Evaluating the Effects of Ankle-Foot-Orthoses, Functional Electrical Stimulators, and Trip-specific Training on Fall Outcomes in Individuals with Stroke

by

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ABSTRACT

This dissertation aimed to evaluate the effectiveness and drawbacks of promising fall prevention strategies in individuals with stroke by rigorously analyzing the biomechanics of laboratory falls and compensatory movements required to prevent a fall. Ankle-foot-orthoses (AFOs) and functional electrical stimulators (FESs) are commonly prescribed to treat foot drop. Despite well-established positive impacts of AFOs and FES devices on balance and gait, AFO and FES users fall at a high rate. In chapter 2 (as a preliminary study), solely mechanical impacts of a semi-rigid AFO on the compensatory stepping response of young healthy individuals following trip-like treadmill perturbations were evaluated. It was found that a semi-rigid AFO on the stepping leg diminished the propulsive impulse of the compensatory step which led to decreased trunk movement control, shorter step length, and reduced center of mass (COM) stability. These results highlight the critical role of plantarflexors in generating an effective compensatory stepping response. In chapter 3, the underlying biomechanical mechanisms leading to high fall risk in long-term AFO and FES users with chronic stroke were studied. It was found that AFO and FES users fall more than Non-users because they have a more impaired lower limb that is not fully addressed by AFO/FES, therefore leading to a more impaired compensatory stepping response characterized by increased inability to generate a compensatory step with paretic leg and decreased trunk movement control. An ideal future AFO that provides dorsiflexion assistance during the swing phase and plantarflexion assistance during the push-off phase of gait is suggested to enhance the compensatory stepping response and reduce more falls. In chapter 4, the effects of a single-session trip-specific training on the compensatory stepping response of individuals with stroke were evaluated. Trunk movement control was improved after a single session of training suggesting that this type of training is a viable option to enhance compensatory stepping response and reduce falls in individuals with stroke. Finally, a future powered AFO with plantarflexion assistance complemented by a trip-specific training program is suggested to enhance the compensatory stepping response and decrease falls in individuals with stroke.

DEDICATION

I dedicate this dissertation to my parents whose unconditional love and support help me achieve any goals.

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TABLE OF CONTENTS

CHAPTER Page

APPENDIX

LIST OF TABLES

LIST OF FIGURES

Figure Page

CHAPTER 1

INTRODUCTION

1.1. Significance

Falls are the leading cause of injury among older adults. According to CDC, in 2014, older Americans experienced 29 million falls leading to 7 million injuries and cost the US health care system an estimated 31 billion dollars. During 2014, approximately 27,000 older adults (aged over 65 years old) died as the result of falling [1]. Falls lead to severe injuries such as hip fracture, wrist fracture, and head injuries [2–6]. Moreover, falls lead to increased morbidity, immobility, fear of falling [7–10], and reduced quality of life [11–15] Individuals with stroke are one the largest groups at major risk of falling [8]. Individuals with stroke are 1.77 times more likely to fall compared to age-matched neurologically unimpaired individuals [16], making falls the most common medical complication post stroke [7,8,17].

1.2. Impaired postural control and gait deficits in individuals with stroke

Impaired postural control and gait deficits which are caused by numerous post-stroke sensory and motor deficits such as decreased multisensory integration, spasticity, muscle weakness, and abnormal muscle tone [18–20], lead to heightened risk of falling [8,9,21]. Whole-body postural control is critical for fall prevention during quiet stance, voluntary movements (e.g. sit to stand, gait), as well as following an external postural perturbation [8]. In community-dwelling individuals with stroke, most falls occur during walking [8,9,22–25] and due to external postural perturbations (e.g. trips and slips) [25]. Post-stroke gait deficits such as foot drop (i.e. inability to lift the forefoot off the ground during the swing phase of gait) increase the risk of stumbling and falling [26,27]. More importantly, delayed and impaired reactive responses (e.g. compensatory stepping response and reach-to-grasp movement) to an external postural perturbation put individuals with stroke at heightened risk of falling [28–30].

