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The Effect of Peripheral Neuropathy on Balance Performance in Community-Dwelling Adults with Type I Diabetes Mellitus

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THE EFFECT OF PERIPHERAL NEUROPATHY ON BALANCE PERFORMANCE IN COMMUNITY-DWELLING ADULTS WITH TYPE I DIABETES MELLITUS

by

Laura J. Eckel
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 and Health Science

in partial fulfillment of the requirements

for the degree of

Master of Physical Therapy

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1999

This Independent Study, submitted by Laura J. Eckel in partial fulfillment of the requirement 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.

Beverly Johnson
(Faculty Preceptor)

Beverly Johnson
(Graduate School Advisor)

Thomas Mohr
(Chairperson, Physical Therapy)

PERMISSION

Title: The effect of Peripheral Neuropathy on Balance Performance in Community-Dwelling Adults with Type I Diabetes Mellitus.

Department: Physical Therapy

Degree: Master of Physical Therapy

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Signature Laura Eckel

Date Dec. 12, 1998

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ABSTRACT

Purpose: Balance is affected by visual, somatosensory, proprioceptive, and vestibular input. Anything that alters one of these elements could potentially cause a decrease in postural stability. One disease which reduces the somatosensory input from the foot and ankles is diabetic neuropathy. The purpose of this study is to determine the correlation between Type I DM and balance performance, thereby adding to the current knowledge of postural control and the impact, if any, DM has on balance.

Methods: Twenty-five voluteer subjects with Type I DM and 25 age-matched control subjects participated in the study. Semmes-Weinstein monofilaments were used to determine plantar sensation. Following this the Berg Balance Assessment was administered to assess functional balance performance. A Pearson Correlation multiple regression was used to determine the correlation between sensation, DM, and balance performance.

Results: Significance was established between reduced sensation and decreased balance control in both the experimental and control groups. A significant correlation was also found between an increase in age and decreased sensation scores.

Conclusion: Assessing the balance of all patients who are at risk for reduced sensation should be implemented as a screening procedure for determining any decrease in postural stability.

CHAPTER I

INTRODUCTION

Falls manifest a serious threat to the independence and health of older adults. It has been found that fall-related injuries increase exponentially with age and that approximately half of elderly people who receive medical treatment for falls are discharged to nursing homes. One in three persons over the age of 65 and nearly one in two persons over the age of 80 will experience a fall once a year. Even though merely five percent of these falls result in serious injury, the psychological effects may lead to impaired mobility and an overall decrease in a person's quality of life.[1,2,3]

Deterioration in postural balance may be a significant contributor to several of these falls, due to a decreased ability to correct for the many postural disturbances experienced during activities of daily living, such as slips, trips, pushes, and self-induced displacements which occur during turning, reaching, and transfers.[4] Balance is affected by a combination of sensory elements responsible for the detection of body motion, including visual, motor, proprioception, and vestibular input. If one of these elements should happen to be altered by disease, it stands to reason that a decrease in postural stability would result.[5]

One disease which greatly reduces somatosensory input from the feet and ankles is diabetic neuropathy, which is the most prevalent complication of Type I DM, affecting 20-50% of patients who have had DM for more than 10 years. Deficits resulting from diabetic neuropathy manifest themselves in various ways depending on the number and type of nerve components affected, as well as the severity therein.[6] All of these various, wide-spread deficits strain health care resources, as is shown by the annual cost of diabetes estimated at $14 billion.[7] Integration of our growing understanding of the postural affect diabetes has on balance into specific clinical assessment and treatment tools will enrich a physical therapist's repertoire for preventing and treating postural deficits.

Problem Statement

There is a need to further assess the relationship between diabetic neuropathy manifest in people with Type I DM and balance control due to the lack of research in the area of balance deficiency in the diabetic population. Research has suggested that effective treatment of balance deficiencies requires that the specific sensori-motor components underlying functional tasks be identified. Protocols can then be designed which serve to improve the patient's function.

Purpose of Study

To determine the correlation between Type I DM and balance performance. To identify if somatosensory components contribute significantly to decreased balance control. To educate physical therapists and other health care professionals regarding the impact of sensory components on balance training.

Significance of Study

If DM significantly decreases balance performance, specific balance-training programs may be developed for the DM population as prophylactic and curative approaches. Decreased balance increases the risk of falling, so it is imperative to determine the results of decreased sensory input from specific systems.

The subjects, via their participation in the study, will have the opportunity to increase their awareness of their individual balance risk factors associated with Type I DM as they will be informed of their Berg Balance Score and the significance of it.

Research Questions

Is balance performance affected in subjects who have DM without diabetic neuropathy?

Is balance performance affected in subjects who have DM with diabetic neuropathy?

Does somatosensory input play a significant role in decreased balance performance?

Hypothesis

Our null hypothesis is that there will be no significant correlation between Type I DM and decreased balance. Our alternate hypothesis is that there will be a significant correlation between DM and decreased balance.

CHAPTER II

LITERATURE REVIEW

Over the past years, research in the area of posture and balance control has broadened and actually shifted, so that there is no universal agreement on how to define posture and balance and their underlying neural mechanisms.[8,9] In the clinical setting, however, balance and equilibrium are generally defined as situations where the body position is controlled in reference to the support surface. We also know that the overall goals of the balance control system are safety and function,[5] which are vitally important to independence in our everyday activities, and that any assessment of a patient's dysequilibrium and lack of balance which is to be made to determine causal effects depends on the therapist's assumptions about the components that make up normal postural control.[10,11] Based upon these assumptions we have two main theories of motor control to describe the neural mechanisms of posture and balance, and to provide the groundwork for asking questions about the underlying basis for normal versus abnormal movements. It is important to note that theories can never be judged right or wrong.[10]

The first theory is the reflex/hierarchical concept of motor control, which is established on the belief that posture and balance is maintained by organized reflex mechanisms. During development there is a gradual shift from primitive spinal reflexes controlling movement to higher levels of reflexes dominating movement, until mature cortical responses take over.[8,11,12] This theory does not explain the complexity and adaptability of postural control, nor the variety of compensation strategies found in patients with postural deficits. Scientists no longer believe that balance can be viewed a simple, reflexive response to sensory stimuli, and studies have shown that adequate postural control requires a complex interaction of both muscular and neuromuscular components, being able to correctly respond to externally imposed perturbations and be able to anticipate displacements that result from internal movements, such as picking up a box. [11,13]

The second theory, known as the systems model, is the current research prototype, and it is from this perspective that balance will be viewed in this paper. Rather than viewing balance as stereotyped responses to sensory stimuli, the systems approach assumes that postural control results from the interaction of many body systems that work together to control the position and motion of the body in space.[8] Stability and orientation are the two main goals of this model, with the task of postural control being a dynamic problem that may be adapted to current conditions.[11] Therefore, it is a flexible, functional motor skill that can be changed through training and experience.[14] Indeed, results from platform perturbation studies have shown that balance control is proactive and adaptable based on one's prior experience and intention.[14,15]

There are certain components necessary to maintain our center of mass over our base of support, including sensory detection of body motion, sensory interaction processes, the ability of the central nervous system to extract relevant sensory information, and execution of musculoskeletal responses to generate forces for controlling body position.[5,8] During quiet stance, the body sways back and forth and remains balanced due to body alignment, which decreases the effect of gravity, and increased muscle tone in our anti-gravity muscles to counteract the gravitational force.

