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Effect of Tactile Feedback on Reducing Body Sway in Elderly

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in conjunction with the
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Effect of Tactile Feedback on Reducing Body Sway in Elderly

by

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A Dissertation submitted in partial satisfaction of
the requirements for the degree
Doctor of Philosophy in Rehabilitation Sciences

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Each person whose signature appears below certifies that this dissertation in his/her opinion is adequate, in scope and quality, as a dissertation for the degree Doctor of Philosophy.

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ABBREVIATIONS

COG	Center of Gravity
COP	Center of Pressure
BMI	Body Mass Index
SD	Standard Deviation
T2DM	Type 2 Diabetes Mellitus
ANOVA	Analysis of Variance
Sway	Body Sway

ABSTRACT OF THE DISSERTATION

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by

Faris Shuleih Alshammari

Doctor of Philosophy, Graduate Program in Rehabilitation Science
Loma Linda University, June 2015
Dr. Jerrold Petrofsky, Chairperson

Context: Body sway increases in the elderly due to normal aging and a high incidence of disease such as diabetes. Increased body sway is associated with an elevated risk of falling. Falling is one of the major causes of morbidity and mortality in the elderly.

Objectives: The purpose of this study was to examine the effect of 6 minutes training of tactile feedback (novel intervention) compared to visual feedback on body sway in the elderly with or without diabetes to develop a new technique for balance training.

Design: A single blinded randomized controlled trial.

Setting: Loma Linda University, Loma Linda, CA

Participants: 51 subjects: 28 normal healthy older adults and 23 older adults with Type 2 diabetes.

Intervention: Subjects were assigned to tactile feedback or visual feedback randomly.

Outcome Measures: Body sway was measured using a balance platform. The magnitudes of X and Y coordinates of the subject's center of gravity were used to calculate body sway.

Results: No significant difference between 2 groups using visual feedback or using tactile feedback were found. Results showed a significant reduction in body sway using tactile feedback in elderly while standing on foam with eyes open (1.0± .31 vs. 1.9± .8, p=.006) and eyes closed (1.8± .7 vs. 3.3± 1.5, p=.001). In the group with diabetes, there was a significant reduction in body sway using tactile feedback while standing on foam with eyes closed (1.4± .5 vs. 2.3± .8, p=.045) but not with eyes open. There was a significant reduction in body sway in elderly group with diabetes using visual feedback while standing on foam with feet apart and eyes open (1.3 ± .5 vs. 2.1 ± 1.1; p=.018) and eyes closed (2.0 ± .8 vs 3.1 ± 2.1; p=.003). In elderly group without diabetes, there was a significant reduction in body sway using visual feedback while standing on foam with feet apart and eyes open (1.4 ± .7 vs1.8 ± .9; p=.023), and eyes closed (1.9 ± .9 vs. 3.4 ± 1.8; p=.002).

Conclusion: We found that the tactile feedback, a novel technique, improves body balance in elderly with or without diabetes.

CHAPTER ONE

INTRODUCTION

Balance is the ability of the body to maintain posture during static and dynamic stressors to prevent falls.[1] The balance process involves 3 main components; first is the input; second is the central processing; and third is the output. Input is provided to the central nervous system (CNS) through the somatosensory system, vision, and the vestibular system. Central processing takes place in the brain by integrating the sensory information together to make a plan of action. Output is projected through the musculoskeletal system and its function is to execute the plan of action which is provided by the CNS.[1]

Balance deficits are noted due to loss of coordination between these 3 components, delay in sensory or motor signal transmission, or delay in central processing. Balance deficits are manifested as an increase in body sway, inability to maintain body posture, and increased risk of falls.[1,2]

Aging involves multiple degenerative changes that affect the CNS, peripheral nervous system (PNS), and musculoskeletal system.[3] This results in balance deficits due to poor sensory input, delay in the central processing, or inability to implement the plan of action correctly due to muscles weakness, changes in muscles tone, or joints pain and stiffness.[3-5] These changes result in balance deficits including increased body sway in the elderly.[2-5]

The sensory input from visual, vestibular, and somatosensory systems is affected by aging. [3,6] The sensitivity to low-frequency spatial motion in vision decreases with aging.[6] The sensitivity and the number of hair cells and nerves in the vestibular system decreases with aging.[7] Also, Otocnia degeneration, rupture in the Saccule, and microfracture of Otic capsule has been noted in elderly.[7] In addition, the incidence of peripheral neuropathy increases with aging. For example, one study showed a 20% prevalence of neuropathy in the elderly.[8] Deterioration in vision, the vestibular system, and the somatosensory systems with aging affects the sensory input in the balance system resulting in poor body balance. This is shown by increasing the sway and the risk of falling in the elderly.[2,4,5,9]

Wolfson and colleagues studied the difference in body sway in normal older adults compared to young people.[10] They used the EquiTest dynamic posturography platform (Neurocome International, Clackmas, OR). They reported that the body sway was significantly higher in old adults compared to young subjects in 5 out of 6 test conditions. This shows how the aging process affects balance.

The elderly population is increasing dramatically in the United States (US). According to the Department of Health and Human Services (DHHS), the number of people who were 65 years old or older was 39.6 million in the year 2009. However, the expected number of people who are 65 years old or older in 2030 is going to be almost twice the number in the year 2009. Also, DHHS reports that the number of elderly in the year 2010 compared to the year 2000 was increased by 24.6%.[11]

Diabetes that is not controlled affects the visual, vestibular, and nervous systems significantly resulting in poor balance.[12] The prevalence of peripheral neuropathy in people with diabetes is 60-70%.[12] Neuropathy affects the sensory and motor nerves resulting in poor sensation and muscles weakness.[13]

A study showed an association between peripheral neuropathy and vestibular system disorders.[14] Another study showed a direct relationship between the severity of diabetes and vestibular disorders.[15] Vestibular disorders increases the risk of fall more than 2 folds in people with diabetes. [15]

Diabetes affects vision by causing diabetic retinopathy and/or cataracts.[12] Diabetic retinopathy is a leading cause of blindness in older adults with diabetes. [12] Cataracts affect the clarity of vision. Vision is the strongest contributor to body balance because it predominates the vestibular and somatosensory system.[16] Therefore, visual deficits affect the body balance significantly.[9,17]

The prevalence of diabetes has increased rapidly over the last 20 years and it is still on the rise. According to the World Health Organization, the number of people affected with diabetes in the year 2030 is going to be twice their number in the year 2000. This assumption is based on the fact that there were 171 million people affected with diabetes in the year 2000. However, the projected increase in the incidence of diabetes by the year 2030 will be 366 million people.[18] According to the U.S. Department of Health and Human Services, in 2010, the prevalence of diabetes in people 65 years or older was 26.9%, affecting 10.9 million people. This means more than a quarter of the elderly people suffer from diabetes.[19]

Elderly people are more prone to have diabetes because the incidence of diseases increases with aging.[3] This means that, the balance in elderly with diabetes is affected because of the aging process itself and due to diabetes resulting in more sway and a higher incidence of falling.

Studies showed a direct relationship between body sway and falling among the elderly.[2,20] Therefore, increasing body sway with age is a sign of balance system deficits and indicates a higher risk of falling.

Falling is one of the leading causes of morbidity and mortality in the elderly because it results in fatal and nonfatal injuries. [21,22] According to the Center for Disease Control and Prevention (CDC), one third of older adults who are 65 years or older fall every year. Another study has shown a higher percentage of fall incidence.[21] Fernie and colleagues reported that 42% of 205 older subjects had at least one fall within a year.[20]

Stevens and colleagues reported 10,300 fatal falls and 2.6 million nonfatal falls in the year 2000.[22] The medical costs due to fatal falls was 0.2 billion dollars, and the medical costs associated with nonfatal falls was 19 billion dollars.[22] According to the Center for Disease Control and Prevention (CDC), 2.3 million people had fall related nonfatal injuries among older adults were reported in the year of 2010. In the same year, 662,000 of the people who had fallen were hospitalized with medical costs of 30 billion dollars. [21]

Song and colleagues studied the effect of 1 hour of balance training for two times per week for 8 weeks on proprioception and balance in the elderly with peripheral neuropathy.[23] They reported significant reductions in body sway. However, aging affects the fitness which affects the compliance of elderly to participate in such long training session.[23]

The effect of visual feedback on dynamic body balance was assessed by Hamman and colleagues.[24] They examined the ability and speed of moving a point that represents the Center of Gravity (COG) from one target to another and the sway upon reaching the second target. The distance between those targets was 75% of subjects' limits of stability. Results showed a reduction in time that required moving the COG between targets and sway upon reaching the second target.[24]

Cawsy and colleagues examined the effect of the Center of Pressure (COP) magnification on body sway.[25] They used seven different magnifications (1 x, 4 x, 8 x, 16 x, 32 x, 48 x and 64 x). They studied body sway under 2 conditions: the first condition was using an incompliant surface; the second condition was using a compliant surface (foam). Body sway decreased with COP magnification on an incompliant surface. However, the sway reached a plateau at 8X. At the same time, body sway decreased on foam with COP magnification and did not reach plateau.[25]

Menz and colleagues examined the effects of applying passive tactile cues on body sway in young people, elderly people without neuropathy, and elderly people with diabetic neuropathy.[26] They used Velcro to provide tactile stimulation. They applied Velcro on three different places (ankle, calf, or knee) in three different trials. They attached the Velcro into mounted flexible bands to apply tactile sensory input as the subject swayed. They found that the body sway decreased significantly in all groups. At the same time, they found an indirect relationship between body sway and the distance between the Velcro and ankle.[26]

Other studies showed positive effects of tactile sensory input through light finger touch on body sway in the elderly with or without proprioceptive impairments. Light finger touch decreased the fluctuation of COP in tandem stance and bipedal stance in elderly.[27-29] These findings justify the benefit of using a cane in the elderly to help body balance by providing tactile feedback through the hand and providing mechanical support as well.

Sihvonen, Sipila, and Era conducted a randomized clinical trial to examine the effect of 4 weeks of visual feedback training on postural control in elderly women of two residential care facilities.[30] Training was provided for 20-30 minutes. They found significant improvement in balance. Also, they reported that the subjects were motivated to participate in the visual feedback training with high compliance at 97.5%.

In summary, the current regimen in balance training requires 45 minutes to one hour of training which could be challenging for the elderly. Proposed intervention in this study requires 6 minutes of training which could be more comfortable. A study showed that the compliance with visual feedback among the elderly was 97.5% which is considered high.[30] Also, in the same study, the elderly were more motivated to participate in such training.

To our best knowledge, there were no studies done on tactile intervention using the system used in this study or studying the carryover of tactile intervention. This makes the tactile intervention used in this study a novel intervention. Therefore, the purpose of this study was to examine the effect of 6 minutes training of tactile feedback compared to visual feedback on body sway in the elderly without diabetes compared to age matched elderly with diabetes.

CHAPTER TWO

TACTILE INTERVENTION AS A NOVEL TECHNIQUE IN IMPROVING BODY STABILITY IN HEALTHY ELDERLY AND ELDERLY WITH DIABETES

Running Title: Tactile Feedback and Diabetes

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Key words: Diabetes, Balance, Tactile, Feedback, Sway, Elderly

Abstract

Background: Body sway increases in the elderly due to normal aging and high incidence of disease such as diabetes. Prevalence of sway is greater in the elderly with diabetes due to damage to the central and peripheral nervous systems. Increase in body sway is associated with an elevated risk of falling. Falling is one of the major causes of morbidity and mortality in the elderly. The purpose of this study was to develop a new technique to improve body stability and decrease body sway in the elderly people with or without diabetes.

Methods: Twenty two subjects, twelve elderly (mean age 75.5± 7.3 years) and ten age matched elderly with diabetes (mean age 72.5± 5.3 years), were recruited for this study. Subjects received tactile feedback as a tingling sensation resulting from electrical stimulation triggered by body sway.