1.3. Compensatory stepping response in individuals with stroke

Compensatory stepping response following a postural perturbation, a critical response for balance maintenance and fall prevention [31–34], is impaired in individuals with stroke [35–37]. Impaired compensatory stepping responses in stroke survivors are best characterized by reduced trunk stability [30,38,39], shorter step length [30,38,40], delayed step initiation [28,36,39,40], multiple stepping [35], and inability to initiate stepping response with paretic limb [29,35]. Recent studies have shown that impaired compensatory stepping response in stroke survivors is correlated to increased number of falls [28,29].Thus, in order to reduce high risk of falling in stroke survivors, it is essential to develop robust interventions to enhance the compensatory stepping response.

1.4. Ankle weakness and foot drop

Seventy-six percent of stroke survivors suffer from ankle weakness [41] leading to gait deficits (e.g. foot drop), reduced walking speed, and increased risk of falling [8]. Approximately 20% of stroke survivors have foot drop [42], a lower limb motor deficit that causes poor ankle dorsiflexion required to clear foot from the ground during the gait, thereby increases the risk of stumbling and falling [27,43]. Moreover, reduced forward propulsion [44,45] due to decreased calf muscle activation during push-off phase [46,47], not only reduces walking speed [48], but relates to reduced knee flexion angle [49] during gait, which causes inadequate toe clearance during the swing phase and thereby increasing risk of stumbling and falling [8]. Ankle push-off power provides kinetic energy and speed of the trailing limb [50], which is crucial for generating an adequately rapid and propulsive compensatory stepping response to prevent a fall. Consequently, reduced propulsion due to ankle weakness might impede the speed and effectiveness of a compensatory stepping response. Therefore, in order to reduce risk of falling in stroke survivors, it is essential to effectively address ankle weaknesses/impairments – which have previously shown to increase risk of falling in elderly population [51].

1.5. Strategies to prevent falls

Two promising strategies to enhance compensatory stepping response and address ankle and gait deficits (key factors for fall prevention) are training interventions and assistive devices. While several forms of these interventions are currently used, the high rate of falling in stroke survivors suggests that existing interventions are not adequately effective. Lack of knowledge about the impact of these interventions on falling rate in stroke survivors necessitates a rigorous evaluation of the existing interventions to determine whether fall risk can be reduced through these interventions. This dissertation aims to evaluate the impact of these two interventions on fall outcomes and compensatory stepping response of stroke survivors to establish the most robust solutions to reduce falls.

1.5.1. Ankle-Foot-Orthoses (AFOs) and Functional Electrical Stimulators (FES)

Ankle-foot orthoses (AFOs) are commonly prescribed to treat foot drop and facilitate gait. The most commonly used AFOs are passive thermoplastic models [52,53] which are designed to hold the paretic ankle joint at a certain angle and facilitate foot clearance during the swing phase, ankle stability during the stance phase, and heel strike [54]. Several studies have reported that wearing a passive AFO improves gait parameters such as gait velocity, stride length, and cadence in stroke survivors [55–61]. While the reported improvements are beneficial and are suggested to help reduce risk of falling in stroke survivors, the impact of wearing an AFO on falling rate is not well evaluated [8].

While the effects of wearing an AFO on mobility, walking, and static balance of stroke survivors have been well studied, there is a lack of knowledge about the impacts of AFO use on fall risk under dynamic conditions (e.g. trip and slip) where most falls occur. AFO use has shown to improve gait parameters (e.g. walking speed and step length) [52,61,62], functional mobility measures such as Timed Up & Go (TUG) [58,63–65], and functional balance measures such as Berg Balance Scale (BBS) [58,63,66] and functional reach test [67]. Furthermore, several studies have shown that wearing an AFO improves weight-bearing symmetry [60,61,68–70] as well as postural stability – quantified by center of pressure sway measures [60,71]; however, two recent review articles have found no improvements in postural sway and mixed results in functional balance (e.g. Berg Balance Scale) [61,72]. Thus, the effects of wearing an AFO on static postural stability is still inconclusive. Further, the improvements in walking and balance have been generally shown by short-term effects of AFO use but with no attention to long-term or chronic use [61]. While the impact of AFO use on anticipatory postural control, functional balance, and mobility has been well studied, it is unknown how AFOs impact reactive postural control (e.g. compensatory stepping response) following external postural perturbations – which cause most falls in community-dwelling stroke survivors [25].