The somatosensory, visual, and vestibular systems all provide feedback to influence muscle tone. Visual inputs sense the position and motion of the head. Somatosensory inputs report the position and motion of the body's orientation with reference to a support surface, and the vestibular system reports the position and motion of the head with respect to gravity and internal forces.[8,16,17]

Once the center of mass moves outside ideal alignment, compensatory muscle strategies are used to return the center of gravity over the body's base of support. Research in neurologically intact young adults suggests that the nervous system combines certain muscles together into units called synergies. Synergies can be thought of as a way for the nervous system to coordinate all the joints and muscle activity to form a single movement. There are three stereotypical patterns of movement that have been identified which restore the center of mass to a position of stability, controlling anterior-posterior body sway.[8,18]

First is the ankle movement strategy, most effective when a small change is necessary and the support surface is firm and secure. The ankle strategy requires adequate range of motion and strength in the ankles.[19] The ability to sense the support surface is necessary also, which was demonstrated by Nasher, in a study in which normal subjects were perturbed by horizontal translations while wearing pressure cuffs about their ankles, cutting off sensation to their feet. Results showed that subjects used more hip strategy with the pressure cuffs, and ankle strategies were more frequently used without the pressure cuffs, suggesting that patients cannot select or control the ankle movement strategy without somatosensory input from the feet.[8,18,19]

The second strategy, the hip movement strategy, produces large and rapid motion at the hip joint to restore stability in response to much larger, faster perturbations than the ankle strategy. It is also used when standing on a very small or compliant support base. This strategy may be limited in people with weakness or decreased range of motion in their hip joint. Like the hip strategy, the stepping strategy is also less efficient than the ankle strategy when restoring balance. The stepping strategy is used primarily to control body sway in situations where both the ankle and hip strategy are inadequate, and when the perturbation displaces the center of mass outside the base of support of the feet. Subjects then use this "stumbling" strategy to move their base of support under their falling center of mass.[8,14,18-20]

These movement patterns appear to be selected based not only on the current support-surface and its inputs, but also by expectation, practice, and a person's prior experience. Because knowledge of prior results is incorporated into the central nervous system, external events may be anticipated and reliance on feedback-mediated strategies reduced. Postural adjustments don't occur solely as a result of sensory feedback in response to displacements, but also due to "feedforward" responses in participation of expected perturbations.[10,13]

Researchers agree that neurologically intact subjects may use a combination of the three strategies identified, and can shift from one strategy to another depending on what the situation may be,[8,18] which leads us to an important question. How does the CNS know when and how to apply these restoring forces? The CNS must be aware of the body's location in space and be able to make the appropriate musculoskeletal responses by organizing information from sensory receptors throughout the body.

More than one causal effect may play into decreased balance. Inaccurate sensory input and/or decreased muscle strength and control, or inappropriate selection of a postural movement strategy are all sensorimotor components interacting to produce dysequilibrium. Perceiving one's orientation requires a combination of peripheral inputs provided by the visual, somatosensory, (which include proprioceptive, cutaneous, and joint receptors) and the vestibular system of the inner ear. All of these senses are necessary because no one sense can directly measure the position of the body in space. Also, at any time one of the senses may be perceiving orientationally wrong information during sensory conflict situations. During times like this, the brain ignores all inaccurate senses, and just relies on the orientationally accurate input. This is a process called sensory organization. It is because we have redundant sensory orientation information available that we remain balanced during periods of sensory conflict. This redundancy also provides a mechanism for sensory compensation; in the event that disease would destroy one sensory modality, balance reactions could still take place by using the remaining sensory information available.[19,21,22] In fact, in our everyday activities we undergo periods of sensory compensation during simple tasks like walking in a room with reduced lighting or on uneven, unpredictable surfaces. During these altered sensory environments, postural control requires selecting the most reliable sensory input for orientation.[10,23] We do know that optimal postural stability requires input from all three senses.[19,24]

However, some studies suggest that under normal conditions neurologically intact adults preferentially rely on input from the somatosensory system, which is opposite that of young children, who tend to rely more heavily on their visual system.[8] An unpublished study reports that both somatosensation and vision are more sensitive to subtle movements than is the vestibular system.[19,25] Dietz also indicated that muscle responses to vestibular signals were 10 times smaller than that of the somatosensory system, suggesting the vestibular system plays only a small role in postural control.[8,26] Studies have even suggested that vestibular input is not required for postural stability during quiet stance when other sensory information is available.[24,27]

It is important to consider what the potential effect of sensory loss may have on the coordination of movement strategies used to restore postural equilibrium, because sensory loss may not only affect the detection of postural displacement, but the interpretation of self-initiated sensory input responding to postural movements. Researchers have found that there is a difference in what movement strategy is selected to restore postural stabiltiy depending not only on the mechanical constraints of the task, but also on what sensory information is available at that time.[14,20,24,28] As was stated earlier, the ankle movement strategy requires somatosensory input from the feet.[19] This study by Nasher, Horak, and Shupert also found that the hip movement strategy requires vestibular information. Therefore, somatosensory loss resulted in an increased frequency of the hip movement strategy used for postural correction. These results suggest that cutaneous and joint somatosensory information from the feet are useful in making sure that the form of postural movement strategy is appropriate for the current situation. Specifically, subjects in this study with somatosensory loss used an increased hip movement strategy even in situations where an ankle movement strategy would have been effective, inferring that decreased somatosensory input from the feet hinders the ability to select or control the ankle movement strategy.[24,27]

Thus, postural control can truly be described as a sensorimotor task. The movement strategy selected will affect which type of sensory information is available, and sensory information regarding the center of gravity and environmental context will affect which movement strategy is to be selected.[8,10,11]

Due to the direct effect of somatosensation on balance control and the type of movement strategy selected to control stability, it is interesting to examine a disease that often destroys the somatosensory modality in the feet and ankles to determine its effect on balance and posture. One such disease is type I diabetes mellitus, or also known as IDDM (insulin dependent diabetes mellitus). By definition, diabetes mellitus (DM) is a disease of the endocrine system, characterized by glucose intolerance and alterations of the metabolism of energy nutrients, and diagnosed by the presence of chronic hyperglycemia.[7] To gain a better understanding of DM, an overlook of the disease process will be reviewed.

First of all, blood glucose serves as the primary fuel supply for the brain and our muscles when we exercise. Our glucose level in the blood is controlled within very narrow parameters, and the disease DM is typified by failure of this control, allowing the blood glucose level to rise. Insulin is a hormone that is responsible for glucose homeostasis by regulating glucose transport into muscle and fat cells, as well as inducing protein synthesis, preventing muscle breakdown, and stimulating cellular growth. Insulin is synthesized in pancreatic beta cells of the islets of langerhans and released in a negative feedback manner. When insulin is not released as it should be glucose becomes unable to enter the muscle and adipose tissue, the liver begins to produce glucose, and plasma blood glucose levels rise, known as hyperglycemia. Glucose eventually is lost in the urine, resulting in osmotic fluid loss, while those tissues dependent on insulin to transport glucose into the cells are starving. The brain responds to this by prompting the body to eat and drink excessive amounts. This leads to the three classic signs of DM: polydipsia, polyuria, and polyphagia. Continued effects from the lack of insulin include a production of fatty acids as fat in the adipose tissue becomes metabolized, which then undergos a change in the liver to keto acids. Normally, keto acids can by used by neural and muscle tissue for energy metabolism, but may also lead to a decreased pH, and eventually diabetic ketoacidosis, which is also a primary symptom of DM.[6,7]

