedures used to obtain informed consent.

Before beginning participation in this study, each patient will be issued a copy of an information and consent form. (See attached). Each subject will be asked to read and sign the consent form. This will indicate that they understand the study and its purpose. They will also be given a copy of the consent form to take with them, for use if further questions or concerns come up. They will also report to UND PT department for an initial meeting. During this meeting the subjects with be issued a copy of the information and consent form, as stated earlier. The subjects will then be introduced to ambulation on a treadmill in order to prepare the subjects for the study and to determine the appropriate (self-selected) walking speed for each subject in advance.

b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research.

The research will be carried out at the UND Physical Therapy Department using their Gate Keeper Treadmill, Lite Gait, GAITRite system, electronic goniometer, and EMG equipment.

c) Indicate who will carry out the research procedures.

The student advisor, the four researchers, and one additional faculty member from the Physical Therapy Department at UND will conduct the research project.

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

Informed consent will be obtained from each participant prior to initiation of the study. Participants will complete a 'patient history in-take form' (see attached). Participants will be weighed using a standard scale to determine the appropriate amount of support to be used during the activity.

Self adhesive electrodes will be placed on the skin of each participant after the area has been shaved and cleaned with rubbing alcohol. According to EMG standards, electrodes will be placed on the following muscles: adductors, gluteus medius, rectus femoris, vastus lateralis, biceps femoris, gastrocnemius, and anterior tibialis. Placement of each electrode will be a measured distance between the motor point and insertion of each muscle. To determine when initial contact occurs, an electrode will be placed on the plantar surface of the calcaneous. After placement of the electrodes, participants will walk on the treadmill to determine their self selected speed and to adapt to walking with electrodes on. Once the participants have determined their speed on the treadmill they will be hooked up to the analyzing equipment. A receiver will pick up EMG signals and then feed into a computer for data recording and display.

First, each participant will be measured in relaxed standing to determine a baseline for EMG. Next, participants will ambulate over ground on the GAITRite system to determine velocity and EMG measurements will be recorded for 30 seconds. Participants will draw out of a hat to determine the order of ambulation for the remaining three conditions. Between each of the four conditions, participants will rest for 3-5 minutes and then begin walking on the treadmill at a self selected speed. The participant will walk for 2 minutes for each condition on the treadmill. The four ambulation conditions will be over ground, treadmill without harness, treadmill with harness at full body weight, and treadmill with 15% PBWS. Each ambulation condition will be performed by each participant. EMG activity will be recorded at the end

of the first and second minute in each of the treadmill ambulation conditions. After completion of the study the EMG recordings will be evaluated.

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

Consent forms of participants will be in locked storage at the University of North Dakota Physical Therapy Department. Records from the study will be destroyed using a paper shredder three years after the conclusion of the study. The only individuals with access to the information will be the four student researchers, the student advisor, one faculty member, and IRB auditors.

f) Describe the qualifications of the individuals conducting all procedures used in the study.

The four researchers are UND students currently enrolled in the Physical Therapy program and have attended instrumentation classes for EMG, the GAITRite and Lite Gait equipment. The student advisor and one assisting faculty member involved in this study are competent in the use of all equipment being used. All persons involved in this project are CPR certified.

g) Describe compensation procedures (payment or class credit for the subjects, etc.).

There are no compensation procedures for this project.

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.

3. Risk Identification.

a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.

Risks to the participants are slight but as with the use of any exercise equipment there is a risk for minor injury (i.e. fatigue, falls, muscle strain). In addition, participants may also experience a mild irritation from the adhesive on the electrodes used in EMG.

b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.

Information from the consent forms and data collection will not be linked in order to protect participant confidentiality.

4. Subject Protection.

a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).

Participants will be educated on the control and safety features of the treadmill.
Participants will be informed of possible skin irritation from EMG electrodes.

b) Describe procedures you will implement to protect confidentiality (such as coding subject data, removing identifying information, reporting data in aggregate form, etc.).

Information of results collected from participants will not be linked to the consent forms to protect participant confidentiality. Names will not be used on research data forms for participants, instead numbering of forms will be used to identify participants.

c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.

Before beginning the study each participant will be given a copy of the information and consent form to read and sign. Participants will be able to read and comprehend documents as well as be competent and independent in their decision-making. A copy of the consent form will be provided to each participant to keep.

d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study.