The impact of AFO use on compensatory stepping response following a postural perturbation, which is critical for fall prevention [31–34,73,74] is unevaluated. Instead, the impact of AFO use on static balance and mobility, which have not been proven strong predictors of falls [23,30,75], has been generally evaluated and utilized for fall risk assessment. Ankle impairments – the primary reason for prescribing AFOs – might impede the effectiveness of a compensatory stepping response and thereby increase risk of falling. It is unclear how mechanical effects of an AFO combined with ankle joint impairments, impact the effectiveness of compensatory stepping response. Thus, in order to have a more realistic assessment of how AFO use impacts fall risk, a rigorous evaluation of AFO's impact on compensatory stepping response following postural perturbations is essential.

Constraining the ankle joint motion by wearing a passive AFO may adversely impact the efficacy and speed of ankle strategy and compensatory stepping response required for balance maintenance, thus potentially increase risk of falling. Constraining the ankle joint may inhibit proprioceptive sensory information as well as propulsion which have critical roles in reactive postural control. Plantarflexor muscles which are the primary contributors to generating forward propulsion during gait [76–80] are commonly impaired in stroke survivors [48,81,82] and AFO use might further inhibit propulsion. There is evidence that wearing a rigid AFO impedes forward propulsion and dynamic balance in healthy adults and children with hemiplegic cerebral palsy [76,83–85]. In a dynamic condition following a trip or slip, impeding forward propulsion, which is the primary contributor to the kinetic energy and speed of the stepping limb [50], might deteriorate the effectiveness and speed of the compensatory stepping response. Fall risk may be increased if the anticipated adverse effects of an AFO on the reactive response to a perturbation outweigh its positive effects on gait deficits. Walking speed which is a widely evaluated measure in the literature to assess the efficacy of AFO use might be a misleading measure not reflective of inhibitory effects of AFO on paretic limb propulsion. For example, walking speed can be compensated by generating larger propulsion on the non-paretic side [86]. In order to achieve a more realistic and reliable assessment of AFO's impact on fall risk, fall outcomes and compensatory stepping responses should be considered for rigorous evaluation. While AFOs are the most widely used orthotic devices in the US [53], their impact on fall prevention ability under dynamic conditions is unevaluated. To our knowledge, the only study evaluating the effects of wearing an AFO on balance control during postural perturbations was carried out in children with cerebral palsy [87] and showed diminished balance control associated with wearing a rigid AFO. Therefore, to determine whether AFOs increase or decrease risk of falling, it is essential to evaluate the impact of AFO use on compensatory stepping response required to prevent a fall as well as fall outcomes. However, AFO users' compensatory stepping response might be affected by a combination of mechanical inhibitory impacts of the AFO on the ankle, ankle impairments (e.g. calf muscle weakness, spasticity), and abnormal movement strategies developed to compensate the ankle weakness (e.g. circumduction, increased hip torque/flexion) [48,88]. Therefore, the results of the study on AFO users might reflect not only the AFO's impact but a combination of all these factors. A preliminary analysis of AFO's impact on young healthy individuals is suitable to solely investigate the mechanical effects of the AFO on the ankle and compensatory stepping response.

Functional Electrical Stimulators (FESs) are an alternative to AFOs to treat foot drop. FES devices lift the forefoot during the swing phase of gait by stimulating the peroneal nerve. Similar to AFOs, FES devices have shown beneficial effects on walking speed [13,26,27,52], static balance measured by Berg Balance Scale (BBS) [13], physical activity [89], and gait asymmetrical patterns [26]. Despite the established benefits of these devices, they are not as commonly prescribed as conventional AFOs because of their high price, lack of coverage by insurance providers, and insufficient evidence for more beneficial impact on walking and balance compared to conventional AFOs [90]. Unlike AFOs, FES devices do not mechanically inhibit the motion of the ankle joint. Therefore, theoretically, FES devices may perform better than AFOs under dynamic conditions where a compensatory stepping response is required. To our knowledge, the impacts of FES devices on compensatory stepping response of stroke survivors are not evaluated. Thus, it is important to investigate whether FES devices have a better effect on compensatory stepping response and prevent more falls compared to AFOs.