Results: The results showed a significant reduction in body sway in the elderly while standing on foam with eyes open (1.0± .31 vs. 1.9± .8, $p=.006$) and eyes closed (1.8± .7 vs. 3.3± 1.5, $p=.001$). In the group with diabetes, there was a significant reduction in body sway while standing on foam with eyes closed (1.4± .5 vs. 2.3± .8, $p=.045$) but not with eyes open.

Conclusion: In this small study, this technique offers a new tool for training people with diabetes and elderly people to improve body stability and balance.

Introduction

Balance is the steadiness of the human body and the ability to maintain posture during static or dynamic stressors.[1] It is a complex mechanism involving integration and coordination among sensory, motor, and biomechanical activities to prevent falls and improve static and dynamic performance. Loss in coordination among those activities causes faulty body movements which are presented as sway, loss of balance, or a possible fall.[1, 2]

The elderly population is growing quickly in the United States. According to the Department of Health and Human Services (DHHS), the increase in the elderly population in the United States (US) in the year 2010 compared to 2000 was about 24.6% and the elderly population is expected to double in 2030 in comparison to the year 2000 due to the addition of the "Baby Boomers". According to the U.S. Department of Health and Human Services, the prevalence of diabetes in people 65 years old or older was 26.9% in 2010 affecting 10.9 million person.[3] According to World Health Organization, there were 171 million individuals affected with diabetes in 2000. However, the projected increase in individuals affected with diabetes by 2030 will be 366 million people.[4]

Aging involves many physiological changes affecting postural control, body stability, coordination, gait, and body balance.[2, 5] This is evidenced by the increase in fall incidence among the elderly.[5-7] Vestibular, visual, somatosensory dysfunction and sensorimotor delay occur in the elderly due to the normal aging process, and due to the high incidence of diseases which affect stability of the human body.

Vestibular activity is reduced in the elderly due to an age related reduction in the sensitivity and number of hair cells and nerves fibers in the vestibular system. This affects postural control significantly and possibly results in dizziness.[8, 9] Decrease in the sensitivity to low frequency spatial motion in vision due to age affects balance as well. Neuropathy decreases the sensitivity of cutaneous, vibration, and/or proprioception senses causing balance defects due to reduced somatosensory input.[10] The incidence of peripheral neuropathy is around 20% in the elderly.[11] Wolfson and colleagues tested the sway in normal older adults versus young subjects using the Equitest Dynamic Posturography Platform (Neuro-Com International).[12] They reported that the sway was greater in the elderly than in the young in 5 out of 6 sensory test conditions.[12] This finding indicates that there are deficits in balance and postural control due to aging which cause the elderly to have greater sway and a higher risk of fall than in young individuals.

Diabetes that is not controlled can affect postural control and balance through causing defects in the Central Nervous System (CNS), Peripheral Nervous System (PNS), vision, vestibular system, and/or musculoskeletal system. Diabetes affects vision by causing diabetic retinopathies which is the leading cause of blindness in old adults.[10] Also, diabetes can cause cataract or glaucoma which affects visual clarity and acuity, and the visual field.[10] Visual impairment impacts body balance because the vision is a strong contributor to body balance and predominates the somatosensory and vestibular input.[13] Sixty to 70% of patients with diabetes suffer from peripheral neuropathies. Peripheral neuropathy affects sensory and/or motor function. This may lead to a loss of tactile, vibration, or proprioception sensation, muscle weakness or atrophy, or diminished vasomotor control.[10] Loss of sensation and/or muscle weakness in peripheral neuropathy affects human balance and postural control and results in a higher risk of falls.[2, 14]

Falling is one of the major causes of morbidity and mortality in the older adult population.[15] According for the Center of Disease Control and Prevention (CDC), one out three elderly people had at least one fall.[16] Fernie et al. reported that 42% of 205 old subjects in his study had at least one fall within a year.[17] Also, according to CDC, there were 2.3 million falls among the elderly in 2010, and 662,000 were treated in emergency room or hospitalized.[16] The medical cost to treat fall related injuries among the elderly in 2010 was around 30 billion dollars.[16]

On the average, thirty percent of falls in the elderly lead to serious physical injuries which increase the mortality rate.[15] There were 10,300 fatal falls and 2.6 million nonfatal falls treated medically in 2001. The medical cost to deal with fatal falls was 200 million dollars and 19 billion dollars to treat fall related injuries.[18] Traumatic Brain Injury (TBI) is a serious injury that leads to death in 47% of elderly people with fatal fall.[15, 16, 19] The mortality rate is high among the elderly due to falls (21,700 older adult died due to fall injuries in 2010).[16]

Based on previous literature, older people with or without diabetes are at high risk of balance disorders which are indicated by increased body sway, reduced postural control, or increased incidence of falls. Falls can lead to fatal or nonfatal injuries. Medical costs to deal with injuries resulting from falls is very high and places a burden on the country’s economy. Therefore, we should find ways to improve body balance and postural stability to reduce body sway to decrease the incidence of falls among old adults and people with diabetes.

Menz and colleagues tested the instant effect of passive tactile stimulation on body sway in young, elderly people without peripheral neuropathy, and elderly with diabetic peripheral neuropathy. They applied Velcro either on the ankle, calf, or knee. They found significant reduction in sway in all groups. At the same time, the sway reduction was correlated directly with the distance between the Velcro and ankle. This means that, if you apply the Velcro closer to the knee, body sway will be reduced more.[20] Other studies showed that the application of additional tactile input using a light touch of the fingertip reduces the fluctuation of the Center of Pressure (COP) in bipedal stance or tandem Romberg stance in subjects with intact or impaired somatosensory input.[21-23]

The current regimen in balance training requires about 1 hour of training for 2-3 times per week for 6-8 weeks as indicated by Song et al.[24] This kind of training can be exhausting for older adults due to fitness limitations or general health issues which may be a boundary for old adults to participate in such training. The purpose of this study was to examine the effect of tactile feedback on body sway in the elderly compared to age matched subjects with diabetes. To our knowledge, tactile feedback is a novel intervention because there has not been any studies done in this regard in the literature using the same approach or feedback system that is tested here.

Methods

Twenty two subjects participated in this study. They were recruited using flyers and phone calls from physical therapy centers, senior homes, sport centers, or Loma Linda University. The subjects, 65-90 years of age, were divided into 2 groups, an elderly group and a group with diabetes. There were 10 subjects in the group with diabetes and 12 subjects in the elderly group. Subjects were excluded if they had cognitive disorders, neurological disorders, alcohol/substance abuse, took medications that affect body balance, vestibular pathology, unable to stand for 10 minutes continuously, or enrolled in balance training interfering with the provided intervention within the last month. All subjects were screened with a 10 g monofilament test for neuropathy and only one subject failed the test. All protocols and procedures were approved by the Institutional Review Board of Loma Linda University and all subjects signed a statement of informed consent. The demographics of the subjects are shown in table 1. There were no significant differences in age, height, or weight between the two groups.

Table1- Mean± SD of demographic characteristics by study group (N=22)

	Elderly (n=12)	Elderly with diabetes (n=10)	P-Value
Age (years)	74.3± 7.3	72.5± 5.3	.518
Height (cm)	163.0± 6.6	169.3±9.2	.075
Weight (kg)	75.6± 14.2	74.9±29.2	.942

Technique for Measuring Body Sway

The displacement of the subjects' center of gravity (COG) was measured using a balance platform of $1m^2$ in size and 10 cm in height. Four stainless steel bars with 16 strain gauges were mounted at the four corners under the platform's surface (TML Strain Gauge FLA-6, 350-17, Tokyo, Japan). The output of the 4 Wheatstone strain gauge bridges was amplified with a BioPac 100 C low-level bio potential amplifiers and recorded on a BioPac Mp-150 system through a 24-bit A/D converter. The sampling rate was 2000 samples per second.[25]

Sway was presented as a line on a screen detecting the magnitude and angular displacement of the body. The magnitudes of X and Y coordinates of the subject's center of gravity were used to calculate the displacement of the center of mass of exerted body load on the platform. Mean (M) and Standard Deviation (SD) were obtained by finding the average of the sway magnitude of Y and X over an interval of 6 seconds.

Design of Tactile Feedback Intervention

The magnitude of body sway measured by the platform was presented on a screen through the BioPac System and using Acknowledge 4.2 software as a white line. A photo cell, sensitive to the light emitted by the sway line, was attached to the screen. A relay station was connected between the stimulator (STIMSOC, BioPac Systems, Inc, CA, USA) and stimulator output to control the trigger for stimulation. Stimulation consisted of a square wave of 200 ms duration at a frequency of 40 Hz. The amplitude depended on the threshold of tactile sensation of the subject and ranged between 5-20 mA. Stimulation was triggered depending on the input from the photo cell which was attached to the screen. If the sway exceeds 50% of average body sway for the subject, the photo cell would convey a signal to the relay station ordering it to close the circuit and trigger the electrical stimulation through the stimulator output. Two electrodes were attached to the lateral aspect of subject's right lower leg. The subject would feel the electrical stimulation as a tingling sensation cuing him/her to stop sway and hold steady. This mechanism resulted in tactile feedback triggered by the body sway to improve body stability among elderly by decreasing body sway. (Figure 1)

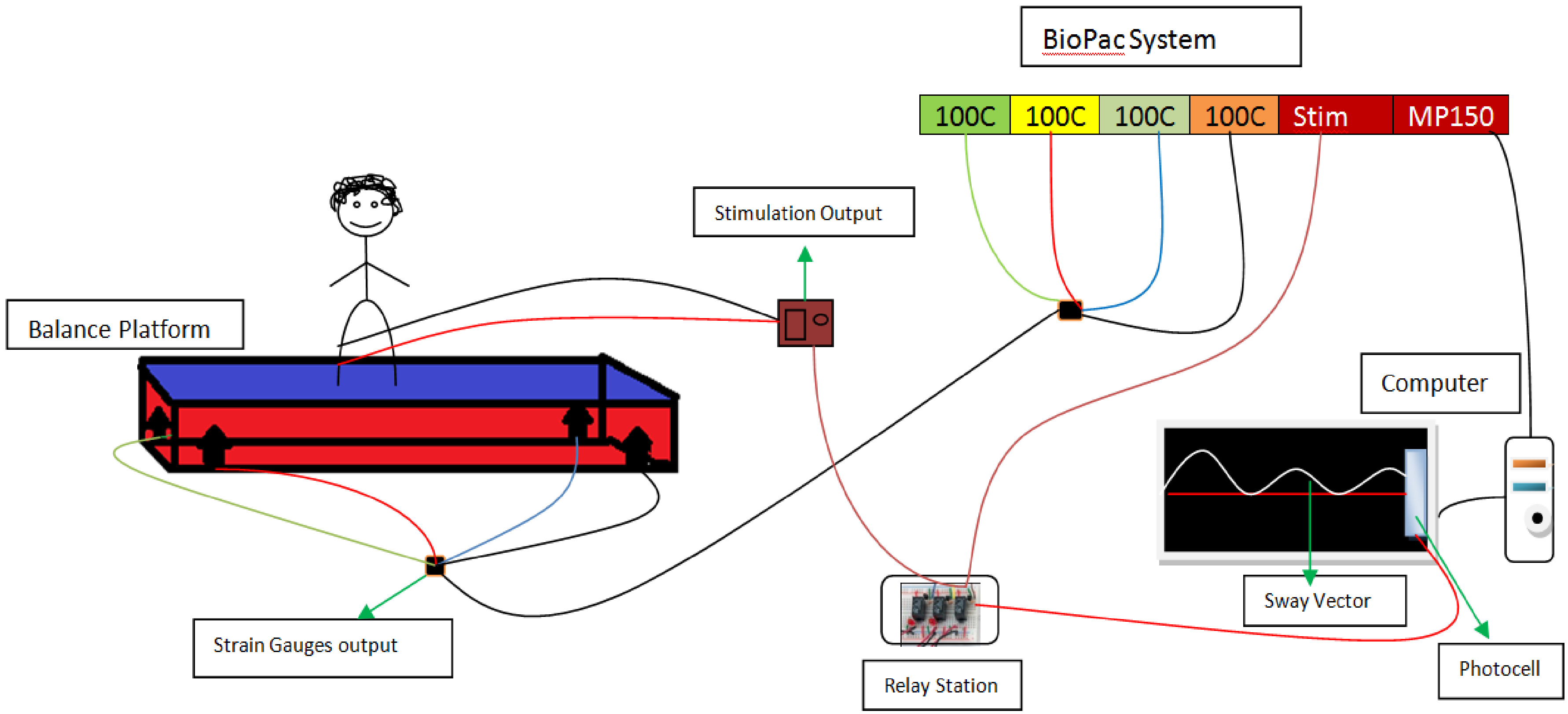

Figure1: Tactile Feedback System

Balance Tasks

Four balance tasks, each lasting for 10 seconds, were included in this study. Two surface compliances (firm surface and foam) were used. The trial was conducted in a darkened room to increase the challenge of the tasks. The four balance tasks were:

1) Standing on a firm surface (platform) with feet apart and eyes open; 2) Standing on a firm surface (platform) with feet apart and eyes closed; 3)Standing on compliant surface (foam) with feet apart and eyes open; and 4) Standing on compliant surface (foam) with feet apart and eyes closed.