Describe: 1) the storage location of the research data (separate from consent forms and subject personal data)
2) who will have access to the data
3) how the data will be destroyed
4) the storage location of consent forms and personal data (separate from research data)
5) how the consent forms will be destroyed

Results and consent forms will be kept in locked, separate storage areas in the Physical Therapy Department at the University of North Dakota. Records from the study will be destroyed using a paper shredder three years following the conclusion of this study. The only individuals with access to the information will be the people who audit IRB procedures, the four student researchers, the student advisor and one faculty member.

e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.).

If injury should occur during the study, medical treatment will be available as it would be for any member of the community. The participant and their third party payer will be responsible for paying for such treatment.

f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.

If injury should occur during the study, medical treatment will be available as it would be for any member of the community. The participant and their third party payer will be responsible for paying for such treatment.

III. Benefits of the Study

Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). **Please note:** payment is not a benefit and should be listed in the Protocol Description section under Methodology.

The purpose of this study is to evaluate individuals who are status-post stroke during ambulation over ground, on a treadmill without support, and on a treadmill with PBWS to determine if there are any differences in muscle activation of major muscle groups in the lower extremity. According to our hypothesis, we hope to find no significant differences between the ambulation conditions. Previous studies have been conducted validating the use of PBWS treadmill training in restoring functional ambulation. However, these studies have not included objectively measuring possible reasons for the improvement in function. We will focus on muscle activation in hopes to provide researchers and clinicians with possible theories behind the results of PBWS treadmill training.

IV. Consent Form

A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects. Refer to the RD&C website for further information regarding consent form regulations. **Please note:** Regulations require that all consent forms, and all pages of the consent forms, be kept for a minimum of 3 years after the completion of the study, even if the subject does not continue participation. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. It is recommended that the consent form be written in the third person (please see the examples on the RD&C website), and at no higher than an 8th grade reading level. A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp. The consent form must include the following elements:

a) An introduction of the principal investigator

b) An explanation of the purposes of the research

c) The expected duration of subject participation

d) A brief summary of the project procedures

e) A description of the benefits to the subject/others anticipated from this study

f) A paragraph describing any reasonably foreseeable risks or discomforts to the subject

g) Disclosure of any alternative procedures/treatments that are advantageous to the subject

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

i) A description of how confidentiality of subjects and data will be maintained. Indicate that the data and consent forms will be stored separately for at least three years following the completion of the study. Indicate where, in general, the data and consent documents will be stored and who will have access. The following statement must be included in all consent forms and informational letters: "Only the researcher, the adviser, [if applicable] and people who audit IRB procedures will have access to the data." Please make appropriate additions to the persons that may have access to your research data. Indicate how the data will be disposed of. Be sure to list any mandatory reporting requirements that may require breaking confidentiality.

j) The names, telephone numbers and addresses of two individuals to contact for information (generally the student and student adviser). This information should be included in the following statement: "If you have questions about the research, please call (insert Principal Investigator's name) at (insert phone number of Principal Investigator) or (insert Adviser's name) at (insert Adviser's phone number). If you have any other questions or concerns, please call Research Development and Compliance at 777-4279."

k) If applicable: an explanation of who to contact in the event of a research-related injury to the subject.

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

m) Regarding participation in the study:

1) An indication that participation is voluntary and that no penalties or loss of benefits will result from refusal to participate.

2) An indication that the subject may discontinue participation at any time without penalty, with an explanation of how they can discontinue participation.

3) An explanation of circumstances which may result in the termination of a subject's participation in the study.

4) A description of any anticipated costs to the subject.

5) A statement indicating whether the subject will be informed of the findings of the study.

6) A statement indicating that the subject will receive a copy of the consent form.

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

Signatures:

Beth Nordmark
Rhonda Breitbach
Kelly Malmin — 5-18-05

(Principal Investigator) Date:

Cindy Flom-Meland — 5-18-05

(Student Adviser) Date:

Requirements for submitting proposals:
Additional information can be found on the IRB web site at **www.und.nodak.edu/dept/orpd/regucomm/IRB/index.html.**

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

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

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

INVESTIGATOR LETTER OF ASSURANCE OF COMPLIANCE WITH ALL APPLICABLE FEDERAL REGULATIONS FOR THE PROTECTION OF THE RIGHTS OF HUMAN SUBJECTS

We Kelly Malmin, Rhonda Breitbach, Beth Nordmark, Jennifer A Pederson
(Name of Investigators)

agree that, in conducting research under the approval of the University of North Dakota Institutional Review Board, I will fully comply and assume responsibility for the enforcement of compliance with all applicable federal regulations and University policies for the protection of the rights of human subjects engaged in research. Specific regulations include the Federal Common Rule for Protection of the Rights of Human Subjects 45 CFR 46. I will also assure compliance to the ethical principles set forth in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research document, The Belmont Report.