1.5.1.1. Objectives and hypotheses

This series of studies aimed to evaluate the impacts of wearing passive AFOs as well as FES devices on fall risk of individuals with stroke following dynamic postural perturbations that mimic the environmental conditions that lead to the most falls in the community. Trips are one of the most prevalent causes of community falls [91,92]. Treadmill postural perturbations evoking stepping responses similar to those elicited following a trip [93] were used in these studies. As a preliminary study and to solely evaluate the mechanical impacts of an AFO, young healthy individuals were fitted with a semi-rigid AFO and their compensatory stepping response was evaluated without and with the AFO on either leg. The **first objective** was to evaluate the impact of a semi-rigid thermoplastic AFO on the compensatory stepping response in young healthy individuals following trip-like treadmill perturbations. Compensatory stepping response kinematics were compared between these conditions 1) AFO on the stepping leg, 2) AFO on the support leg, and 3) No AFO. It was **hypothesized** that AFO use would impair the compensatory stepping response measured by decreased step length, less stable trunk control (increased trunk flexion and velocity), and reduced dynamic stability. Moreover, it was **hypothesized** that changes in the compensatory stepping response would be correlated to a reduced propulsive impulse of the step.

Despite well-established positive impacts of AFOs and FES devices on balance and gait, AFO and FES users still fall at a high rate of 40% [94]. The **second objective** was to investigate the underlying biomechanical mechanisms leading to high risk of falling in long-term AFO and FES users with chronic stroke. Fall outcomes and compensatory stepping response of individuals with stroke (AFO users, FES users, and Non-users) during treadmill perturbations that mimic over-ground trips [93] were evaluated. Further, to determine the impact of AFO and FES devices on the compensatory stepping response and fall outcomes, subjects were tested without the presence of AFO/FES as well. It was **hypothesized** that both AFO and FES users would fall more often than Non-users and have more impaired compensatory stepping response characterized by decreased trunk movement control and reduced capability to generate a step with the paretic leg. Also, it was expected that AFO users would fall more often and have more impaired compensatory stepping responses compared to FES users. Finally, it was **hypothesized** that AFO and FES use would not enhance the compensatory stepping response.

1.5.2.Training interventions

While currently used exercise-based fall prevention training programs have shown to reduce falls in neurologically unimpaired older adults [95–98], these programs have been unsuccessful in reducing the number of falls in stroke survivors [8,99–103]. These programs mainly focus on enhancing muscles strength, static balance, voluntary postural control, and mobility [100,102–105] with no attention to reactive postural control. Mobility in stroke survivors (e.g. walking speed and walking capacity) has been shown to improve through these programs [99,101]. While the mobility enhancements are beneficial, most falls occur due to delayed and impaired compensatory stepping response following a postural perturbation [28–30,39] during walking [8,9,22–25]. Thus, enhancing the compensatory stepping response is suggested to be a key factor to reduce the number of falls. A more targeted fall prevention intervention focusing on enhancing the reactive response (e.g. compensatory stepping response) to postural perturbations might be required to effectively decrease falls in stroke survivors.

Trip-specific training – a novel fall prevention intervention including repeated exposures to postural perturbations in a safe manner – has been recently raised as a potential solution [30,106,107]. Trip-specific training has been designed to enhance the compensatory stepping response required to prevent a fall following a trip. Trip-specific training has been shown to effectively reduce the number of prospective falls by older adults [106,108] and by individuals with Parkinson's disease [109,110]. Importantly, the improvements can be seen in as little as two weeks [108] or even one session [111,112]. Further, the improvements are retained up to one year [113,114]. Postural perturbations are delivered through a sudden movement such as waist push or pull, treadmill belt translation, and over-ground trip while the individual is fitted in a harness that prevents falls and injuries. Importantly, improvements achieved through one modality (treadmill perturbations) have shown to translate to other environmental conditions (over-ground trips) [115,116]. Specifically, older women who received treadmill perturbations showed reduced falls following over-ground trips [116]. Despite the potential of this type of training and currently high risk of falling in stroke population, the efficacy of trip-specific training is unevaluated in stroke survivors. To our knowledge, only two groups have evaluated the efficacy of a training program including postural perturbations (by pushing or pulling the subject) in stroke survivors [117–119]. Two of the studies [117,118] showed a reduced number of falls in training group. However, in both studies training programs included other parts such as voluntary movements training which might have affected the results. Further, one of the studies [118] was not a randomized controlled trial and only studied individuals with subacute stroke. While their results suggest trip-specific training as a solution to reduce falls in stroke population, the limitations of their results leave the question of whether stroke survivors are amenable to trip-specific training unanswered. Therefore, it is essential to evaluate the independent effects of trip-specific training on fall outcomes and compensatory stepping response of individuals with chronic stroke to investigate whether stroke survivors are amenable to this fall prevention intervention. Stroke survivors are afflicted with numerous neuromuscular deficits such as spasticity/flaccidity, abnormal synergistic patterns of muscle activation, muscle weakness [8,120–125], and diminished capacity for motor learning [126–128] making exercise-based programs less effective.