Diabetes mellitus can be broken down into two broad categoris: type I insulin dependent and type II diabetes, non-insulin-dependent diabetes mellitus, or NIDDM. Type I diabetes makes up 10% of the individuals with DM in the United States, and is most commonly diagnosed in young people between the ages of five and 20. Individuals with type I DM have absolute insulin deficiency due to autoimmune destruction of insulin producing cells. Thus requiring people with type I DM to be on chronic insulin therapy. People with type II DM are usually diagnosed after the age of 40, with certain factors increasing their risk of developing the disease, such as obesity, female sex, family history, and a lack of exercise. Type II DM is manifest by a relative insulin deficiency due to a lessened responsiveness and tissue sensitivity to the hormone insulin. It may be that there is a decreased number of insulin receptors, and as the disease progresses, insulin production may also become impaired. If diet alone does not decrease the blood glucose level, these individuals with type II DM may be on oral hypoglycemic agents or even insulin.[7,29]

The associated chronic complications of diabetes are quite extensive, and generally placed into two broad categories: neuropathic and vascular complications, with two subdivisions of the vascular complications, macrovascular and microvascular. The macrovascular complications include cardiovascular disease, peripheral vascular disease, and ischemic cerebrovascular disease, or strokes. Microvascular complications include retinopathy (eye disease), and nephropathy (kidney disease), which are thought to be caused from capillary basement membrane thickening due to hyperglycemia.[7] All of these complications are highly associated with poor diabetes control, although there is no proof at this time.[6,30] While vascular disease may be important in the lower extremities of some people, most lower extremity complications are due to neuropathic complications.[6]

The neuropathic complications of diabetes, and the role this plays in postural balance control is very large. Symptoms of neuropathic complications are found in 25% of individuals with diabetes due to some alteration in their nerve function.[7] Sensory, motor, and autonomic components of the nerve are affected, though sensory symptoms are most notable. Autonomic neuropathy is characterized by atriovenous shunting that is made manifest in the feet as an increased skin temperature, dry skin, osteopenia (bone loss), and eventually stress fractures. Motor neuropathy is subtle, and usually there is no dramatic loss of muscle power in the foot. However, it does attribute to clawing of the toes due to an imbalance of the interosseus muscles of the foot, also leading to more direct pressure on the metatarsal head.[6,31] The most prevalent somatosensory syndrome experienced by individuals with diabetic neuropathy is a distal symmetric primarily sensory polyneuropathy.[29,32,33] This is a peripheral limb deficit involving distal sensorimotor fibers in a stocking-glove distribution, including a loss of nerve axons accompanied by demyelination. The characteristics of distal symmetric neuropathy are determined primarily by which nerve fiber is affected. Large fibers are associated with a loss of position, vibration, and light touch sense and diminished ankle reflexes. Small fiber neuropathy is characterized by a loss of pain sensation and temperature difference.[33] Distal symmetrical peripheral diabetic neuropathy first shows signs and symptoms in the toes and progresses proximally. The etiology for this is not clear, but these are the longest axons in the body, and this may be a relevant factor.[6]

From a science perspective, a patient who has diabetic neuropathy presents a neurophysiological model that can contribute more to our basis of understanding the postural control mechanism, as we already know that the integrity of ankle proprioception is a vital factor for postural control. It is clear that balance and postural stability rely upon peripheral somatosensory inputs, and that higher levels in the CNS integrate this sensory information and induct a motor reflex response.[34,8] This leads one to believe that patients with diabetic sensory neuropathy, because of their lessened lower limb proprioception, would have decreased postural stability, and an increased likelihood for falls.[32] Although many clinicians do believe that diabetic neuropathy may compromise postural control, there is a lack of reported research to support this belief.[6]

The first quantitative evidence that the neuropathic diabetic patient had a problem with gait and posture came from a study performed by Cavanagh, who found that subjects with diabetic neuropathy were 15 times more likely to report an injury during ambulation than control subjects who had DM but no neuropathy.[6,35] In this same study, a significant relationship was found between subjects with peripheral neuropathy and a decreased level of perceived safety.[35]

Further research completed on patients with DM and peripheral neuropathy has documented an increased range of sway in quiet stance, correlating to the severity of the neuropathy, and not compensated for by other sensory systems.[6,32,36] This finding is deemed significant because body sway is considered to be a measure of postural stability.[36] Therefore, a greater range of sway indicates poor postural control.

To examine what role somatosensory loss plays in the selection of motor strategy used to maintain upright stance, normal subjects had pressure cuffs placed around their lower extremities to disrupt blood flow and diminish accurate somatosensory input. Following a perturbation of the support surface, these ischemic subjects used a mixed ankle-hip strategy to regain their balance. Normal subjects selected a pure ankle strategy with which to maintain their stance.[19,35] As was stressed previously, the ankle strategy is dependent upon appropriate somatosensory feedback,[19,24] so it seems reasonable that patients with severe peripheral neuropathy would tend to rely on the hip movement strategy for balance control, which may not be as efficient or safe as the ankle movement strategy.[24]

Preliminary findings suggest that diabetic peripheral neuropathy can lead to delayed EMG postural responses to surface perturbations, meaning that the onset of their postural responses may be delayed due to a slowing of sensory or motor conduction, primarily triggered by proprioceptive inputs from the ankle. Decreased proprioception was made evident in a study where DM patients manifested a higher detection level to passive ankle rotation during weight-bearing stance than their age-matched non-neuropathic control subjects. This finding is important, as it may be a relevant factor in the movement strategy selection and the compensation patterns used by patients with peripheral neuropathy.[14,24,32,37]

One study was completed to examine the sensory effects of symmetrical distal diabetic polyneuropathy in DM patients and what changes, if any, would be found in balance control. To do this, patients were examined in situations demanding 1) complete vision, 2) no vision (eyes closed), and 3) in an augmented visual situation. The results of this study plainly showed a postural deficit and a difficulty integrating sensory information in the neuropathic group compared to the control subjects. In fact, the neuropathic subjects were less stable with vision than the control subjects were with their eyes closed, suggesting that even with vision, patients with sensory loss secondary to DM may have impaired balance control.[32]

All of these results show that the impaired postural control of diabetic-neuropathic subjects is related to the decreased peripheral (sensory and motor) neural conduction and resulting reduction of somatosensory input from the foot and ankle.

Effective treatment of any balance deficit requires that the therapist understand all factors that impair balance, one of which is aging. Although it has already been determined that impaired balance lies within the diabetic population, typically falls and decreased balance control are associated with the elderly population, and is accepted as an inevitable part of growing old. This raises the question of what contribution age-related factors causing the decreased balance in older adults makes compared to the underlying pathological problems that increase with age. Evidently there is difficulty in seperating the effects of aging alone from the subtle pathological and life-style changes that accompany growing old.[38,39] One source reports that the variability between adults rises with age and subtle pathologies accumulate making it difficult to determine the effects of age on the body, specifically the balance control system. Often there may be more than one pathology present in the elderly so that instead of one problem in the postural control system, there is an accumulated deficit within many different components, and individuals exhibit different combinations of postural balance deficits. This makes it very difficult to test for the effects of one specific component loss, such as somatosensation.[39]

Duncan did a study on the effect of decreased balance control on functional mobility in older men and found that the age-related decrease in physical function was due to an accumulation of deficits rather than by a single impairment. This study did find that age was correlated with a slower walking speed, decreased stride length, and a reduced functioning of the visual, vestibular, and sensori-motor systems.[40,41]

Recent research has shown a significant deterioration in the somatosensory, vestibular, and visual systems that comes on with age. Both cutaneous and vibratory sensation, and ankle joint sensation were shown to be lessened in the elderly.[42,43] This is very important when viewing a study which showed that somatosensation was vital in controlling the amount of body sway in older individuals who fall, and that these individuals were forced to depend on an inefficient movement synergy to maintain balance, which wouldn't have to rely as heavily on proprioceptive input, primarily the hip strategy.[44]