I understand the University's policies concerning research involving human subjects and agree to the following:

1. Should I wish to make changes in the approved protocol for this project, I will submit them for review PRIOR to initiating the changes.

2. If any problems involving human subjects occur, I will immediately notify the Chair of the IRB, or the IRB Coordinator.

3. I will cooperate with the UND IRB by submitting Research Project Review and Progress Reports in a timely manner.

I understand the failure to do so may result in the suspension or termination of proposed research and possible reporting to federal agencies.

J A Peder
Beth Nordmark
Rhonda Breitbach
Kelly L Malmin
Investigator Signatures

5-18-05
Date

STUDENT RESEARCHERS: As of June 4, 1997 (based on the recommendation of UND Legal Counsel) the University of North Dakota IRB is unable to approve your project unless the following "Student Consent to Release of Educational Record" is signed and included with your "Human Subjects Review Form."

STUDENT CONSENT TO RELEASE OF EDUCATIONAL RECORD[1]

Pursuant to the Family Educational Rights and Privacy Act of 1974, I hereby consent to the Institutional Review Board's access to those portions of my educational record which involve research that I wish to conduct under the Board's auspices. I understand that the Board may need to review my study data based on a question from a participant or under a random audit.

The study to which this release pertains is

Muscle activation in individuals who are status-post a stroke during over ground, treadmill and body weight supported gait: a comparative study.

I understand that such information concerning my educational record will not be released except on the condition that the Institutional Review Board will not permit any other party to have access to such information without my written consent. I also understand that this policy will be explained to those persons requesting any educational information and that this release will be

350593-4
311510-1
354794-9
228728-5
NAID #

Jennifer A. Pederson
Beth Nordmark
Rhonda Breitbach
Kelly L Malmin
Printed Name

5-18-05
Date

Jennifer A. Pederson
Beth Nordmark
Rhonda Breitbach
Kelly L Malmin
Signature of Student Researcher

[1]Consent required by 20 U.S.C. 1232g.

APPENDIX B

INFORMATION AND CONSENT FORM

Muscle activation in individuals who are status-post a stroke during over ground, treadmill, and body weight supported gait: a comparative study.

Cindy Flom-Meland, a faculty member of the UND Physical Therapy Department, together with Kelly Malmin, Rhonda Breitbach, Jennifer A. Pederson, and Beth Nordmark, students in the Physical Therapy program at UND, invite you to participate in their research study. The purpose of this study is to evaluate people who are status-post stroke during ambulation over ground, on a treadmill without support, and on a treadmill with partial body weight support (PBWS) to determine if there are any differences in muscle activity of major muscle groups in the legs.

Your participation is welcome in this study if you are over the age of 50, if you do not have a history of an injury or a surgery on your legs, or if you are able to walk by yourself with or without the use of canes, crutches, a walker, etc.

You will be asked to donate a total of 2 hours of your time. During the 2 hours, you will be required to walk on a treadmill at a self selected speed for about 30 minutes. The remaining minutes will include placement of electrodes on different muscles and reflectors on various areas before walking on the treadmill. Participating in this study will provide us with information to help us evaluate if PBWS treadmill training changes the use of certain muscles after you have had a stroke. These findings will benefit future researchers and clinicians when they are using PBWS treadmill training to help someone re-learn how to walk after a stroke.

The PBWS treadmill training we will be using in this study is a form of exercise that is considered to be low-risk for injury. However, as with any type of activity, there is some potential risk for injury. This risk will be reduced by providing you with proper training on the treadmill and continual guidance by the researchers. The electrodes have an adhesive back, similar to Band-Aids, and can possibly cause a mild skin irritation. If an injury should occur while this study is being performed, medical treatment will be available in the same manner that it is to the general public. Payment for any needed treatment will be provided by you and your third party payer. By signing this form, you are not giving up any legal rights that you have in case of negligence or other legal fault of anyone that is involved in this study.