Thus, it is unknown if the same trip-specific training proven effective in neurologically unimpaired older adults is amenable to stroke survivors. Disease-related modifications might be required in order to establish a robust protocol for stroke survivors unless these deficits can be addressed by the training intervention. Evaluating the impacts of trip-specific training on compensatory stepping response and fall outcomes can contribute to establish the most effective training protocol for stroke survivors in which disease-related deficits (e.g. inability or reluctance to step with paretic limb) are considered.

1.5.2.1. Objectives and hypotheses

This study aimed to assess the viability of trip-specific training as an effective fall prevention intervention in individuals with stroke. The **third objective** was to evaluate the ability of a single session of trip-specific training to enhance compensatory stepping response of individuals with stroke. Compensatory stepping response of individuals with stroke was assessed before and after a single session of trip-specific training consisting of 15 perturbations evoking forward stepping responses similar to those elicited following a trip [93]. It was **hypothesized** that compensatory stepping response would be enhanced (specifically characterized by enhanced trunk stability) after the trip-specific training. However, to achieve a reduced number of falls, an extensive version of the training program with multiple sessions, including different intensities of perturbation might be required.

CHAPTER 2

THE IMPACT OF ANKLE-FOOT-ORTHOSIS (AFO) USE ON THE COMPENSATORY STEPPING RESPONSE REQUIRED TO AVOID A FALL DURING TRIP-LIKE PERTURBATIONS IN YOUNG ADULTS: IMPLICATIONS FOR AFO PRESCRIPTION AND DESIGN

2.1. Abstract

Ankle-foot-orthoses (AFOs) are commonly prescribed to treat foot drop and enhance walking in fall-prone individuals (e.g. stroke). AFOs improve static balance but AFO-users are still at high fall risk. To our knowledge, no one has studied the biomechanical effect of AFO-use on the compensatory stepping response required to avoid falling during dynamic conditions such as trip, the leading cause of falls. The objective of this study is to evaluate the impact of a semi-rigid thermoplastic AFO on the compensatory stepping response in young healthy individuals following trip-like treadmill perturbations. We found that the AFO on the stepping leg (AFO-step) decreased trunk stability (increased trunk flexion and velocity), shortened the compensatory step length, and reduced dynamic stability (smaller Dx). AFO on the support leg (AFO-support) was only marginally different from the No-AFO condition. Detrimental changes in compensatory stepping response (e.g. decreased trunk stability) were linearly correlated to diminished propulsive impulse of the step. In summary, AFO-use on the stepping leg is associated with impaired compensatory stepping response (e.g. reduced trunk stability) and decreased propulsive impulse in young adults. It is important to note that AFO-use enhances static stability and decreases the probability of a trip/stumble occurring indicating they are important for fall prevention. Still, our results suggest that AFO-use may impair the compensatory stepping response after a trip/stumble has occurred and may suggest that preserving plantarflexion function may support the compensatory stepping response. Further study of these devices and their impact on compensatory stepping response in fall-prone individuals is warranted.

2.2. Introduction

Ankle-foot-orthoses (AFOs) are the most commonly prescribed orthosis in the U.S [53]. AFOs treat foot drop and enhance gait by increasing walking speed [52,61,62], decreasing asymmetrical gait patterns [129], and enhancing joint control [130] in individuals with distal weakness (e.g. stroke, peripheral neuropathy). Despite the high prevalence of their use in fall-prone populations, AFOs impact on fall risk, particularly under dynamic conditions, is not well evaluated [8].