One study was done not only to determine whether visual and somatosensory contributions are the same in the young and old, but also to determine whether any differences between the young and old were caused from a diagnosed pathology in the sensory systems. The results from this study were very interesting and are as follows: both the young and old subjects relied strongly upon ankle proprioceptive input for balance control and tended to lose their balance when the movement strategy pattern was altered. It appeared that the aging process did affect the appropriate selection of the movement strategy in response to a displacement, and these older subjects used the hip strategy more frequently than the younger subjects, just as did subjects with significant peripheral neuropathy.[42]

An important finding from this study was that the loss of redundant sensory inputs seemed to have a greater affect on the older adults when compared to the younger subjects.[42] These same results were noted by Woolacott, who found that as long as there were two sensory inputs, both the young and the old could maintain proper balance, but when only the vestibular system was providing input, the elderly lost their balance due to the lack of redundancy.[45]

It was also found that the elderly population activates additional muscles in their response to displacements, which may be due to a lack of confidence resulting in a stiffening of the joints and reduction in the degrees of freedom to try to control the response better.[42] Other authors conclude that maybe the fear of falling and poor balance are due to simply an apprehension of falling and the resultant decrease in stance duration during balance tests.[44,46]

Research has correlated increased sway with an increase in age,[1,47] which is a sign of poor postural control. But one researcher[48] noted that in his study, when a neurological exam was given to the older adults, many of them did show some form of mild sensory or motor deficiency. He reported that if these subjects were to be excluded from the study, the postural differences between the young and old subjects would be less. This contributes to the understanding that some of the deficiencies are due to an underlying pathology.

It is proven that muscle strength declines with age and the musculoskeletal system is an important contributor to balance control.[42] Another factor that may increase the risk of falls in the elderly is the inability of the nervous system to integrate the sensory inputs and quickly select the most accurate sense, especially in a sensory conflict situation.[19,34,44] Visual input declines after the age of 65, whereas before this age it was a very important sense for maintaining balance; therefore, it becomes less able to supplement peripheral input, leading to an increase in sway.[38]

Globally, many things may be causal factors leading to decreased balance control in the elderly: muscle weakness, decreased range of motion, diminished reflexes, visual/vestibular/sensory deficits, central sensory integration difficulty, abnormal movement synergies, and motor control problems.[42]

Based on the results found, it appears that many of the pathological changes associated with diabetes and impaired balance are also manifest in the elderly. It may then seem that having diabetes would accentuate the usual age-related deterioration in function, and careful emphasis needs to be placed on proper balance training in the management of older diabetic neuropathy patients.

These training programs may be very beneficial because such programs can focus on necessary components of balance, such as adequate muscle strength.[36] Clinicians may be able to improve function by addressing the accumulated manifestations of the impairment, recognizing that even minor deficits add to the overall burden of the disease.

Obviously, such factors as somatosensory loss cannot be regained, but therapy could still include training to increase the patient's reliance on his visual input, or even the addition of ambulatory aids to prevent falls.[19,21] In addition, clinicians should always separate and treat those deficits that are correctable. Alleviating these deficits may provide sufficient compensation to improve the patient's function.[40,41] The therapist's job is to first identify the balance deficiency as specifically as possible, and then decide how this could be compensated for in a treatment program designed for their problem.[21] The basic characteristics of rehabilitation emphasize individualized treatment with sensory input based upon the patient's needs and responses. Activities should be rich in proprioceptive, vestibular, and visual input and include active participation of the patient.[49]

This study proposes to determine the effect of peripheral neuropathy on balance performance in the hopes that further information regarding balance deficiencies exhibited by the DM patient will lead to effective and timely utilization of balance training programs.

CHAPTER III

METHODOLOGY

Subjects

This study consisted of 25 volunteer subjects with Type I Diabetes Mellitus (DM) with or without peripheral neuropathy and 25 age-matched control subjects currently residing independently in the community and surrounding area. Volunteers were recruited from the local area via flyers describing the study, word of mouth, and through a diabetic newsletter. Additional brochures were sent to individuals with DM via a mailing list obtained from a local diabetic support group and the local diabetic association. Subjects responded by phone or by written response to participate in the study.

Inclusion criteria for the experimental group consisted of: Type I DM, age of 18 years or older, ability to comprehend and follow directions, sufficient strength for functional gait without an assistive device, no vestibular disorder, no other neurological disorder (other than diabetes), no amputation, intact skin throughout the lower limb, and no uncorrected visual deficit interfering with functional gait.

The age-matched control group consisted of 25 volunteers without DM who met the rest of the experimental group's inclusion criteria, of which were 15 females and 10 males. Of the 25 subjects in the experimental group, 15 were female and 10 were male. Ages of the subjects (n=50) ranged from 18 to 87 years with a mean of 36.83 years.

Volunteers were excluded from the study if they failed to meet any of the inclusion criteria listed above. Data from two of the volunteers was excluded due to failure to meet the specific predetermined selection criteria. One had a Charcot joint, the other had significant visual deficits interfering with functional gait.

Subjects were informed of the purpose of the study and the testing procedure prior to testing. Each participant was asked to sign an informed consent statement approved by the University or North Dakota Institutional Review Board. (Appendix A)

Instrumentation

The screening instruments used in this study were the Semmes-Weinstein Monofilaments (3.61 and 4.31) and the Berg Balance Measure. Both can be easily administered in the clinic or the client's home.

The Semmes-Weinstein Monofilaments (Appendix B), developed by Sidney Weinstein and Josephine Semmes in the 1960's, were used to test relative thresholds of pressure and touch sensation on the plantar surface of the foot. This test identified those with peripheral neuropathy. Bell-Krotoski reports high reliability (0.84) , validity, and objectivity of the monofilaments, using standard protocol .[52] Decreased response to stimuli at the predetermined critical level of 4.31was considered a sign of peripheral neuropathy.[51] This is consistent with the North Coast Medical, Inc. instructions for application of the monofilaments, which state that the 4.31 monofilament is used to confirm protective sensation. Traditionally, the 3.61 monofilament, which applies less force due to a smaller diameter, is indicative of normal sensation on the plantar surface of the foot.[53] This tool has been useful for diagnostic purposes, as well as monitoring and predicting direction of neuropathy.[52] Sensation testing with monofilaments are cost-effective when considering both the cost of the instrument and the amount of professional time required for testing.

The Berg Balance Assessment (Appendix C) is an efficient and easily administered balance assessment, requiring only standard household items and 15-20 minutes of time to complete. A stepstool, a 12-inch ruler, and two hard-backed chairs were utilized to complete the Berg Balance Assessment. This test is scored on a 0 to 4 scale (0= inability to perform task, 4=independent) to determine the subject's ability to perform specific tasks, and is frequently used in the clinical setting as an assessment of the patient's functional status. It has good inter-rater reliability (0.98), intra-rater reliabiltity (.99), and content validity amongst the elderly population.[54] Berg et al[54] found that subjects who score below 45 (of 56) are 2.7 times more likely to experience falls than those scoring above 45.[1,55] In this study, a control group was used for norms to account for the wide variety of ages. Prior to testing, the researchers practiced using these testing procedures on family members and friends to become adept and reliable. All testing was performed in a quiet, well-lit environment free of distractions. Adequate space was ensured for testing purposes and unrestricted movement. Documented, standardized protocols were followed for both assessments.