All the information gathered in this study will be kept completely confidential. Your name and any information that may otherwise identify you or tie you to this study will not be exposed at any time. The results of this study will be kept in a locked cabinet within the Physical Therapy Department at the University of North Dakota. They are required to be kept for three years following the completion of this study, but will be completely destroyed after that. No person involved in this study, either as researchers or as subjects, will be given any financial payment.

Your participation in this study is fully voluntary. Your decision whether or not to participate in this study will in no way change any future relations with UND. If you do choose to participate in this study, you or the researches can choose to terminate participation at any time without penalty.

If you have any question or concerns about this study at any time, please do not hesitate to contact Cindy Flom-Meland at UND at 777-2831. You may also reach any of the student investigators at the Department of Physical Therapy at UND between the hours of 8:00 AM – 4:30 PM at 777-2831. If you have any other questions or concerns, please call the Office of Research and Program Development at 777-4279.

I HAVE READ AND UNDERSTAND THE PREVIOUS INFORMATION AND VOLUNTARILY AGREE TO PARTICIPATE IN THIS STUDY. ALL OF MY QUESTIONS HAVE BEEN ANSWERED AND I AM ENCOURAGED TO ASK ANY QUESTIONS IN THE FUTURE. A COPY OF THIS CONSENT FORM HAS BEEN GIVEN TO ME.

_____ _____

Participant's Signature Date

_____ _____

Investigator's Signature Date

APPENDIX C

PATIENT HISTORY INTAKE FORM

Birth date: _____ Gender: _____

Date stroke occurred: _____

Side of body involved: (Circle one) Left Right

1. Have you ever had physical therapy?(Circle one) Y N

   If yes, how long did you have therapy? _____

2. Are you currently in physical therapy? (Circle one) Y N

   If yes, how long have you currently been in therapy?
   _____

3. Have you ever used a treadmill before? (Circle one) Y N

   If yes, when was the last time you used it?
   _____

   How many days per week do (or did) you walk on the treadmill?_____

   How many minutes do (or did) you walk on the treadmill at a time?
   _____

4. Do you use an assistive device to walk? (Circle one) Y N

   If yes, list assistive device used. _____

APPENDIX D

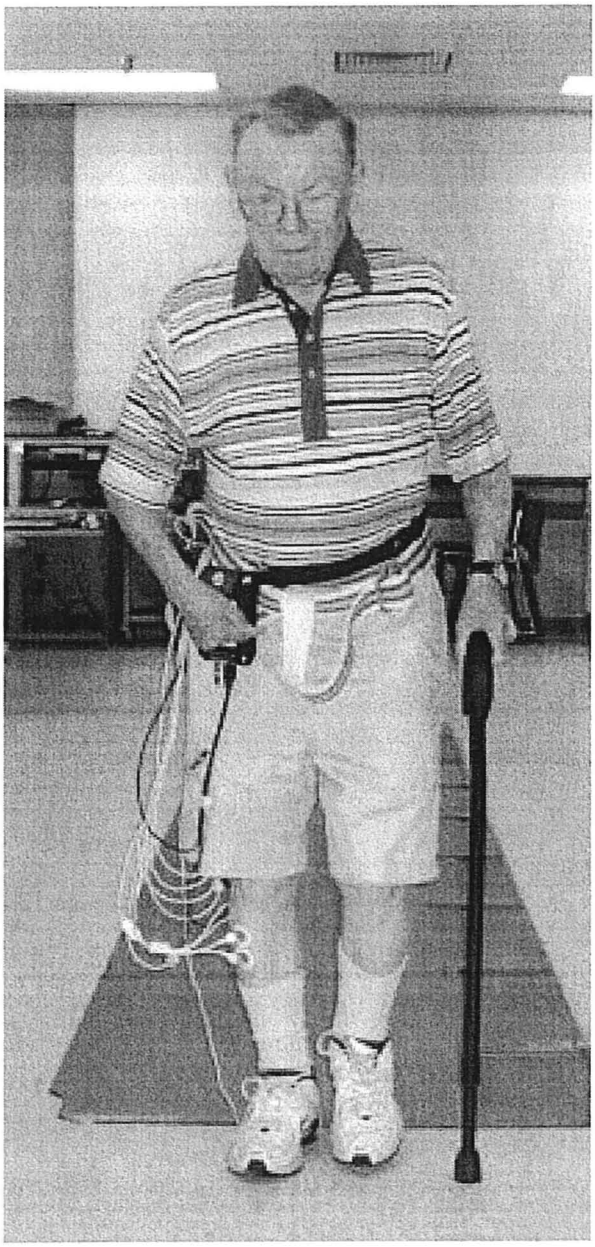

Figure 5. Set-up of electrode placement.