Under static balance conditions, AFOs enhance Berg Balance scores [131,132], reaching distance [67], and static postural stability [131]. Despite these advantages, AFO-users are still at substantial risk of falling. A long-term, randomized controlled trial of AFO-users reports a fall rate of 40% over 12 months after prescription regardless of the type of AFO (thermoplastic or nerve stimulator) worn [94]. Further, individuals with acute stroke who wear an AFO early after stroke are 2.75 times more likely to fall compared to individuals with stroke who have a clinical need for an AFO but are not prescribed it until 8 weeks post-stroke [133]. These data indicate that AFO users are at significant risk of falling but to our knowledge, no one has evaluated the biomechanical effect of an AFO on the compensatory stepping response required to prevent a fall after a balance disturbance such as trip or slip – the most prevalent causes of falls [25,92,134–137].

AFOs restrict ankle movement and affect the mechanics of motion, which may impair the compensatory stepping response. The most commonly prescribed AFO is the thermoplastic model [53] which either completely restricts or allows only small motion of the ankle. This restriction of motion decreases and in some cases eliminates plantarflexion force which has been shown to be important in driving forward propulsion [76,79,138,139] and controlling whole-body angular momentum during locomotion [76,140]. Further, rigid AFO use has been shown to impede forward propulsion and dynamic balance during gait in healthy adults and children with cerebral palsy [76,83,84]. Following an external balance perturbation such as trip, an effective compensatory stepping response, characterized by a long step, stable trunk movement, and stable center of mass (COM) is critical to avoid a fall [30,93,141,142]. Therefore, decreasing or eliminating forward propulsion through AFO usage may impair the compensatory stepping response leaving individuals with a diminished capacity to avoid a fall following a dynamic balance challenge.

The objective of this study is to evaluate the impact of a semi-rigid thermoplastic AFO on the compensatory stepping response in young healthy individuals following trip-like treadmill perturbations. We used treadmill perturbations that mimic over-ground trips [93]. Treadmill perturbations were used instead of over-ground trips because they allow more “trips”, under multiple conditions. We hypothesized that AFO use would impair the compensatory stepping response measured by decreased step length, less stable trunk control (increased trunk flexion and velocity), and reduced dynamic stability. Finally, we hypothesized that changes in the compensatory stepping response would be correlated to a reduced propulsive impulse of the step.

2.3. Methods

Ten healthy adults including 3 females and 7 males (age = 22.8 ± 2.9 years, weight = 71.6 ± 10.7 kg, height = 176.7 ± 11.4 cm) participated in this study. To participate, subjects could not have any neurological and/or musculoskeletal disorders and/or injuries. The study was carried out at Arizona State University (ASU) under the IRB approved protocol STUDY00002970.
Subjects provided written informed consent prior to the experiment. Subjects’ age, height, and weight were recorded. Subjects were fitted with a pre-fabricated semi-rigid AFO (Fig. 2.1). Subjects were tested with the AFO on each leg and also without the AFO. Conditions were randomized across the subjects. For each condition, subjects were asked to walk 5 minutes around our laboratory space to warm up and get accustomed to the condition. Moreover, subjects performed a 2-minute warm-up walk for each condition on an instrumented dual-belt treadmill (GRAIL, Motek Medical BV, Amsterdam, The Netherlands) with self-selected comfortable speed while fitted in a safety harness.

Figure 2.1. Pre-fabricated semi-rigid AFO used in the present study.

After the acclimation period, subjects were asked to stand quietly on the treadmill. Graded posteriorly- and anteriorly-directed balance perturbations that required one or multiple steps to regain balance were delivered. Posteriorly-directed perturbations, evoking a forward step, were the test condition because they have been shown to mimic the mechanics of over-ground trips [93]. Anteriorly-directed perturbations were delivered in a randomized fashion to reduce anticipation of the perturbation and certainty of the direction.