Procedures

The subject was asked to stand quietly on the platform with eyes open for 10 seconds. Then, the subject was asked to stand quietly on the platform with eyes closed for 10 seconds followed by 1 minute of rest. Following the 1 minute of rest, the same procedures were repeated again while the subject stood on foam.

After finishing the baseline measurements, the subject received the tactile feedback intervention. Two electrodes were placed on the proximal third of the lateral aspect of the right lower leg to provide the subject with tactile feedback. The subject was asked to stand quietly on the platform for 4 minutes divided into 2 sessions, 2 minutes each with 2 minutes of rest between them. The subject was asked to keep the eyes open in the first training session, then close the eyes in the second training session. Following that, the subject was given 2 minutes rest. Then, the subject was asked to stand quietly on foam for 2 minutes with their eyes open. If the subject swayed during the training session, he/she would feel tingling on his lower leg to remind him/her to stop swaying. Post intervention measurements were conducted following 2 minutes of rest after the second session of intervention and 5 minutes of rest following the post intervention measures. Post intervention measures were the same as the measures prior to the intervention.

Data Analysis

The general characteristics of the subjects were summarized using means and standard deviations for quantitative variables, and frequencies and relative frequencies for categorical variables. A 2x3 mixed factorial analysis of variance (ANOVA) and one way repeated measures ANOVA were used to examine the difference in mean body sway between and within subjects. The level of significance was set at .05.

Results

There was no significant difference in mean body sway between the elderly group and group with diabetes on any of the tasks pre intervention, post intervention or 7 minutes post intervention. Body sway decreased significantly in all tasks that involved using foam in the elderly group. The average body sway decreased in the elderly group when standing on foam with feet apart and eyes open post intervention compared to pre intervention ($1.0 \pm .31$ vs. $1.9 \pm .8$ $p=.006$; Figure 2). Sway decreased significantly in the elderly group when standing on foam with feet apart and eyes closed post intervention compared to pre intervention ($1.8 \pm .8$ vs. 3.3 ± 1.5, $p=.001$; Figure 3). There was no significant difference in mean body sway when standing on foam with feet apart and eyes open in the group with diabetes. Body sway decreased significantly in the group with diabetes when standing on the foam with feet apart and eyes closed post intervention when compared to pre intervention (1.4± .5 vs. 2.3± .8 p=.045; Figure 4). There was no significant difference in mean body sway between immediate post intervention measures and 7 minutes post intervention measures.

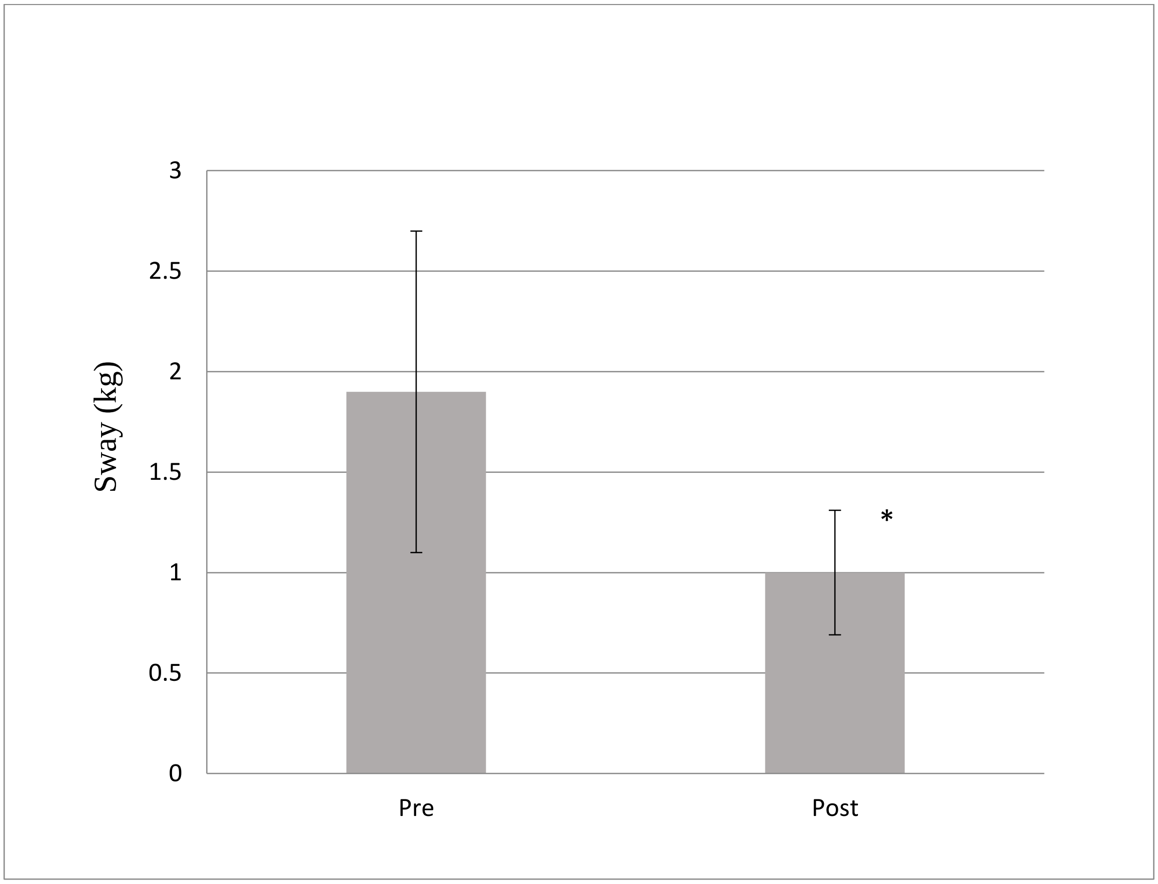

Figure 2. Mean body sway (kg) while standing on foam with eyes open in the elderly group pre and post intervention.
*: p =.006

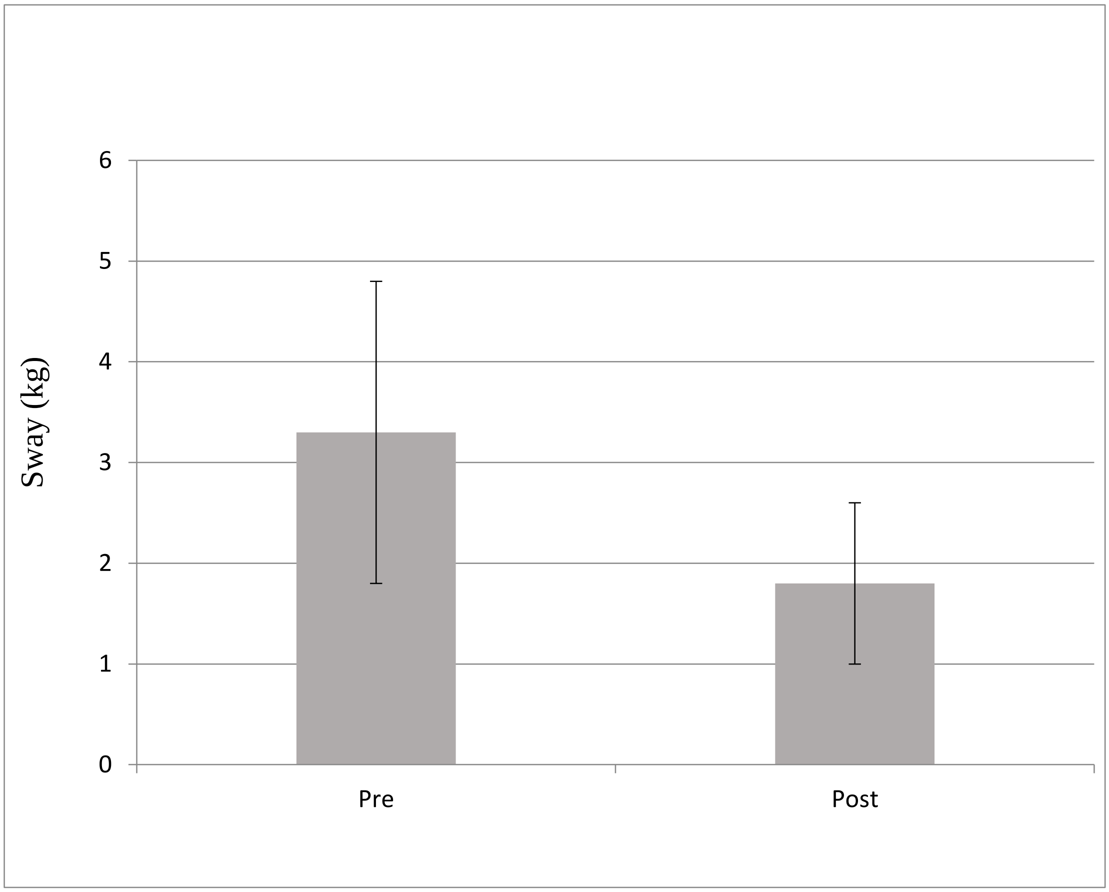

Figure 3. Mean body sway (kg) while standing on foam with eyes closed in elderly group pre and post intervention.
*: p = .001