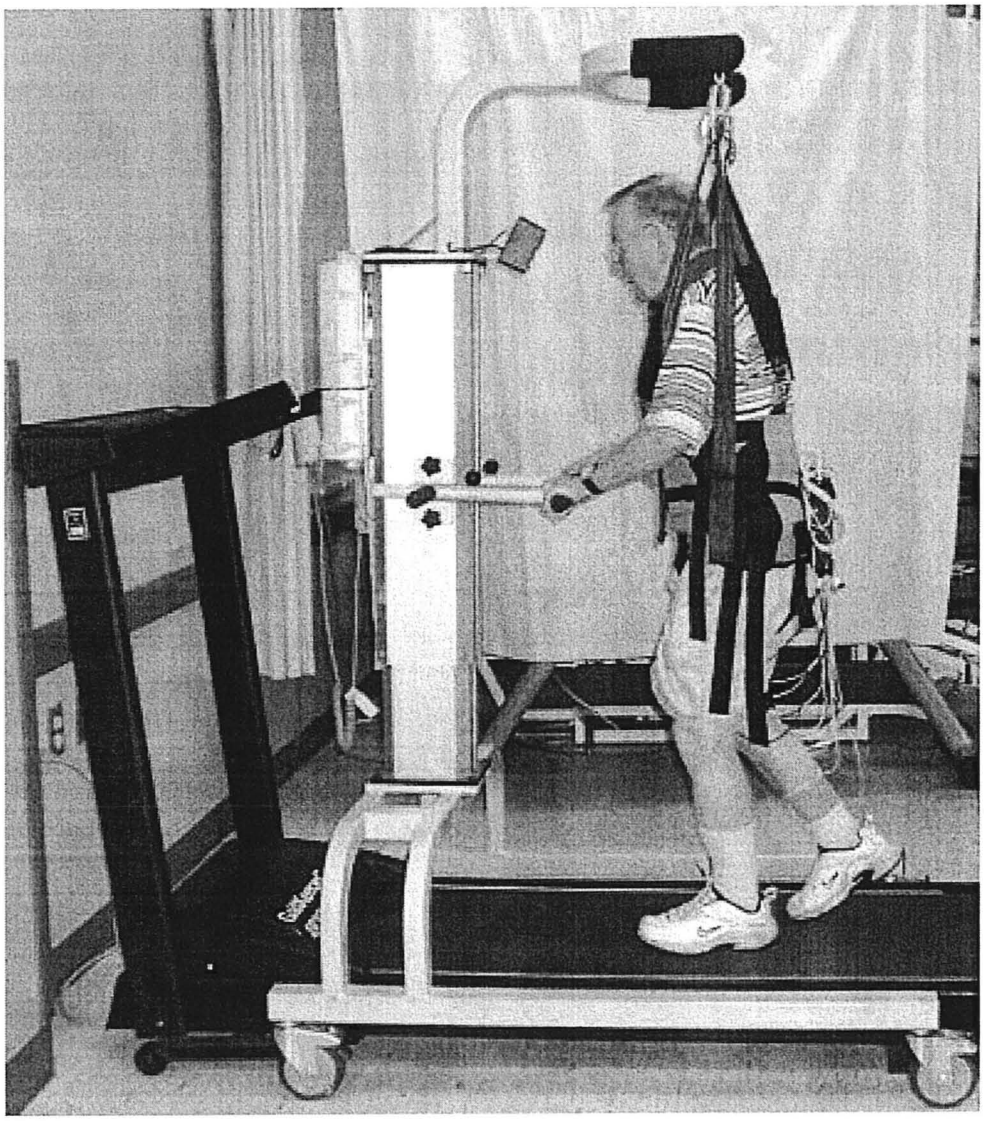

Figure 6. Set-up of LITEGait harness and treadmill.

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