Under each condition, subjects received two rounds of randomized perturbations consisting of 3 levels (small, medium, and large) of posteriorly- and 3 levels (small, medium, large) of anteriorly-directed perturbations. In addition, one acclimation round, which was not included in the analysis, was delivered at the beginning of the first condition. Perturbations had a trapezoidal velocity profile similar to previously published work in young healthy adults, older adults, and stroke survivors [30,143]. Displacement, constant velocity, acceleration, and deceleration of the posteriorly-directed perturbations' velocity profiles were as follows: small: 15% of body height (m), 1.26 m/s, 12.6 m/s^2, -12.6 m/s^2, medium: 32% of body height (m), 1.26 m/s, 12.6 m/s^2, -12.6 m/s^2, and large: 45% of body height (m), 1.26 m/s, 12.6 m/s^2, -12.6 m/s^2. The displacement, constant velocity, acceleration, and deceleration of anteriorly-directed perturbations were as follows: small:

9% of body height (m), -1.0 m/s, -10.0 m/s^2, 10.0 m/s^2, medium: 20% of body height (m), -1.1 m/s, -11.0 m/s^2, 11.0 m/s^2, and large: 35% of body height (m), -1.1 m/s, -11.0 m/s^2, 11.0 m/s^2. 3D kinematic data were recorded via a 10-camera motion capture system (Vicon, Oxford, UK) at 100 Hz using 22 passive-reflective markers attached to the subject's body landmarks according to modified Helen Hayes marker set [144]. Markers' data were smoothed using a 4th order Butterworth filter with a 6 Hz cutoff frequency (Vicon Nexus 2.6.1, Vicon, Oxford, UK). Kinematic variables of the compensatory stepping response were calculated using smoothed markers' trajectory data and MATLAB software (Mathworks, Natick, MA). Ground reaction force (GRF) data of each leg was collected through the force plate (Bertec, Columbus, OH) embedded in each belt of the instrumented dual-belt treadmill at 2000 Hz and a 4th order Butterworth filter with a 20 Hz cutoff frequency was applied through MATLAB software. GRFs were normalized by the subject's weight.

The following metrics were calculated during the first compensatory step: Trunk flexion and velocity, Step length, Dx, Reaction time, Step duration, Ankle flexion angle and velocity, Foot progression angle and velocity, and Propulsive impulse of the stepping leg. Variables are defined in Table 2.1 and illustrated in Figure 2.2. Trunk, ankle, and foot progression measures were calculated at initiation (SS: Step Start) and completion (SE: Step End) of the first compensatory step. SS (i.e. toe-off) and SE (i.e. foot contact) were detected using vertical GRF of the stepping leg with a 20 N threshold. A custom build MATLAB script detected SS and SE and they were verified manually by the experimenter.

Table 2.1. Definition of the dependent variables.

Dependent variables	**Definition**
Step length	The anterior-posterior displacement between stepping and support foot centers at SE.
Trunk flexion	The angle between the trunk segment and vertical line in the sagittal plane relative to the initial angle of the trunk at perturbation onset. Anterior trunk inclination is considered positive direction.
Trunk flexion velocity	First derivative of Trunk flexion with respect to time.
Dx (COM-BOS)	The anterior-posterior displacement between the center of mass (COM) and the boundary of base of support (i.e. stepping leg toe marker) at SE. Positive values represent COM within (i.e. posterior to) the base of support.
Reaction time	The time between perturbation onset to toe-off (i.e. SS).
Step duration	The time between step initiation (SS) and completion (SE).
Ankle flexion angle	The sagittal plane angle between the foot and shank segments deviated from the right angle (90 degrees). Positive angles represent plantarflexion and negative angles represent dorsiflexion.
Ankle flexion velocity	First derivative of the Ankle flexion angle with respect to time.
Foot progression angle	The sagittal plane angle between foot and ground/treadmill surface (horizontal plane) with positive values representing a foot inclination with toe marker inferior to the heel marker.
Foot progression velocity	First derivative of the Foot progression angle with respect to time.
Propulsive impulse	The integration of anteriorly-directed shear ground reaction force of the stepping leg during forward propulsion with respect to time normalized to the subject's weight.