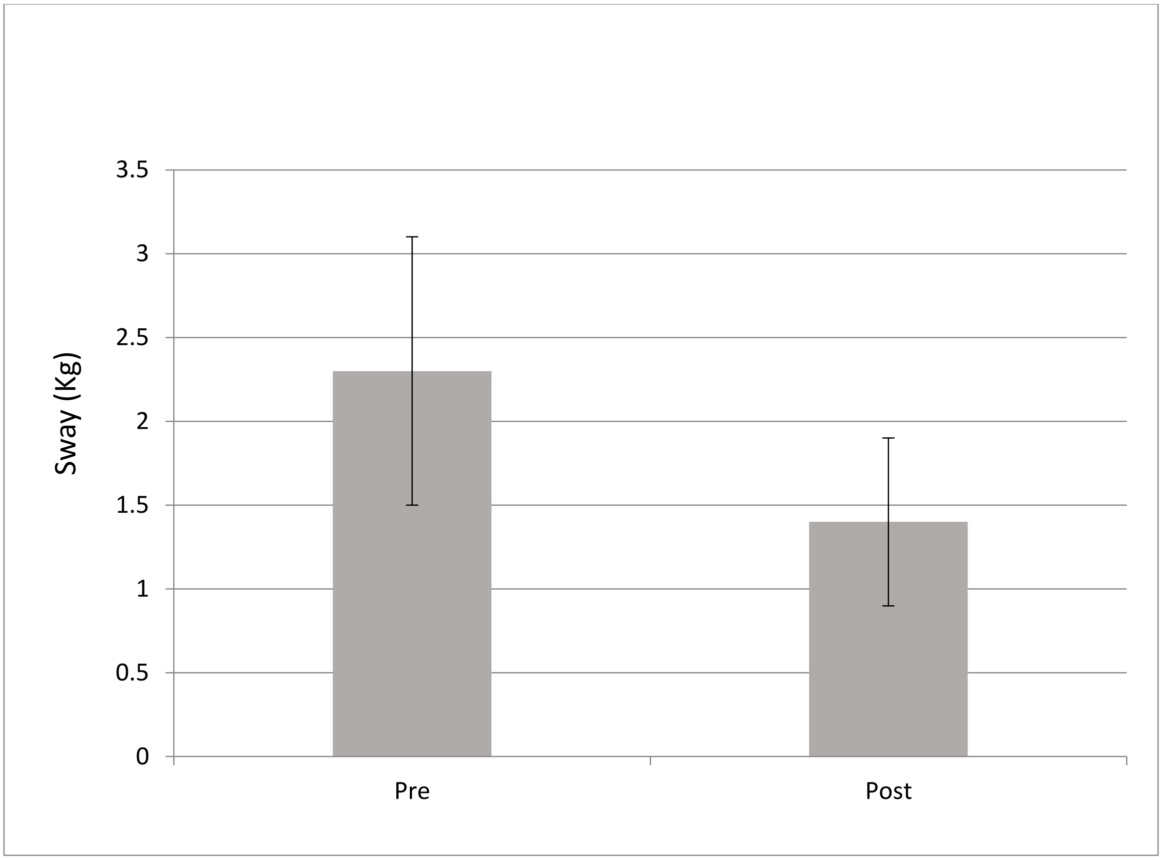

Figure 4. Mean body sway (kg) while standing on foam with eyes closed in group with diabetes pre and post intervention.
*: p =.045

Discussion

Balance deteriorates with ageing due to the normal aging process and the high incidence of disease among the elderly population. Sensory deficits in the lower extremity, visual impairment, and vestibular impairment contribute significantly to poor postural control in elderly.[26-30] The case is worse with elderly people with diabetes because the disease can affect the central and peripheral nervous systems, vestibular system, and vision, resulting in poor sensory input and limited central processing of the information received by the brain leading to poor body balance.[10, 31, 32] Defects in body balance result in increased body sway, decreased postural stability, and increased incidence of falls.

According to Center for Disease Control and Prevention (CDC), there was 2.3 million falls among the elderly in 2010, and 662,000 were treated in emergency rooms or hospitalized.[16] The medical cost to treat fall related injuries among elderly in 2010 was around $30.0 billion.[16]

On the average, Thirty percent of falls in the elderly lead to serious physical injuries which increase the mortality rate.[15] There were 10,300 fatal falls and 2.6 million nonfatal falls treated medically in 2001. The medical cost to deal with fatal falls was 200 million dollars and 19 billion dollars to treat fall related injuries.[18] Traumatic Brain Injury (TBI) is a serious injury that leads to death in 47% of the elderly people with fatal fall.[15, 16, 19] The mortality rate is high among the elderly with falls where 21,700 older adult died due to fall injuries in 2010.[16]

The results of the current investigation showed significant reductions in body sway in the elderly group while standing on foam with the eyes open or closed. However, the significant reduction in body sway in the group with diabetes was only while standing on the foam with the eyes closed but not with eyes open. There was no significant reduction in body sway in the group with diabetes or elderly group while standing on the platform because it was not challenging enough to increase the body sway and show difference in body sway post intervention.

Roger and colleagues found that the reduction in body sway was more in subjects who swayed the most during normal standing.[33] Therefore, we expect less reduction in body sway in the elderly group or the group with diabetes while standing on the platform because this situation is not challenging enough for subjects' body posture because of the hard surface was used.

Body sway decreased in the group with diabetes due to intervention while standing on foam with eyes closed but not with eyes open. This shows that the group with diabetes relies more on their vision in controlling their body balance than using the vestibular system or somatosensory system since vision predominated the inputs of both systems in maintaining body balance in normal situations.[13] This may justify why they did not learn new strategies to control their body sway using tactile stimulation with the eyes open. This is probably an adaptation used by subjects with diabetes to overcome sensory loss and vestibular loss. But, when the subjects were asked to close their eyes, the only way to control their body balance was to rely on the vestibular system and somatosensory inputs. Although the vestibular system and somatosensory sensory inputs are not strong contributors to body balance in people with diabetes when compared to vision, the subjects with diabetes relied on them to learn how to hold their body balance since the eyes were closed.

Menz and colleagues found that body sway decreased in the elderly with diabetic peripheral neuropathy and the elderly without peripheral neuropathy while applying a tactile stimulation on the lower leg using Velcro attached to an elastic band. Velcro was applied at three levels of the lower leg, at the ankle, mid-calf, and the knee. The reduction in body sway was more in applying Velcro at the knee, then mid-calf, and then the ankle.[20] This showed, even in the elderly without peripheral neuropathy, that tactile input was better as the application of stimulation was more cephalic. This can be attributed to mild damage in nerves in the elderly as we go more toward feet, or the fastest conduction of the nerve as we go toward the knee due to the reduction in distance between the nerve ending and somatosensory area. This fact explains why we applied the tactile stimulus in the proximal third of lower leg in our study.

Tactile input through the fingertip helped in reducing body sway and minimizes the fluctuation in the Center of Pressure (COP) in the elderly with or without impaired proprioceptive input in the lower limbs.[21-23] Light touch improves body stability in the elderly with impaired proprioceptive input because it provides tactile input which helps in compensating for poor proprioception. In our study, the elderly without proprioceptive impairment improve as well. This finding suggests that the elderly had mild impairment in peripheral sensory input but did not reach the threshold to be detected through the clinical examination tools as a peripheral neuropathy. This supports the use of a cane in the elderly because it will provide tactile input and mechanical support to improve body stability and reduce the risk of a falling.

The effect of Velcro application and fingertip light touch in the above mentioned studies was studied instantly. There was no measurement of body sway post intervention to find the effect of intervention. In the current study, we studied the effect of tactile feedback following the training session to find the effect post intervention.

In a previous study, the effect of passive tactile application on the shoulder versus the lower leg on postural stability was studied in healthy young adults and people with diabetes with varying degrees of peripheral neuropathy. Results of this study showed more reduction in body sway with a stimulus applied to the shoulder than the lower leg, and the stimulus was more effective with eyes closed or standing on the foam.[33] This study supports the results of our current study because the reduction in body sway was more while standing on foam than on the platform. At the same time, body sway in the group with diabetes decreased more with eyes closed situation than eyes open situation. However, this technique still worked well in the people with diabetes to train balance.

Limitations of this study were the intensity of treatment, the carry over measures, and a small sample size. Future studies are recommended to study the effect of multiple sessions instead of one training session and to study the carry over effect of intervention using a bigger sample size to be more representative of the studied population. Factors that may alter outcomes included duration of diabetes, HBA1C level, age, and gender. All of these factors need to be investigated further. To our knowledge, this is the first study that examined the effect of this novel intervention on body stability among elderly subjects.

Conclusion

In this small study, this technique offers a new tool for training people with diabetes and elderly people to improve body stability and balance.

Author Disclosure Statement

No competing financial interests exist.

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CHAPTER THREE

THE EFFECT OF VISUAL FEEDBACK ON BODY SWAY IN THE ELDERLY COMPARED TO AGE MATCHED DIABETIC SUBJECTS

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Abstract

Background: The elderly population is rapidly increasing in the United States. The aging process and high incidence of disease in elderly people affect body balance and increase sway. Research studies have shown an association between body sway and falling. Falling is one of the major predisposing factors of morbidity and mortality in the older adult population.

Purpose: The purpose of this study was to examine the effect of 6 minutes of visual feedback training on body sway in the elderly with or without diabetes.

Methods: Twenty nine subjects, 16 elderly without diabetes (mean age 78.0± 10.6 years) and 13 elderly with diabetes (mean age 74.3± 4.1 years), were recruited for this study. A monitor was used to project the motion of the Center of Gravity to provide visual feedback to the subjects.

Results and Discussion: Results showed a significant reduction in body sway in the elderly group with diabetes when standing on foam with feet apart and eyes open (1.3 ± .5 vs. 2.1 ± 1.1; p=.018) and eyes closed (2.0 ± .8 vs 3.1 ± 2.1; p=.003). In the elderly group without diabetes, there was a significant reduction in body sway while standing on foam with feet apart and eyes open (1.4 ± .7 vs1.8 ± .9; p=.023), and eyes closed (1.9 ± .9 vs. 3.4 ± 1.8; p=.002;). People with diabetes in this study rely more on their vision to learn how to balance with eyes open. This results in reduction in body sway in the group with diabetes more than the elderly group without diabetes in the situation involves eyes open, and vice versa with situation involves eyes closed.

Conclusion: Visual feedback provides an additional approach for training elderly people with or without diabetes to improve body stability and balance. It requires less time and effort than the conventional balance training.

Introduction

Balance is a complicated mechanism aiming to maintain body posture during the presence of static and dynamic stressors.[1] The balance system has 3 main components. The first component is the input including vision, the vestibular system, and the somatosensory system. The second component is the central processing of the received data. This occurs in the brain and spinal cord. Central processing involves many pathways and integration between different areas in the cerebellum, cerebrum, and spinal cord. [1] The third component is the output which is projected through the musculoskeletal system. Deficits in any of these components or poor coordination between these components can result in postural instability indicated by an increase in body sway and increased risk of falling. [1,2]

The elderly population is rapidly increasing in the United States (US). According to the Department of Health and Human Services, in the year 2009, the number of people who were 65 years or older was 39.6 million. This number represented approximately 12.9% of the United States population. However, by the year 2030, there will be approximately 72.1 million older adults. This signifies that the number of older adults by 2030 is going to be almost twice the number in 2009. In addition, the number of older adults by 2030 is going to be more than twice the number in the year 2000.[3]

Balance disorders are present more in elderly people due to the aging process and high incidence of diseases such as diabetes.[4-6] Aging involves many physiological changes in the sensory, visual, vestibular, motor, and central nervous systems (CNS).[4] The incidence of peripheral neuropathy in the elderly is approximately 20%.[7] Peripheral neuropathy affects the peripheral somatosensory input, distribution of body weight, and muscle strength resulting in poor body balance.[7] Vestibular system impairments are common in the elderly. The aging process involves significant changes in the vestibular system such as metabolic changes, otoconia degeneration, rupture of the saccular membrane, and microfractures of the otic capsule.[8] This significantly affects the body stability by conveying incorrect information about head position and motion, faulty vestibular reflexes, or by causing dizziness.[8,9] Vision is affected due to the aging process.[4,10] The low frequency spatial motion in vision decreases with aging.[10] A previous study has shown a significant indirect correlation between visual dysfunction and body stability.[11] The deficits in the CNS, peripheral nervous system (PNS), musculoskeletal system, vestibular system, and/or vision result in poor postural control. This can be seen either as increased body sway, decreased postural control, or sustained falls in the elderly.[2]

Studies have shown a direct relationship between increasing body sway in older adults and the risk of falling.[2,12] Falling is one of the major causes of morbidity and mortality in the elderly. According to the Center for Disease Control and Prevention (CDC), one out of three adults who are 65 years or older fall every year.[13] The rate of falling was significantly higher among the elderly. Fernie and colleagues reported that 42% of 205 older subjects had at least one fall within a year.[12] Falling is the leading cause of fatal and nonfatal injuries in older adults such as hip fracture and traumatic brain injuries which increase the risk of early death.[13] Stevens and colleagues reported 10,300 fatal falls and 2.6 million nonfatal falls in the year 2000.[14] In the same study, they reported that 0.2 billion dollars were spent to deal with fatal falls, and 19 billion dollars to deal with nonfatal fall related injuries.[14] According to the CDC, in the year of 2010, 2.3 million fall related nonfatal injuries among older adults were reported and 662,000 of these patients were hospitalized.[13] In the same year, the medical cost associated with these injuries was 30 billion dollars.[13]

A study was done to compare the postural control in older adults to young people. Wolfson and colleagues tested the sway in normal older adults compared to young people using the Equitest dynamic posturography platform (Neuro-Com International). They found that sway was greater in the elderly than in the young in 5 out of 6 sensory test conditions.[15] This indicates that postural stability and body balance deteriorates with aging.