Procedure

Subjects were instructed to wear comfortable clothing and walking shoes. Subjects signed an informed consent statement and were then given a survey to identify subjects who met the specific inclusion criteria. (Appendix D) Answers to the brief survey were recorded and discussed. The data of only those subjects who met the inclusion criteria (n=50) were used to obtain the results of this study.

The subject was asked to remove their shoes and socks while sitting on a safe, comfortable chair. Examiner then allowed the subject to feel the pressure of the 3.61 monofilament on his/her hand in order to understand what he/she was feeling for. The procedure was explained to the subject, telling him/her to respond "Yes" if he/she felt the pressure on the foot. It was explained that following the testing of the left foot, the examiner would continue on to the right foot. The subject's lower extremities were then placed upon another chair and the subject was instructed to close his/ her eyes to obliterate visual input while the monofilament testing was performed. Seven specific sites on the plantar surface of each foot (Appendix B) were touched with the 3.61 monofilament. The tester applied enough force to cause the monofilament to bend, at which time the patient would respond "Yes" if he/ she felt the pressure. This procedure was performed three times at each of the seven sites of the foot. If the subject was unable to feel all of the 3.61 monofilament pressures, the procedure was repeated using the thicker, less sensitive 4.31 filament. One researcher recorded the results while the other performed the test. The same researchers performed the Berg Balance and Semmes-Weinstein tests to increase reliability.

Once the Semmes-Weinstein Monofilament Assesment was completed, the subject was instructed to replace his/her socks and shoes in preparation for the Berg Balance Measurement procedure. Standardized protocol was utilized when administering the Berg assessment. (See Appendix C) Throughout this test, one researcher stood within two feet of the subject to guard against falls, while the other researcher administered and scored the performance of each subject. This test measures sitting, standing, and dynamic balance in a variety of conditions, such as standing with eyes closed, turning in a complete circle, functional reach, transferring safely from one chair to another, and stepping onto a footstool. Following this test, subjects were informed of their balance score and any questions or concerns that they had were addressed.

Data Analysis

The independent variables in this study were age of subjects, group (experimental or control), smoking, exercise, 3.61 monofilament response, and 4.31 monofilament response. The dependent variable was the Berg Balance Measure score, indicating balance performance. Multiple regression was utilized to analyze data, with all the variables being entered simultaneously. This was chosen due to multiple variables and limited number of subjects. The Pearson Correlation was used to interpret the data of this study by measuring the degree and direction of linear relationship between two variables. A significance level of $p=.05$ (1-tailed test) was used.

CHAPTER IV

RESULTS

The group of subjects was quite homogenous, showing that 78 percent exercised on a regular basis, eight percent had fallen within the past year, 100% of the experimental group reported that they tested their glucose daily, and two out of the 50 subjects smoked. Ten percent of the subjects subjectively reported less than normal sensation. See Table 1.

Table 1. Descriptives of both groups.

Variable	*Control* (n=25)	*Experimental* (n=25)
Exercise	17	22
Fallen in past year	0	4
Test glucose	NA	25
Smoke	0	2
Foot sensation	Poor=0 Fair=1 Good=24	Poor=0 Fair=4 Good=21

Decreased performance on the higher level dynamic activities of the assessment was evident in both groups. The range of scores in the DM group was 46 to 56. The control group showed increased balance performance with a range of 53 to 56. In Table 2, total Berg Balance Assessment scores are reported for both the diabetic and control groups.

Table 2. Individualized Berg Balance Scores (0-56)

	46	47	48	49	50	51	52	53	54	55	56
DM Group (n=25)	**1**	**0**	**0**	**0**	**1**	**0**	**1**	**1**	**3**	**2**	**16**
Control (n=25)	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**23**

The mean score on the Berg Balance Assessment was 55.30/ 56. The mean score of total 4.31 monofilament responses (combination score of right and left feet) was 33.64/ 42, the 3.61 monofilament total mean was 23.58. See Table 3 for specific means and standard deviations for both groups.

Table 3. Descriptives of all subjects combined (n=50)

Variables	*Mean* Total	*SD* Total	*Mean* Diabetic	*SD* Diabetic	*Mean* Control	*SD* Control
Age (18- 87)	36.34	18.53	35.96	18.53	36.72	18.91
Total Berg Score (#1-#15) (0-56)	55.30	1.81	54.76	2.39	55.84	0.62
Advanced Berg Activities(#11-#15) (0-20)	15.40	1.48	14.96	1.93	15.84	0.62
Total response to 4.31 monofilament (0-42)	38.64	9.22	35.76	12.37	41.52	1.87
Total response to 3.61 monofilament (0-42)	23.58	13.31	19.92	14.54	27.24	11.05

A regression analysis to determine the effects of age, group, and 4.31 monofilament response on the Berg balance score demonstrated that group identity, control or diabetic, was not a contributor to the Berg balance score (t =-1.447, p =.155). Thus a second regression analysis was utilized, using the independent variables of age and 4.31 monofilament response.

The results of the second analysis are reported in Table 4 and Table 5. In summary, age is negatively correlated with the Berg balance score; as age increases, balance score decreases. The 4.31 monofilament scores were negatively correlated with the Berg balance scores, predicting that balance scores are better in subjects with increased sensitivity to the monofilament.

Table 4. Correlations (n=50)

		Total Berg Score	**Age**	**Experimental Group (DM)**	**4.31 Monofilament Total Response**
Pearson Correlation	**Total Berg**	1.000	-.613	-.301	.802
	Age	-.613	1.000	-.021	-.413
	4.31	.802	-.413	-.315	1.000
Significance (1-tailed)	**Total Berg**		.000	.017	.000
	Age	.000		NA	.001
	4.31	.000	.001	.013	

The adjusted R^2 (.728) for the model demonstrated that 73% of the variability on the Berg balance score could be predicted by the variables of age and monofilament response. The overall regression analysis was significant (F=66.65, p<.001). See Table 5.

Table 5. ANOVA

Model		**Sum of Squares**	**df**	**Mean Square**	**F**	**Significance**
1	**Regression**	118.662	2	59.331	66.650	.000
	Residual	41.838	47	.890		
	Total	160.500	49			

Further analysis of the regression model demonstrated that each of the independent variables, age and 4.31 monofilament response, contributed significantly to the prediction equation. Age was shown to be significant with a Beta coefficient of -.339, t value of –4.149, and a significance of .000. The significance levels associated with 4.31

monofilament response were Beta coefficient of .662, t value of 8.100, and a significance of p=. 000.

In summary, the monofilament score offers the largest contribution to the predication equation; a high score here can be used to help predict a high score on the Berg balance scale. Age also contributes to a lesser degree to the prediction equation with a negative beta coefficient; as age increases, the Berg balance score is predicted to decrease.

To conclude the results of this study, both age of subjects and responses to the 4.31 monofilament significantly contributed to balance performance, showing that an increase in age or decrease in sensation, as tested by monofilaments, correlates with decreased balance performance. According to a Beta Coefficient of -.114, the group (experimental versus control) did not determine balance performance, but rather sensation and age.

CHAPTER V

DISCUSSION/CONCLUSION

The results from this study showed that somatosensory input from the plantar surface of the foot provides a critical source of information for stability in balance control. Subjects who were found to have decreased plantar foot sensation demonstrated significantly poor balance performance on the Berg Balance Assessment, thus contributing to the belief that even though we have redundant sensory orientation input to provide a mechanism for sensory compensation, optimal postural stability requires that input be available from the somatosensory system.[19,21,22] This is especially important when we note a past study which found that adults preferentially rely on input from their somatosensory system,[8] and the fact that many older adults tend to have visual impairments, and therefore may be relying upon input from their vestibular and somatosensory systems for safe and independent mobility.