The prevalence of diabetes has increased dramatically over the last 20 years. According to the World Health Organization, there were 171 million people affected with diabetes in the year 2000. However, the projected increase in the incidence of diabetes by the year 2030 will be 366 million people. [16] This indicates that the projected number of people with diabetes in 2030 is going to be at least 2 times more than their number in the year 2000. According to the U.S. Department of Health and Human Services, in 2010, the prevalence of diabetes in people 65 years or older was 26.9%, affecting 10.9 million people.[17]

Uncontrolled diabetes affects body balance significantly by affecting sensory inputs, brain function, and/or motor control.[18] As previously stated, sensory inputs of the human balance system are provided by the eyes, peripheral nerves, and vestibular system. Diabetes can affect vision by causing cataracts or retinal disorders.[18] Research shows that poor vision leads to poor body balance.[11] The prevalence of peripheral neuropathy is between 60-70% among people with diabetes.[18] This affects the sensory information conveyed to the brain. Loss of sensory input or muscle strength in peripheral neuropathy affects the postural stability and body balance significantly.[2,19,20]

Kim and colleagues reported that 60% of patients with diabetic neuropathy develop vestibular disorders.[21] Another study showed a direct relationship between the severity of diabetes and the prevalence of vestibular disorders.[22] The same study showed that the vestibular disorders increased the risk of falls over 2 fold in people with diabetes.[22]

Body sway, increasing with age, is a sign of balance system deficits and is correlated to the incidence of falls.[2,23,24] Fernie and colleagues found in their study that the mean speed of body sway is an indicator for the risk of fall among elderly.[12] This occurs due to impaired sensory input, increased delays in nerve conduction, latency in translating the sensory input into a plan of action, or deficits in the musculoskeletal system.

A study was conducted to examine the effect of different balance training techniques on body sway. Song and colleagues[25] studied the effect of an exercise program on balance and proprioception in older adults with peripheral neuropathy. They used a balance training program for 60 minutes twice a week for eight weeks. They found a significant reduction in postural sway following the training program.[25]

A previous study was done to assess the effect of visual feedback on body sway. Cawsey and colleagues[26] tested the effect of Center of Pressure (COP) magnification using visual feedback on standing sway. They used seven different magnifications (1 x, 4 x, 8 x, 16 x, 32 x, 48 x and 64 x). They found that sway on an incompliant surface was decreased with COP magnification. However, it reached a plateau at 8X magnification of COP. At the same time, the standing sway on foam reduced with increasing magnification of COP and did not reach a plateau.[26]

In another study, Hamman and colleagues[27] studied the effect of visual feedback on dynamic body balance. They tested the ability and speed to move the point representing the Center of Gravity (COG) from one target to another and the sway upon reaching the second target. The distance between those points represented 75% of subjects' limits of stability. The results showed a reduction in transitional time between target to target and sway upon reaching the target.[27]

Sihvonen, Sipila, and Era [28] studied the effects of balance training using visual feedback on falls among frail older women. The training program was conducted over four weeks. The fall incidence was monitored using a monthly diary over a year. An interview about fear of falling and physical activity was conducted before and after the intervention. The findings showed positive effects of visual feedback training on falls. The incidence of falls and fear of falling decreased following the visual feedback training. However, these changes were not sustained and declined during the follow up period. [28]

In summary, body balance is affected by the aging process and the high incidence of disease in elderly. The case is worse in elderly with diabetes due to damages in the CNS, PNS, vestibular system, vision, and musculoskeletal system. Body sway is worse in balance disorders and studies showed a direct relationship between body sway and the incidence of falling. Current regimen in balance training requires a long duration and increased repetition which could be challenging to the elderly due to limited fitness and presence of disease and health disorders. Therefore, the purpose of this study was to examine the effect of 6 minutes of visual feedback training on body sway in the elderly with or without diabetes.

Methods

Twenty nine subjects participated in this study. They were recruited using flyers and phone calls from physical therapy centers, senior homes, sport centers, and Loma Linda University. The subjects, 65-90 years of age, were divided into 2 groups; an elderly group without diabetes and an elderly group with diabetes. There were 13 subjects in the elderly group with diabetes and 16 subjects in the elderly group without diabetes. Subjects were excluded if they had cognitive disorders, neurological disorders, alcohol/substance abuse, took medications that affected body balance, vestibular pathology, unable to stand for 10 minutes continuously, or enrolled in balance training that interfered with the provided intervention within the last month. All protocols and procedures were approved by the Institutional Review Board of Loma Linda University and all subjects signed a statement of informed consent. The demographics of the subjects are shown in table 1. There was a significant differences in weight between the two study groups.

Table1. Demographic data of the elderly subjects with and without diabetes (Mean ± Standard Deviation).

	Elderly without diabetes (n=16)	Elderly with diabetes (n=13)	P[#] value
Age (years)	78.0 ± 10.6	74.3 ± 4.1	.11
Height (cm)	163.3 ± 9.5	167.6 ± 11.2	.29
Weight (kg)	71.5 ±15.2	98.1 ± 28.3	.007
BMI[*] (kg/m^2)	26.7 ± 4.8	34.5 ± 7.8	.005

[*] BMI= Body Mass Index= Weight (Kg)/ Height (m^2)

[#] Independent t-test

Measurements of Body Sway

The displacement of the subjects' center of gravity (COG) was measured using a balance platform of 1m^2 in size and 10 cm in height. Four stainless steel bars with 16 strain gauges were mounted at the four corners under the platform's surface (TML Strain Gauge FLA-6, 350-17, Tokyo, Japan). The output of the 4 Wheatstone strain gauge bridges was amplified with a BioPac 100 C low-level bio potential amplifiers and recorded on a BioPac Mp-150 system through a 24-bit A/D converter. The sampling rate was 2000 samples per second.[29]

Sway was presented as a line on a screen detecting the magnitude and angular displacement of the body. The magnitudes of X and Y coordinates of the subject's center of gravity were used to calculate the displacement of the center of mass of exerted body load on the platform. Mean (M) and Standard Deviation (SD) were obtained by finding the average of the sway magnitude of Y and X over an interval of 6 seconds.

Design of Visual Feedback Intervention

The center of gravity (COG) was presented at the screen as a red dot. Changes in the COG position due to body sway were detected by the sensors on the platform and projected to the screen via Acknowledge 4.2 software. The movement of red dot was in the same direction of body sway. For example, if the subject sways to the right, the red dot will move to the right. This will provide the subject with visual cue to stop swaying and hold the COG steady. This mechanism results in visual feedback triggered by the body sway to improve body stability among elderly by decreasing body sway. The visual feedback system is represented in Figure 1.

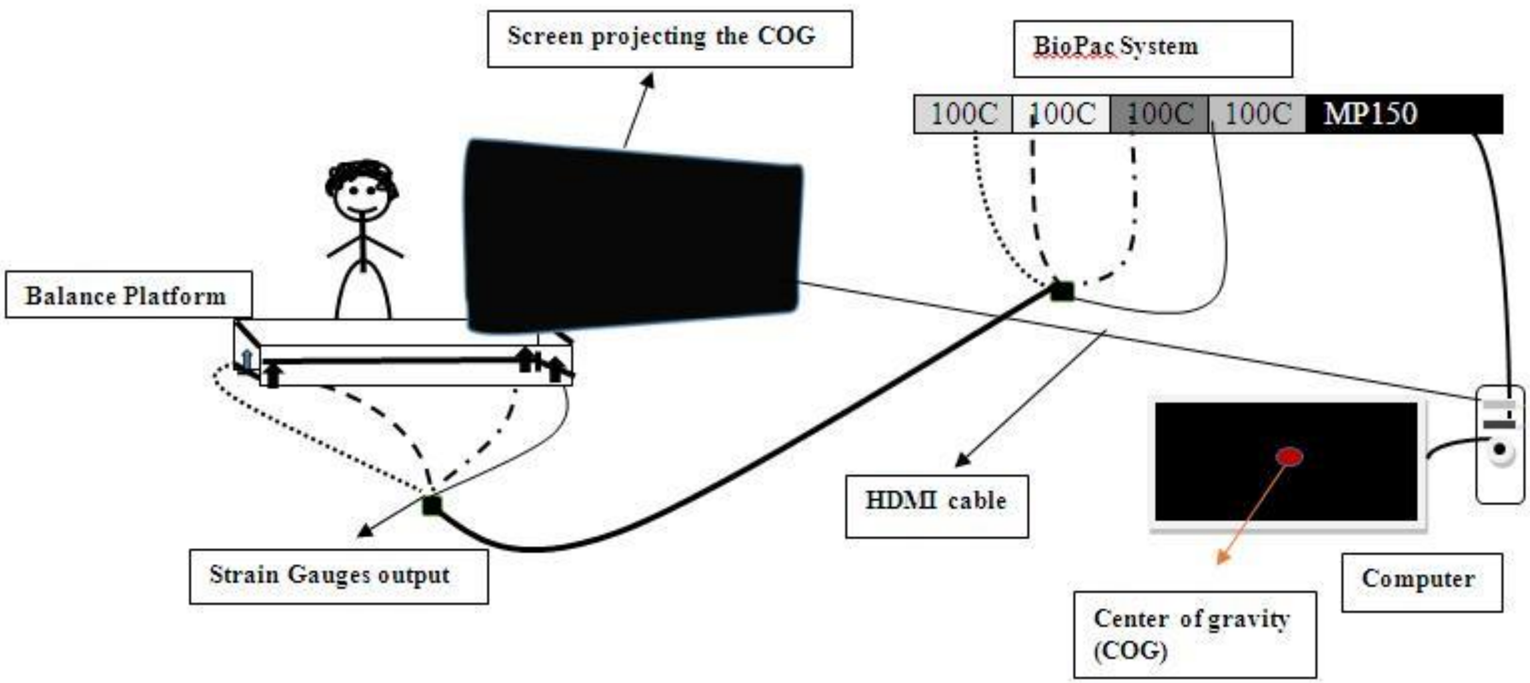

Figure 1. Visual feedback intervention

Balance Tasks

Four balance tasks, with duration of 10 seconds, were included in this study. Two surface compliances (firm surface and foam) were used. The trial was conducted in a darkened room to increase the challenge of the tasks. The four balance tasks were:
1) Standing on a firm surface (platform) with feet apart and eyes open; 2) Standing on a firm surface (platform) with feet apart and eyes closed; 3)Standing on compliant surface (foam) with feet apart and eyes open; and 4) Standing on compliant surface (foam) with feet apart and eyes closed.

Procedures

The subject was asked to stand quietly on the platform with eyes open for 10 seconds. Then, the subject was asked to stand quietly on the platform with eyes closed for 10 seconds followed by 1 minute of rest. Following the 1 minute of rest, the same procedures were repeated again while the subject stood on foam.

After finishing the baseline measurements, the subject received the visual feedback intervention. The subject was asked to stand quietly on the platform and hold the red dot as still as possible. Visual feedback was given for 6 minutes divided into 3 sessions; 2 minutes each with 2 minutes of rest between them. If the subject swayed during the training session, he/she would see the motion of a red dot which representing the COG to give the subject cue to stand steadier. During first session, the subject was asked to hold the red dot as steady as possible by holding the body still. In the second session, the sensitivity of the red dot to COG movement was increased. In the third session, the subject was asked to stand on foam and keep the red dot steady as much as possible by holding still post intervention measurements were conducted following 2 minutes of rest after the second session of intervention and 5 minutes of rest following the post intervention measurements. Post intervention measures were the same as the measures prior to the intervention.

Data Analysis

The general characteristics of the subjects were summarized using means and standard deviations for quantitative variables, and frequencies and relative frequencies for categorical variables. A 2x3 mixed factorial analysis of variance (ANOVA) with adjustment to the BMI were used to examine the difference in mean body sway between and within subjects for the variables which were normally distributed. Nonparametric analyses using Friedman and Wilcoxon Signed Rank was used to examine the difference in mean body sway within groups for the variables which were not normally distributed. The level of significance was set at $p \leq .05$.

Results

There were no significant differences in mean body sway between the elderly group without diabetes and elderly group with diabetes on any of the tasks pre intervention, post intervention, or 7 minutes post intervention. Body sway decreased significantly in all tasks that involved using foam. The average body sway decreased significantly in the elderly group with diabetes when standing on foam with feet apart and eyes open post intervention compared to pre intervention (1.3± .5 vs. 2.1± 1.1; p=.02, Figure 2). The average body sway decreased significantly in the elderly group with diabetes when standing on foam with feet apart and eyes closed post intervention compared to pre intervention (2.0±.8 vs 3.1±2.1; p=.00, Figure 3). The average body sway decreased significantly in the elderly group without diabetes while standing on foam with feet apart and eyes open post intervention compared to pre intervention (1.4± .7 vs1.8±.9; p=.02, Figure 4). Also, the average body sway decreased significantly in the elderly group without diabetes when standing on foam with feet apart and eyes closed post intervention when compared to pre intervention (1.9± .9 vs. 3.4± 1.8; p=.00, Figure 5). However, there was no significant difference in mean body sway between immediate post intervention measures and 7 minutes post intervention measures.

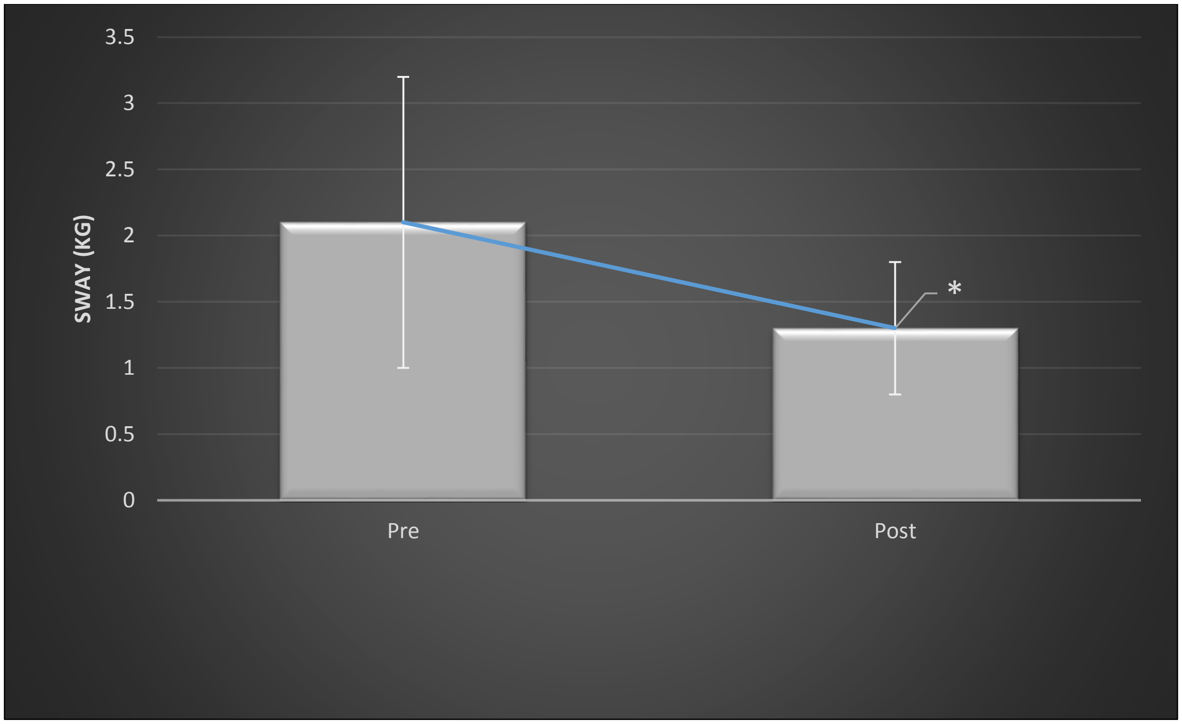

Figure 2: Mean body sway (in kg) ± SD while standing on foam with eyes open in elderly group with diabetes pre- and post- intervention. *p=0.018

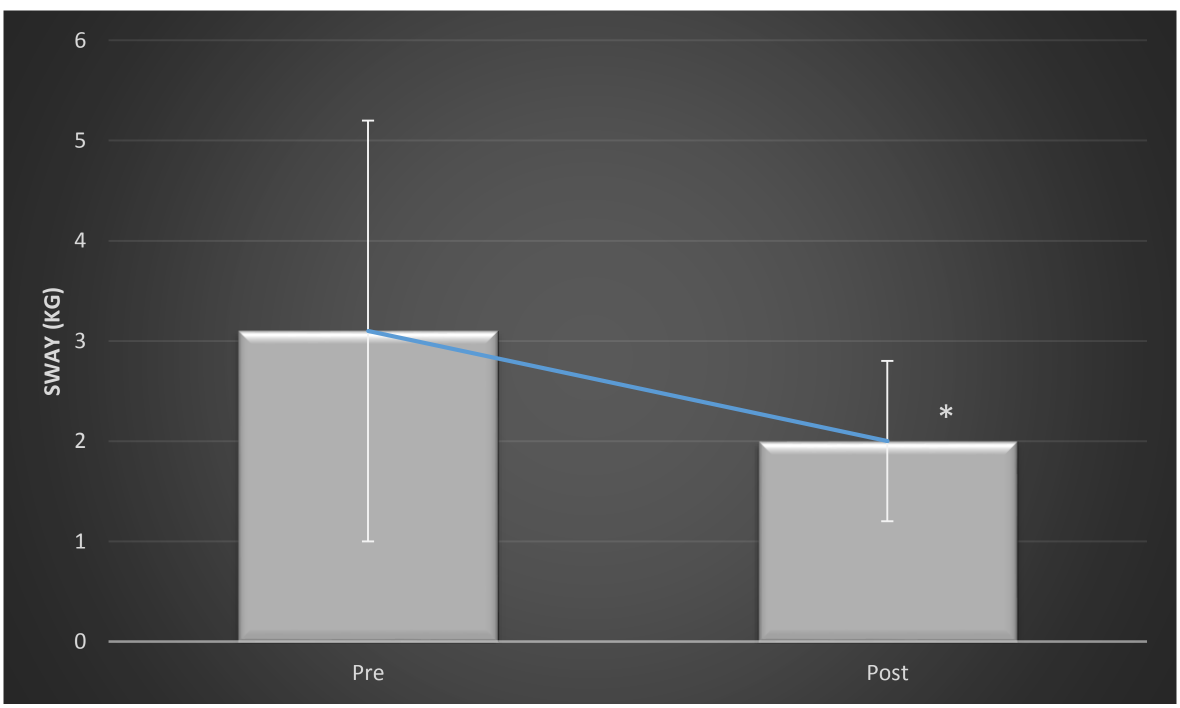

Figure 3: Mean body sway (in kg) ± SD while standing on foam with eyes closed in elderly group with diabetes pre- and post- intervention. *p=0.003

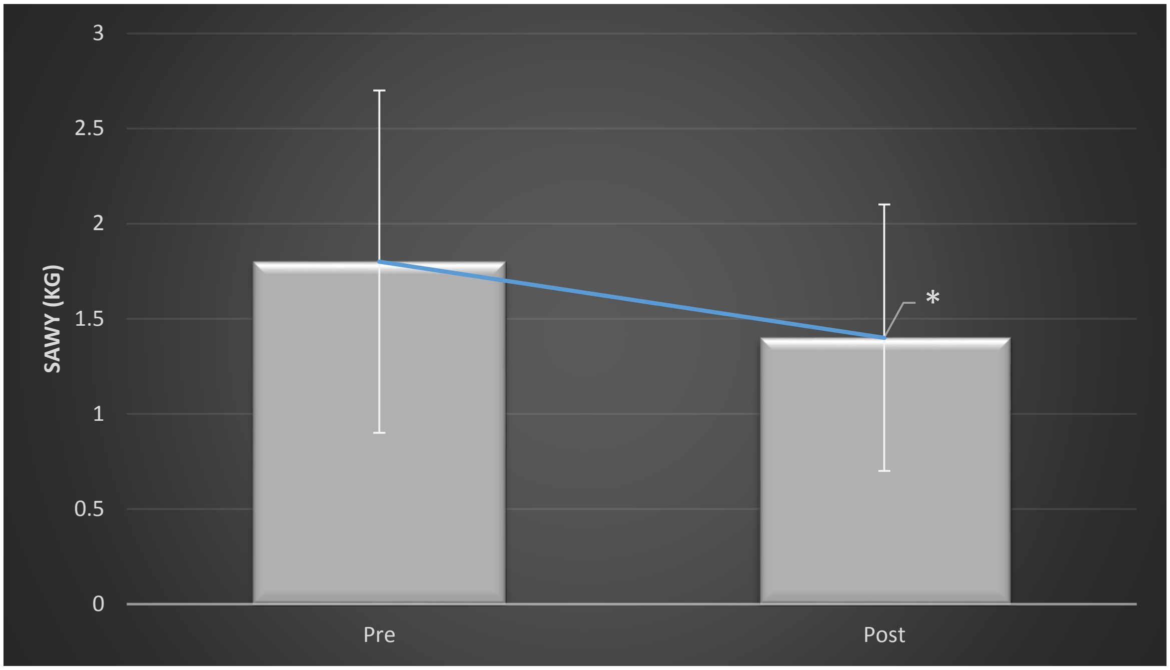

Figure 4: Mean body sway (in kg) ± SD while standing on foam with eyes open in elderly group without diabetes pre- and post- intervention. *p=0.023