When balance scores from Type I DM subjects were compared with age-matched controls, we found that the group, DM versus control, didn't predict balance performance in this study, but contrariwise whether or not the subject exhibited some form of decreased plantar sensation. In other words, peripheral neuropathy is the direct cause of decreased balance performance seen so often in diabetic patients, not the direct pathology of diabetes. Indeed, past studies which were researched also came to the conclusion that impaired balance control seen in diabetic subjects with peripheral neuropathy is directly related to a reduction in somatosensory input from the foot and ankle.[6,32,35,36] One study determined that neuropathic subjects were less stable with vision than control subjects were with vision occluded.[32] This decreased stability is hypothesized to result from the inability of the subject to appropriately utilize the ankle strategy without proper somatosensory feedback from the feet.[24] The importance here lies in the fact that diabetic neuropathy affects 20-50% of all patients who have had diabetes for more than ten years, putting people who exhibit DM and neuropathy at a much higher risk for developing balance deficiencies due to their lack of sensation.[6]

As was consistent with previous literature, [1,42-45,47] a significant correlation was found between an increase in age and decreased balance performance on the Berg Assessment. This was probably due somewhat to both the deterioration of the somatosensory, vestibular, and visual systems and other subtle pathologies that accumulate as one grows older, including muscle weakness, decreased ROM, and decreased reflexes. One important past study found that the loss of redundant sensory inputs seemed to affect the older adults to a greater extent than younger subjects,[42] perhaps due to the decreased ability of the nervous system to integrate all the sensory inputs and quickly select the most accurate sense. As decreased balance appears to be a significant finding in the elderly, careful monitoring of patients who exhibit DM as they grow older is imperative due to the fact that neuropathic patients are already at an increased risk for balance deficiencies.

Determining whether a patient has safe balance must be based on assessing the individual's ability to control his center of mass relative to his base of support under a wide variety of experiences.[10] The Berg Balance Measure does this by including static, dynamic, and rotational activities within its assessment, allowing the examiner to observe the patient under more than one condition. We found that subjects with decreased sensation appeared to have the most difficulty maintaining balance control on the higher level balance activities of assessment, such as alternately placing each foot on a stool, standing with feet in tandem, and standing on one foot. Even subjects with quite significantly decreased foot sensation were able to safely complete the lower level activities such as chair transfers, and standing and sitting without support. Therefore, therapeutic intervention to decrease fall risk would be the most beneficial if a Berg Balance Test was performed in conjunction with a home evaluation to provide a picture of the type of balance tasks the patient must perform throughout the day. Although not proven, one wonders if patients who are forced to perform dynamic, high-level balance activities throughout the day exhibit better postural control than their age-matched controls who don't.

Not only is the role of the physical therapist to develop training programs for patients with a diagnosed balance deficiency, but preventative mechanisms should be developed as well to delay or inhibit the potential of falls relating to impaired balance. Environmental modifications for those who are at increased balance risk should be incorporated, including the removal of hazards. Falls tend to occur where the most time is spent, usually at home, so attention to home modifications is imperative. With more research, including this study, linking diabetic neuropathy and older age to impaired balance, [1,6,32,35,36,42-45,47] a screening test should be delivered to these patients to detect those who should be referred to a physician or other health care provider for an evaluation and intervention to hopefully decrease the likelihood of a debilitating fall.[56] Rehabilitation aimed at identifying balance deficiencies in specific functional components of the postural control system may help patients compensate for their impairment through postural retraining, as well as allow them to identify potentially hazardous situations given their particular deficit so that they may live normal, functional lives.

Findings in this study seem to have clinical significance; however, a number of limitations within this study must be considered. One limitation of this study is that a small sample size was utilized; therefore an unequal distribution between the ages and gender type of the subjects was evident, restricting certain statistical analysis procedures. A second limitation involves the selection of subjects. All of the subjects were volunteers from the local community, which tends to sway the study because volunteers are more apt to be compliant with DM precautions. Subjects were eliminated if they were not independent ambulators without an assistive device, so automatically patients with severe balance deficiencies were not utilized in this study. A third limitation involves the fact that more than one causal factor may have played into the decreased Berg Balance scores. Morphological body differences were not taken into account, nor was the subject's strength or ROM.

It is suggested that future studies analyze therapeutic strategies that would be designed to prevent falls in subjects with decreased sensation. Another area to be studied involves determining what effect insulin has on the body in terms of balance control mechanisms.

In summary, somatosensation does contribute significantly to decreased balance control, as was evident on the Berg Balance Assessment test. This is an important finding as peripheral neuropathy is a highly prevalent finding in patients who have Type I DM. Subjects who displayed peripheral neuropathy demonstrated a lower balance performance than did their age-matched control subjects without decreased sensation. Physical Therapists should keep this in mind when working with DM patients, as prophylactic screening procedures can be used to determine when a patient is at risk for falling, as well as develop balance training programs to help overcome and prevent balance deficiencies. The Berg Balance Measure is a simple, inexpensive assessment that may be used to screen for balance deficiencies, requiring only household items to complete the test. Not only is it valid and reliable, but it asks the patient to perform functional activities that they are required to do throughout the day.[54] This test should be implemented as part of every physical therapist's balance intervention program, in conjunction with Semmes-Weinstein monofilament testing, bearing valuable merit as a measure utilized to document the progression of somatosensory loss in neuropathic patients. Monofilament testing requires only a short amount of time, and has also been proven reliable and valid.[52] Hopefully this study increases clinician awareness regarding sensory loss, its role in balance performance, and the valuableness of the Berg Balance Measure and Semmes-Weinstein monofilaments in screening for deficits before they become manifest as falls.

APPENDIX A

Information and Consent Form

INFORMATION AND CONSENT FORM

Sonya Knutson and Laura Eckel, graduate physical therapy students, are performing this study because further research is needed to determine the effect of Type I Diabetes Mellitus on balance and safety in daily living. This research will then be available to improve management of the disease. We invite you to participate in this balance assessment study. We will inform you of any balance deficiencies in comparison to normal scores of persons your age. You have met all specific inclusion criteria for this study. The procedures to be followed include a foot sensation screening to check for peripheral neuropathy resulting in decreased feeling and the Berg Balance Assessment to determine balance abilities. Any discomfort or risk to you is currently unforeseeable in this single session 30-minute assessment. The Berg Balance Measure is a simple and safe test for balance. These motions are ones that are performed routinely in daily activities. You will be asked to perform functional tasks while sitting or standing. Sugar candy will be available if you experience signs or symptoms of hypoglycemia. You will benefit from an increased awareness of balance deficiencies and risks associated with decreased sensation in the lower extremity. All of your assessment scores will remain confidential, as names will be replaced with numbers. If at any time during this study you choose to withdraw from the study, you are free to do so without it being held against you. We are available to answer any questions you have concerning this study. In addition, you are encouraged to ask any questions regarding this study that you may have in the future. Sonya Knutson and Laura Eckel may be reached at (701) 795-3487. Our advisor, Beverly Johnson, may also be contacted at (701) 777-3871. Copies of this consent form are available upon request. In the event that physical injury should occur, medical assistance will be available, as it is to a member of the general public in similar circumstances. Payment for any such treatment must be provided by you and your third party payor, if any (such as health insurance, Medicare, etc.).

"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. I have read all of the above and willingly agree to participate in this study explained to me by the research investigators."

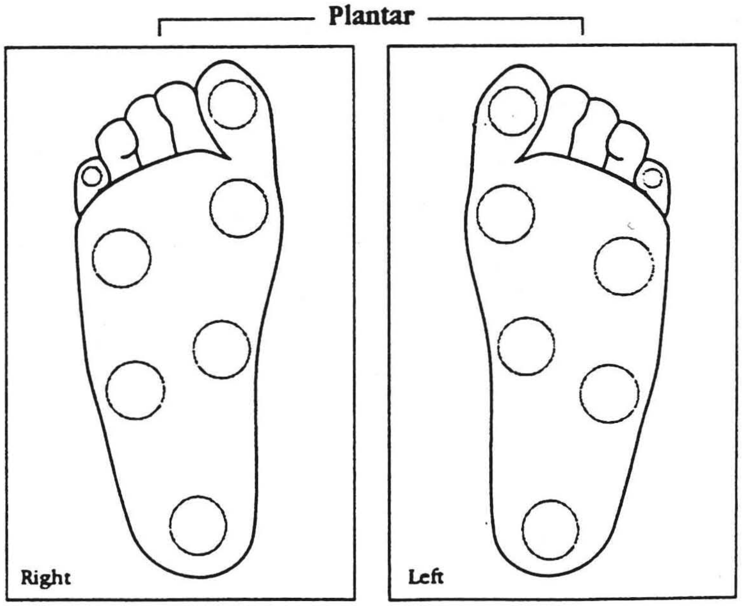
Participant's Signature	**Date**
Witness' Signature	**Date**

APPENDIX B

Semmes-Weinstein Monofilaments

Patient Foot Screening Form

Monofilament Size	Representation	Plantar Surface Threshold
2.83	Green	Normal (dorsal surface)
3.61	Blue	Normal
4.31	Purple	Diminished Light Touch
4.56	Red	Diminished Protective Sensation
5.07	Red	Loss of Protective Sensation
6.65	Red	Deep Pressure Sensation Only



APPENDIX C

Berg Balance Assessment

1. SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hands for support.
( ) 4 able to stand without using hands and stabilize independently
( ) 3 able to stand independently using hands
( ) 2 able to stand using hands after several tries
( ) 1 needs minimal aid to stand or to stabilize
( ) 0 needs moderate or maximal assist to stand

2. STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding.
( ) 4 able to stand safely 2 minutes
( ) 3 able to stand 2 minutes with supervision
( ) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported
( ) 0 unable to stand 30 seconds unassisted

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

3. SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes.
( ) 4 able to sit safely and securely 2 minutes
( ) 3 able to sit 2 minutes under supervision
( ) 2 able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

4. STANDING TO SITTING
INSTRUCTIONS: Please sit down.
( ) 4 sits safely with minimal use of hands
( ) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent
( ) 1 sits independently but has uncontrolled descent
( ) 0 needs assistance to sit

5. TRANSFERS
INSTRUCTIONS: Arrange chairs(s) for a pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands
( ) 3 able to transfer safely definite need of hands
( ) 2 able to transfer with verbal cuing and/or supervision
( ) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

6. STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.
( ) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision
( ) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays safely
( ) 0 needs help to keep from falling

7. STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand for 1 minute with supervision
( ) 2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together
( ) 0 needs help to attain position and unable to hold for 15 seconds

8. REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the finger reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)
( ) 4 can reach forward confidently 25 cm (10 inches)
( ) 3 can reach forward 12 cm safely (5 inches)
( ) 2 can reach forward 5 cm safely (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

9. PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION
INSTRUCTIONS: Pick up the shoe/slipper which is placed in front of your feet.
( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm (1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

10. TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
INSTRUCTIONS: Turn to look directly behind you over toward left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.
( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

11. TURN 360 DEGREES
INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.
( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing
( ) 0 needs assistance while turning

12. PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED
INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times.
( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps > 20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete > 2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

13. STANDING UNSUPPORTED ONE FOOT IN FRONT
INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width
( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead of other independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

14. STANDING ON ONE LEG
INSTRUCTIONS: Stand on one leg as long as you can without holding.
( ) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold = or > 3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but r remains standing independently
( ) 0 unable to try or needs assist to prevent fall

( ) TOTAL SCORE (Maximum = 56)

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APPENDIX D

Subject Survey

Subject Survey

What is your date of birth? ________________

Have you had any fractures in your leg or foot in the past year? YES or NO

Do you have any balance disorders (i.e. Meniere's disease) or other factors causing dizziness or instability? YES or NO

Do you have visual problems that affect your daily activities? YES or NO

How long have you taken insulin? ____________________

Do you use any assistive device (i.e. canes, crutches, walker) for activities of daily living? YES or NO

How would you describe your foot sensation? GOOD FAIR POOR

Have you suffered from any ulcers or sores on your foot? YES or NO

If so, do you currently have an ulcer on your foot or ankle? YES or NO

Have you fallen in the past week? YES or NO Month? YES or NO Year? YES or NO If so, what contributed to your fall(s)?

____

Do you presently smoke on a daily basis? YES or NO

Do you exercise regularly (at least 3 times per week)? YES or NO

Do you test your blood glucose level daily? YES or NO

Are there any other medical conditions that have not been addressed in this survey that affect your ability to walk? YES or NO

If so, please explain.____________________________________

APPENDIX E

Human Subjects Form

_X_ Expedited Review Requested Under Item _3_ (Number[s] of HHS Regulations)

___ Exempt Review Requested Under Item ___ (Number[s] of HHS Regulations)

UNIVERSITY OF NORTH DAKOTA HUMAN SUBJECTS REVIEW FORM FOR NEW PROJECTS OR PROCEDURAL REVISIONS TO APPROVED PROJECTS INVOLVING HUMAN SUBJECTS

Principal Investigators: Laura Eckel/ Sonya Knutson	Telephone: (701)795-3487	Date: 04/ 29/98
Address to which notice of Approval should be sent: 2169 C South 29th Street, Grand Forks, ND 58201		
School/College: University of North Dakota Department: Physical Therapy	Proposed Project Dates: (Month/Day/Year) 06/01/98- 10/01/98	
Project Title: Influence of Type I Diabetes Mellitus on Standing Balance in Independent, Community-Dwelling Subjects		
Funding Agencies (if applicable):		

TYPE OF PROJECT: NEW PROJECT:______ CONTINUATION:________

RENEWAL:_______ DISSERTATION OR THESIS RESEARCH _X_ STUDENT RESEARCH

PROJECT:_______ CHANGE IN PROCEDURE FOR A PREVIOUSLY APPROVED

PROJECT:_______

Dissertation/Thesis Adviser: Beverly Johnson

PROPOSED PROJECT INVOLVES NEW DRUGS (IND)______ INVOLVES NON-APPROVED

USE OF DRUG:_______ INVOLVES A COOPERATING INSTITUTION______

IF ANY OF YOUR SUBJECTS FALL IN ANY OF THE FOLLOWING CLASSIFICATIONS,

PLEASE INDICATE THE CLASSIFICATION(S): MINORS (<18 YEARS):_______

PREGNANT WOMEN:_______ MENTALLY DISABLED:_______ FETUSES:_______

MENTALLY RETARDED:_______ PRISONERS:_______ ABORTUSES:_______UND

STUDENTS (>18 YEARS):_______

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

If your project has been/will be submitted to another institutional review board(s), please list name of board(s):

STATUS:____ SUBMITTED; DATE _______ APPROVED; DATE _______ PENDING

1. ABSTRACT:

(Limit to 200 words or less and include justification or necessity for using human subjects.)