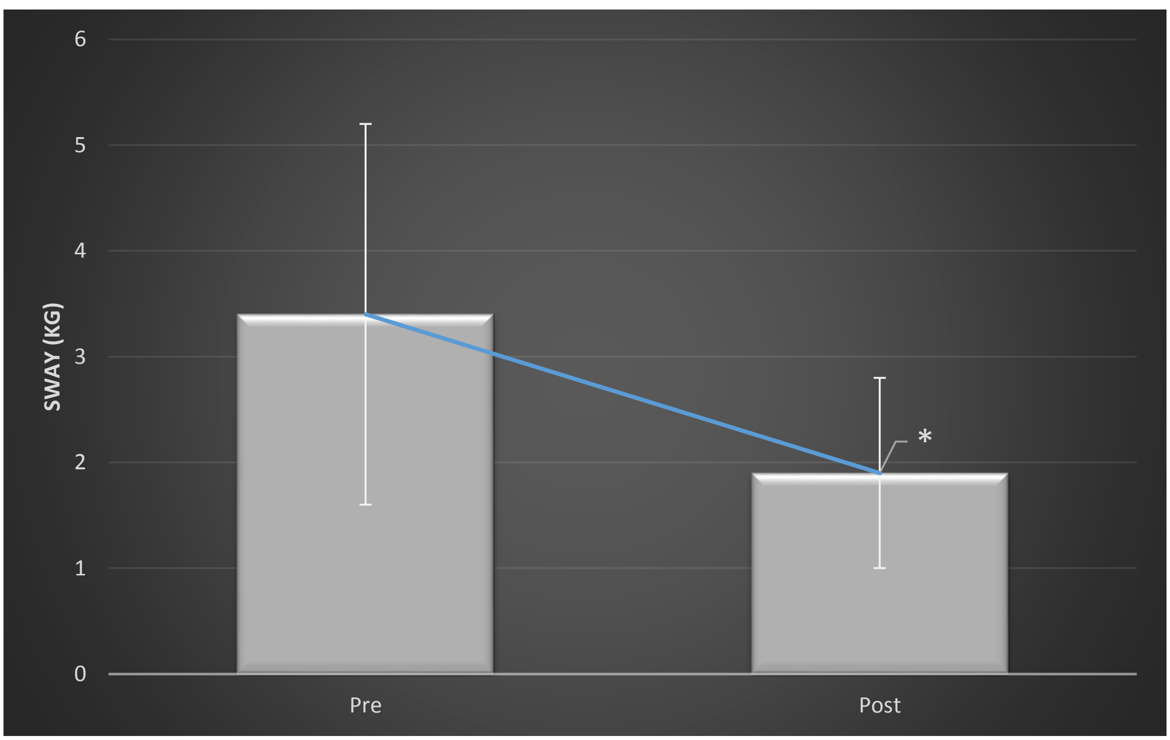

Figure 5: Mean body sway (in kg) ± SD while standing on foam with eyes closed in elderly group without diabetes pre- and post- intervention. *p=0.002

Discussion

Body balance deteriorates with aging. This is due to the normal aging process and the high incidence of disease. Balance disorders result in increased body sway, decreased postural control, and increased incidence of falls.[2,15]

Falling is one of the major predisposing factors of morbidity and mortality in the older adult population. According to the Center of Disease Control and Prevention, one out of three older adults, 65 years or older, fall every year.[13] This puts financial burden on countries to deal with fall related injuries due to the high costs. [13,14]

Body balance mechanism consists of three main components; sensory input, central processing, and output. Sensory inputs are conveyed via vision, the somatosensory system, and the vestibular system. Central processing takes place in the central nervous system including the brain and spinal cord. The output components of body balance are projected throughout the musculoskeletal system to maintain postural control and to prevent falling.

Diabetes can significantly affect peripheral sensory input and can result in peripheral neuropathy. A study has shown association between peripheral neuropathy and vestibular disorders.[22]

The results of this study showed better improvement in body sway in elderly with diabetes when compared to the elderly without diabetes while standing on foam with eyes open. On the other hand, the elderly without diabetes achieved better improvement in body sway than the elderly with diabetes while standing on foam with eyes closed. These findings could be attributed to many reasons.

As cited previously, vision predominates the somatosensory and vestibular systems in body balance.[30] Vision contributes to the body balance more than the somatosensory and vestibular systems. We would expect that vision will be involved more in controlling body balance in people with diabetes due to limited peripheral somatosensory and vestibular inputs.[22,30] This might explain as the reason that the subjects with diabetes, in this study, achieved better improvement than the older subjects without diabetes in the situation involving standing on foam with eyes open. They could have learned a strategy to control their body sway using their visual input.

On the other hand, we expected elderly people without diabetes to have better peripheral somatosensory and vestibular inputs than the elderly people with diabetes. This could be the reason that the elderly people achieved better improvement in body sway than the subjects with diabetes in the situation involving use of foam with eyes closed. This finding suggests that the elderly people without diabetes were able to correlate their visual input to the somatosensory and vestibular inputs greater than the subjects with diabetes.

These findings are supported by a previous study that examined the effect of tactile feedback on body sway. [31] Elderly people without diabetes achieved better improvement than the elderly people with diabetes. This suggests that the elderly people without diabetes responded better to tactile feedback because they had better peripheral somatosensory input than the elderly people with diabetes.[31]

Petrofsky and colleagues conducted a study to assess the motor control during balance tasks in subjects with diabetes.[32] They found more activation in parietal cortex of the cerebrum in subjects with diabetes compared to elderly without diabetes or young subjects doing the same task. Also, the activation of parietal area increased with increasing the complexity of task such as eliminating vision or decreasing the somatosensory input in people with diabetes. This finding suggests possible deficits in the sensorimotor process and the integration of sensory inputs in people with diabetes. Their findings support the findings of this study that the people with diabetes were less able to correlate their visual input to somatosensory and vestibular inputs, during the training sessions, than the elderly without diabetes to learn a new strategy of body balance. This results in less improvement in body sway in people with diabetes when compared to old people without diabetes in the situation that involves standing on foam with eyes closed.

Other studies support the findings of this study. [28,33] Positive effect of visual feedback on body balance in frail elderly women was reported by Sihvonen et al.[33] In the same study, the compliance with visual feedback among subjects was high 97.5% and subjects were motivated to participate in the training. In another study, visual feedback training helped in decreasing the incidence of fall among frail older women.[28] This suggests a promising future for visual feedback to be a useful training tool in physical therapy or rehabilitation centers to improve body balance in the elderly.

The limitations of this study were the small sample size, the intensity of treatment, and the lack of measurements of carryover effects. Future studies are recommended to study multiple visual feedback training sessions on a larger sample size and to have follow up measures to examine the carryover effect of the intervention.

Conclusion

Visual feedback provides an additional approach for training elderly people with or without diabetes to improve body stability and balance. Visual feedback requires less time and effort than the conventional balance training programs.

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CHAPTER FOUR

DISCUSSION

Balance disorders are presented more in the elderly due to the aging process and the high incidence of diseases such as diabetes.[3,5] The aging process involves changes in the balance system components including the somatensory system, vestibular system, vision, CNS, and musculoskeletal system.[2,3,5] This process results in balance deficits. Body balance is affected more in the elderly with uncontrolled diabetes due to further damage in CNS and PNS.[12,31]

The results of this study showed no significant difference between the two groups using visual or tactile feedback. However, more reduction in body sway was seen in the elderly group without diabetes compared to the elderly group with diabetes when using a tactile feedback while standing on foam with eyes open or closed. The elderly with diabetes did not achieve a significant reduction in body sway using tactile feedback while standing on foam with the eyes open. However, more reduction in body sway was noted in the elderly with diabetes while standing on foam with eyes open using visual feedback. On the other hand, more reduction in body sway was noted in the elderly without diabetes using visual feedback while standing on foam with eyes closed.

Tactile feedback was more helpful to the elderly without diabetes compared to the elderly with diabetes. This could be due to the fact that diabetes results in more damage in the central and peripheral nervous systems, especially the peripheral nerves in lower limbs resulting in peripheral neuropathy.[12,15,32] This affects the somatosensory input, mainly the sensory signals coming from the lower limbs, vestibular system, and the integration among the received sensory inputs to make a precise plan of action to avoid excessive body sway or fall.

Elderly subjects with diabetes achieved maximum improvement with visual feedback in the situation involve standing on foam with their eyes open. This could be attributed to the reason that the elderly with diabetes rely more on their vision to maintain body posture due to limited proprioceptive and vestibular inputs. Therefore, they have difficulty maintaining their body posture and balance in a dark room.[31]

We recommend using a combination of visual and tactile feedback training for elderly people with diabetes to achieve the maximum improvement on body sway and stability. On the other hand, tactile feedback is sufficient for elderly people without diabetes to achieve maximum improvement on body sway and stability.

Previous studies showed that the tactile input through light finger touch was helpful in reducing body sway in elderly people with or without impaired proprioceptive sensation in their lower limbs.[27-29] Diabetes and aging affect peripheral nerves more in the lower limbs more than upper limbs.[33] Therefore, the tactile input from finger touch was helpful. [27-29] Also, the time required to transmit somatosensory signals from hand to the brain is shorter than transmitting the signals from the feet to the brain. Therefore, tactile input from finger could decrease body sway more than tactile input from the feet due to reduction in processing time to correct the unexpected acceleration of COG. The findings of the mentioned study support the use of a cane to provide tactile feedback to decrease body sway. Also, it suggests using tactile feedback system on the hand. However, this could not be helpful in the daily life because our goal is to train the patients to correlate the residual somatosensory input from their lower limbs with the visual and vestibular inputs to decrease body sway and risk of falling.

Sihvonen and colleagues reported positive effects of visual feedback in frail elderly women on body sway.[30] In another study, they examined the effect of visual feedback on the incidence of falling and fear of fall in frail elderly women.[34] The training program was conducted over 4 weeks. The incidence of falls was monitored using a monthly log for a year. Also, they conducted interviews with subjects regarding the fear of fall and physical activity. The incidence and fear of falling decreased following visual feedback training. In the same study, they reported high compliance (97.5%) of subjects with a visual feedback training program.[34] Also, we expect the tactile feedback to have higher compliance than the conventional balance training programs because it requires less time and effort from the elderly people. Based on the above findings, there is a promising future for visual and tactile feedback to be used in physical therapy settings for balance training to improve postural stability in elderly and decrease risk of fall.

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APPENDIX A

INFORMED CONSENT FORM

LOMA LINDA UNIVERSITY

School of Allied Health Professions

Informed Consent to Participate in Research

"VISUAL FEEDBACK COMPARED TO TACTILE FEEDBACK IN REDUCING SWAY IN ELDERLY COMPARED TO AGE MATCHED DIABETIC SUBJECTS"

You are invited to take part in a student research project for academic credit. Your participation in this research study is strictly voluntary, meaning that you may or may not choose to take part. Before you agree, you need to take time to carefully read and understand what your participation would involve. To decide whether or not you want to be part of this research, the purpose, procedures, risks, and possible benefits of the study are described in this form so that you can make an informed decision.

PURPOSE OF THE STUDY AND STUDY PROCEDURES

You are invited to participate in a study to see the effect of training using vision compared to training using lower leg sensation in reducing body sway. There will be two groups in this study: an elderly group and an aged matched diabetic group. If you choose to participate, you will need to be between 65 and 90 years old and either in good health or having Type 2 Diabetes for at least 2 years. If you have Type 2 Diabetes, your A1C level should be between 6 - 9 and you should be taking medications for diabetes. You need to have any balance deficits or have complaints of body instability. You will be excluded from this study if you have cognitive disorders, neurological disorders, alcohol/substance abuse, vestibular pathology, any balance training during the last month, taking medication that affects balance, or unable to stand for at least 10 minutes continuously.

There will be 4 groups of subjects with 25 subjects in each group. The first group will be normal elderly people receiving training that uses their vision, a second group will be diabetic elderly people receiving the same training as the previous group, the third group will be normal elderly people receiving training that uses their lower leg sensation, and the fourth group will be diabetic elderly people receiving the same training as the third group. Measurements will be taken before feedback training and immediately after training. You will come for one visit for approximately 1 hour. In this visit, we are going to measure your body sway, A1C level, blood sugar level, height, weight, ankle range of motion, ankle muscle strength, body fat percentage, and test your peripheral sensation. You will be assigned randomly into one of two training groups (vision or sensation) and then receive training session, followed by body sway measurement again. The study procedures will be held in Nichole Hall at room A640 or your physical therapy center.