The purpose of this proposed study is to determine the effect of the diabetes disease process on balance performance. Balance is affected by a combination of sensory elements responsible for the detection of body motion, including visual, motor, proprioception, and vestibular input. Balance combines stability and mobility to maintain upright stance, with the ultimate goal of safety and function. Diabetes mellitus (DM) affects vascular, neurological, and mechanical aspects, which play a large role in balance. A significant decrease in sensory input is one complication of Type I

DM, which will be the primary focus of this study. Other diabetic changes will be assessed also, to determine their impact on balance. Forty volunteer subjects with insulin-dependent DM will be recruited from the community, support groups, and clinics. Each subject will be an independent individual who meets specific inclusion criteria. Sensory loss will be tested with Semmes-Weinstein Monofilaments. Finally, the Berg Balance Measure will be administered to assess balance. Presently, there is a lack of research relating to balance risks associated with DM. Knowledge of balance risks will encourage prophylactic measures for the DM population.

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 (if seeking outside funding).

2. PROTOCOL:

(Describe procedures to which humans will be subjected. Use additional pages if necessary.)

SUBJECTS: The study will consist of 40 volunteer subjects with Type I Diabetes Mellitus (DM) with or without peripheral neuropathy currently residing independently in the community and surrounding area. Subjects will be recruited via flyers, the diabetic newsletter, and word of mouth. The specific inclusion criteria is: age 18 or older, ability to comprehend and follow requests, sufficient strength for functional gait, no assistive device currently required for daily activities, no vestibular disorders, no other neurological disorders, no severe orthopedic or arthritic problems, no amputations, intact skin throughout lower limb, and no visual problems interfering with daily living.

A voluntary age-matched control group will be recruited and assessed in the same manner as the DM group to establish age-matched norms. The inclusion criteria will be volunteers without DM who meet the rest of the experimental group's inclusion criteria.

Subjects will be informed of the purposes, procedures, and potential risks and benefits of the study. They will then be asked to sign an informed consent statement.

INSTRUMENTATION: The Semmes-Weinstein Monofilaments will be used to test relative thresholds of pressure/ touch sensation on the plantar surface of the foot. This test will identify those with peripheral neuropathy, which will be defined by a critical level. It only requires five minutes to perform. This tool meets sensibility and repeatability requirements for an objective sensory test instrument.

The Berg Balance Measure is an efficient and easily administered balance assessment, requiring only fifteen to twenty minutes to complete. This is scored on the patient's ability to perform specific tasks. The Berg Measure has good inter-rater and intra-rater reliability. Content validity of this measure was established through the manner in which it was constructed.

PROCEDURE: Standard published testing protocols will be followed for all tests. The volunteers will be instructed to wear comfortable clothing and walking shoes. All subjects will be given a survey to identify subjects who meet the inclusion criteria. Each individual will then be asked to sign the informed consent statement. Each participant will lie comfortably on a plinth. A tablet will be held in the patient's line of vision to obliterate his/her vision while the monofilament testing is performed. The response will be charted during the test. Following this, the Berg Balance Measurement procedure will be administered. Each task will be demonstrated and/or instructions given as written. This will test task performance. (See addendum.) The results will be recorded on the Berg Balance Scale Form by an observer during the subject's performance.

Upon request, results of the study will be provided to participants. If subjects show balance deficiency, they will be offered a brochure regarding the prevention of falls.

DATA ANALYSIS: Reliability, means, standard deviations, and ranges will be calculated and recorded, comparing samples within the group utilizing an independent-measures t- test. This analysis will show the correlation between DM and balance performance.

LIMITATIONS OF STUDY: Aging may contribute to balance deficiencies. This limitation is not accounted for, as aging is a complex process involving many aspects of life. To decrease this limitation, we established criteria to eliminate subjects with visual insufficiency, muscle strength inadequate for independent ambulation, and the inability to understand or comprehend commands. As subjects selected will be volunteers only, there is a risk that more compliant, rather than non-compliant, persons will offer to participate in our study. Potentially, the increased compliance could mean less severe progression of DM due to the individual's management of their disease.

Human error during testing will also present a limitation to this study. To lessen this, one tester will consistently perform the testing, while the other person will always score & record the results.

3. BENEFITS:

(Describe the benefits to the individual or society.)

Effective treatment of balance problems requires the understanding of underlying sensory components. This study is intended to determine the relationship between DM and balance. Once this relationship has been identified, specific treatment protocols can be formulated to increase the patient's functional capabilities. In this, physicians, physical therapists, and other health care professionals will benefit. The participants in this study will benefit by becoming more aware of how DM relates to their foot sensation and balance proficiency or deficiency. Prophylactic treatment programs may be encouraged if it is shown that DM does affect balance performance, thereby decreasing the risk of falling during daily activities.

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.)

There are only minimal risks to the individuals participating in this study. The Berg Balance Measure is a simple and safe test for balance. These motions are ones that are performed routinely in daily activities. Subjects will be asked to perform functional tasks while sitting or standing while a tester stands closely by to assist in the event that the subject should lose his or her balance. The risk of hypoglycemia with insulin-dependent diabetes exists, so we will provide sugar candy to alleviate signs and symptoms if they present. The voluntary subjects will be chosen based on health status and willingness to participate.

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 subjects will not occur.

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

The consent form to be used in this study is attached. This will establish the participant's understanding of the study procedures, risks, and benefits. All personal assessment scores will remain confidential, as names will be replaced with numbers, and scores will be kept for five years in a file cabinet in a locked office. All procedures to be used have been determined to be safe and without risk to the patient. We have included numbers to address any questions or concerns that the participants may have following the study.

For FULL IRB REVIEW forward a signed original and thirteen (13) copies of this completed form, and where applicable, thirteen (13) copies of the proposed consent form, questionnaires, etc. and any supporting documentation to:

Office of Research and Program Development

University of North Dakota

Grand Forks, North Dakota 58202-7134

On campus, mail to: Office of Research & Program Development, Box 7134, or drop it off at Room 105, Twamley Hall.

For EXEMPT or EXPEDITED REVIEW forward a signed original and a copy of the consent form, questionnaire, etc. and any supporting documentation to one of the addresses above.

The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of Human Subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedures governing the use of human subjects.

SIGNATURES:

Principal Investigator:	**Date:**
Project Director or Student Adviser:	**Date:**
Training or Center Grant Director:	**Date:**

(Revised 3/1996)

REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW
University of North Dakota Institutional Review Board

DATE: May 28, 1998 **PROJECT NUMBER:** IRB-9806-315

NAME: Laura Eckel; Sonya Knutson **DEPARTMENT/COLLEGE:** Physical Therapy

PROJECT TITLE: Influence of Type I Diabetes Mellitus on Standing Balance in Independent, Community-Dwelling Subjects

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on June 1, 1998 and the following action was taken:

☒ Project approved. **EXPEDITED REVIEW NO.** 3. Next scheduled review is on June 1999.

☐ Project approved. **EXEMPT CATEGORY NO.** ________. No periodic review scheduled unless so stated in the Remarks Section.

☐ Project approved **PENDING** receipt of corrections/additions. These corrections/additions should be submitted to ORPD for review and approval. **This study may NOT be started UNTIL final IRB approval has been received**. (See Remarks Section for further information.)

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

☐ Project **denied.** (See Remarks Section for further information.)

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

PLEASE NOTE: **Requested revisions for student proposals MUST include adviser's signature.**

cc: B. Johnson, Adviser

Lynn Anderson 6/1/98
Signature of Designated IRB Member Date
UND's Institutional Review Board

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

(1/98)

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