_________Initial
_________Date

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#5120358 Chair R L Rigsby

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DEPARTMENT OF PHYSICAL THERAPY | Nichol Hall, Loma Linda, California 92350
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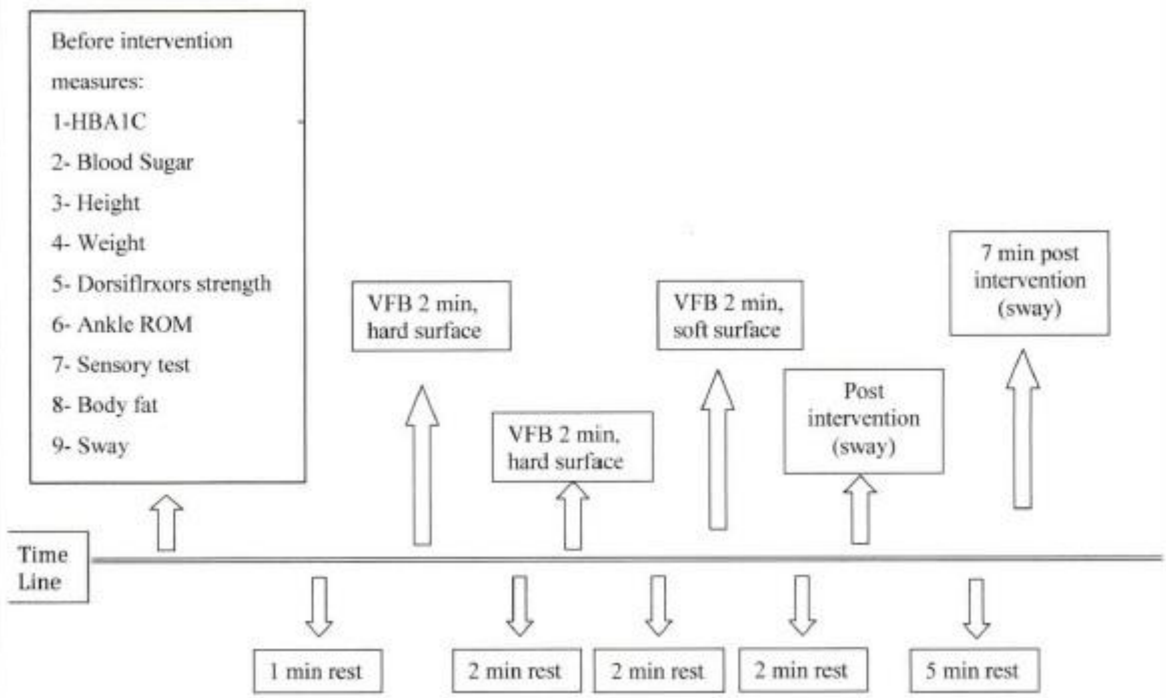
"VISUAL FEEDBACK COMPARED TO TACTILE FEEDBACK IN REDUCING SWAY IN ELDERLY COMPARED TO AGE MATCHED DIABETIC SUBJECTS"

Research study protocol summary:

- Groups which will receive visual feedback (VFB): subject will sign informed consent then the study protocol will be as following:



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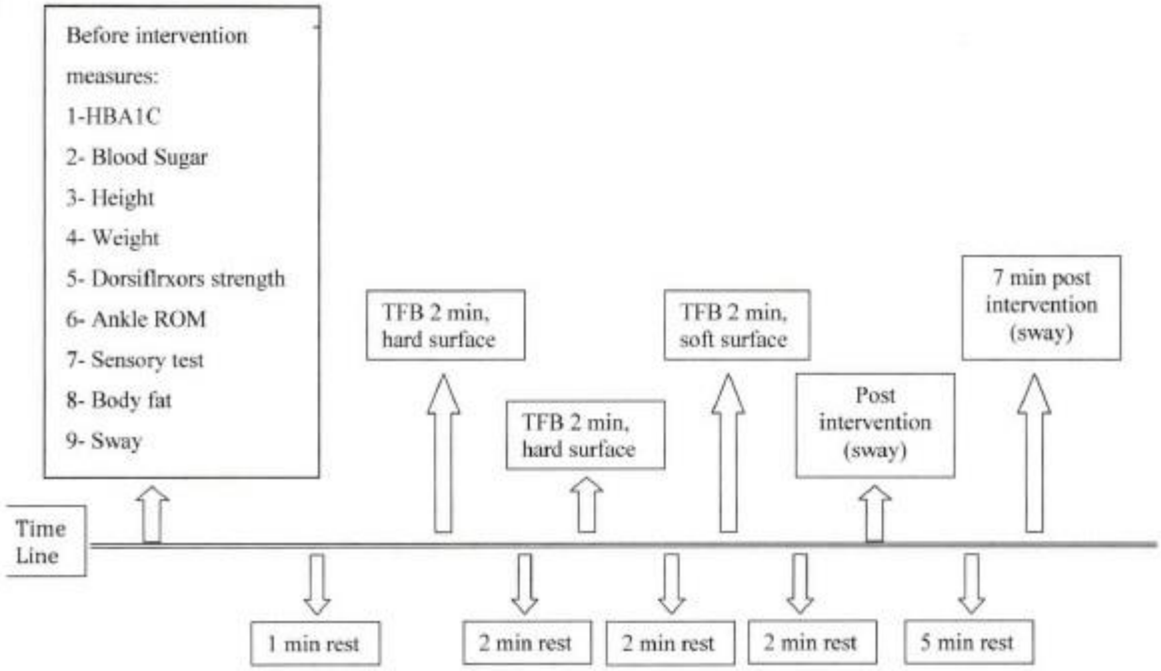
_________Initial
_________Date

"VISUAL FEEDBACK COMPARED TO TACTILE FEEDBACK IN REDUCING SWAY IN ELDERLY COMPARED TO AGE MATCHED DIABETIC SUBJECTS"

- Groups which will receive tactile feedback (TFB): subject will sign informed consent then the study flow will be as following:



POSSIBLE RISKS AND DISCOMFORTS

The risks for this study are minimal or no greater than those encountered in daily life. You might have temporary discomfort due to continuous standing for 2 minutes on platform and another 2 minutes of standing on foam or due to fingertip puncture. As well, you might fall while standing on the platform or foam with eyes closed. If you experience any of these symptoms, you must notify the study investigator immediately. Trained physical therapists will be conducting this study which helps in monitoring and minimizing the risks. At the same time, a gait belt will be applied on your waist and trained physical therapists will be standing beside you during the study to prevent any possible risk of fall by holding the belt and support as needed.

BENEFITS

You are not likely to benefit from participating in this study personally, but this study might help us finding new ways and interventions to treat postural instability and balance disorders.

_________ Initial
_________ Date

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"VISUAL FEEDBACK COMPARED TO TACTILE FEEDBACK IN REDUCING SWAY IN ELDERLY COMPARED TO AGE MATCHED DIABETIC SUBJECTS"

PARTICIPANTS RIGHTS

Participation is voluntary. You may leave the study at any time. If at any time during a procedure you experience tiredness or discomfort beyond what you are willing to endure, just tell the person conducting the procedure you want to stop. This decision will NOT affect your standing with those conducting the study or loss of benefits that you are entitled to.

To report any injury related to participation in the study, you should call Jerrold Petrofsky, Study Coordinator at 909-558-7274, during daytime hours (8:00 am-5:00 pm PST). If you require medical assistance, your personal physician or local emergency room should be contacted.

Participation Rights Summary:

- You are free to withdraw from this study at any time. If you decide to withdraw from this study you should notify the research team immediately. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, or if your safety and welfare are at risk.
- If you experience any of the discomforts listed above, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare.
- Likewise, your participation in the study may be stopped by the study staff/investigator for any reason without your agreement.

CONFIDENTIALITY

All records will be confidential and stored in a locked cabinet in a locked room. We will not disclose your participation without your written permission. Any publication resulting from this study will refer to you by ID number and not by your name. Your privacy rights are described in the attached Authorization for Use of Protected Health Information.

COSTS/COMPENSATION

There is no cost for participating in this study. You will receive a $25 gift card as an incentive for the completion of the study.

________ Initial
________ Date

"VISUAL FEEDBACK COMPARED TO TACTILE FEEDBACK IN REDUCING SWAY IN ELDERLY COMPARED TO AGE MATCHED DIABETIC SUBJECTS"

IMPARTIAL THIRD PARTY

If you wish to contact a third party not associated with the study for any questions or a complaint, you may contact the Office of Patient Relations at Loma Linda University, Loma Linda University Medical Center, Loma Linda, California 92354. Phone (909) 558-4647. patientrelations@llu.edu

INFORMED CONSENT STATEMENT

I have read the contents of the consent form and have listened to the verbal explanation given by the investigator. My questions regarding the study have been answered to my satisfaction. I hereby give voluntary consent to participate in the study described here. Signing this form does not waive my rights nor does it release the responsibilities of the principal investigator, Jerrold Petrofsky Ph. D. or Loma Linda University of their responsibilities. I may call Dr. Jerrold Petrofsky during routine office hours at (909) 558-4300 ex 82186 or leave a voice mail message at this number during non- office hours.

______________________________ __________________

Signature of subject Date

________ Initial
________ Date

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"VISUAL FEEDBACK COMPARED TO TACTILE FEEDBACK IN REDUCING SWAY IN ELDERLY COMPARED TO AGE MATCHED DIABETIC SUBJECTS"

INVESTIGATOR'S STATEMENT

I have reviewed the contents of the consent form with the person signing above. I have explained potential risks and benefits of the study. I further certify that I encouraged the subject to ask questions and that all questions asked were answered. I will provide the subject with a signed and dated copy of this consent form.

Signature of investigator ______________________________

Phone Number ________________________ Date ________________

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APPENDIX B

AUTHORIZATION FOR USE OF PROTECTED HEALTH INFORMATION

INSTITUTIONAL REVIEW BOARD
Authorization for Use of Protected Health Information (PHI)

Per 45 CFR §164.508(b)

OFFICE OF SPONSORED RESEARCH
Loma Linda University • 11188 Anderson Street • Loma Linda, CA 92350
(909) 558-4531 (voice) / (909) 558-0131 (fax)

TITLE OF STUDY: **The Effect of Visual Feedback Compared to Tactile Feedback in Reducing Sway in Elderly Compared to Age Matched Diabetic Subjects**

PRINCIPAL INVESTIGATOR: Jerrold Petrofsky

Others who will use, collect, or share PHI: Faris Alshammari

The study named above may be performed only by using personal information relating to your health. National and international data protection regulations give you the right to control the use of your medical information. Therefore, by signing this form, you specifically authorize your medical information to be used or shared as described below.

The following personal information, considered "Protected Health Information" (PHI) is needed to conduct this study and may include, but is not limited to: Name, Address, Telephone number, date of birth, results of all tests and procedures performed, and any adverse events.

The individual(s) listed above will use or share this PHI in the course of this study with the Institutional Review Board (IRB) and the Office of Research Affairs of Loma Linda University.

The main reason for sharing this information is to be able to conduct the study as described earlier in the consent form. In addition, it is shared to ensure that the study meets legal, institutional, and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk.

All reasonable efforts will be used to protect the confidentiality of your PHI, which may be shared with others to support this study, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the PHI may share with others if they are required by law, and they may share it with others who may not need to follow the federal privacy rule.

Subject to any legal limitations, you have the right to access any protected health information created during this study. You may request this information from the Principal Investigator named above but it will only become available after the study analyses are complete.

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#5120358 Chair R L Rigsby

IRB 12/07/2011

- This authorization does not expire, and will continue indefinitely unless you notify the researchers that you wish to revoke it.

You may change your mind about this authorization at any time. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for this study. However, study personnel may continue to use the health information that was provided before you withdrew your permission. If you sign this form and enter the study, but later change your mind and withdraw your permission, you will be removed from the study at that time. To withdraw your permission, please contact the Principal Investigator or study personnel at 909-558-7274.

You may refuse to sign this authorization. Refusing to sign will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are entitled. However, if you do not sign this authorization form, you will not be able to take part in the study for which you are being considered. You will receive a copy of this signed and dated authorization prior to your participation in this study.

I agree that my personal health information may be used for the study purposes described in this form.

Signature of Patient *or* Patient's Legal Representative	Date
Printed Name of Legal Representative (if any)	Representative's Authority to Act for Patient
Signature of Investigator Obtaining Authorization	Date

Loma Linda University
Adventist Health Sciences Center
Institutional Review Board
Approved 1/7/14 Void after 1/6/2015
5120358 Chair R L Rugleyrd

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