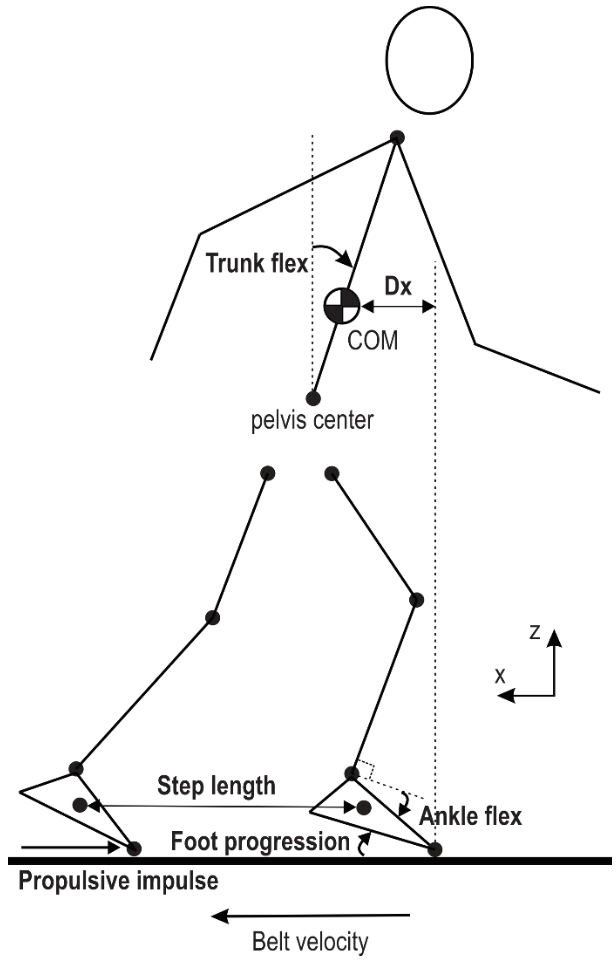

Figure 2.2. Schematic of the subject's body configuration at the completion of the first compensatory step with kinematic and kinetic variables. All variables are depicted in positive orientation. Note: ankle plantarflexion is considered positive flexion (as shown in the figure) and ankle dorsiflexion is considered negative flexion. Abbreviations: flex = flexion.

We compared the first compensatory step between 3 conditions: 1) AFO on the stepping leg (AFO-step), 2) AFO on the supporting leg (AFO-support), and 3) No-AFO. We hypothesized that AFO use would impair the compensatory stepping response measured by decreased step length, less stable trunk control (increased trunk flexion and velocity), and reduced dynamic stability. To test this hypothesis, we performed an ANOVA using Generalized Linear Mixed-effects Model (GLMM) [145] with conditions (AFO-step, AFO-support, No-AFO) and perturbation level (small, medium, large) as independent variables, and previously defined measures (Table 1; e.g. Trunk flexion) as dependent variables. Subjects were considered as a random factor. We used Tukey

HSD for all post-hoc comparisons of the conditions. We further hypothesized that changes in the compensatory stepping response would be correlated to a reduced propulsive impulse of the step. We performed a linear regression analysis with Propulsive impulse as the independent variable and Trunk flexion and velocity, Step length, and Dx as the dependent variables. Statistical analyses were performed using R (R Development Core Team, 2006). Linear regression plots were created using SPSS 25 (IBM, Armonk, NY). Significance level was considered as $p<0.05$.

2.4. Results

The AFO on the stepping leg (AFO-step) condition was associated with larger Trunk flexion and Trunk flexion velocity, smaller Step length, and reduced Dx compared to the No-AFO condition while AFO on the non-stepping/support leg (AFO-support) was mostly similar to the No-AFO condition (Fig. 2.3). Trunk flexion at SS and SE were 19.7% and 10.0% larger during AFO-step compared to No-AFO (P=0.0003; P=0.001, respectively). Trunk flexion velocity at SS was 11.7% larger during AFO-step compared to No-AFO (P=0.0001) but Trunk flexion velocity at SE was not different (P=0.30) between AFO-step and No-AFO. Step length and Dx during AFO-step were 6.1% and 10.7% smaller compared to No-AFO (P=0.01; P=0.006, respectively). Step duration and Reaction time were not different between AFO-step and No-AFO (both P>0.13).

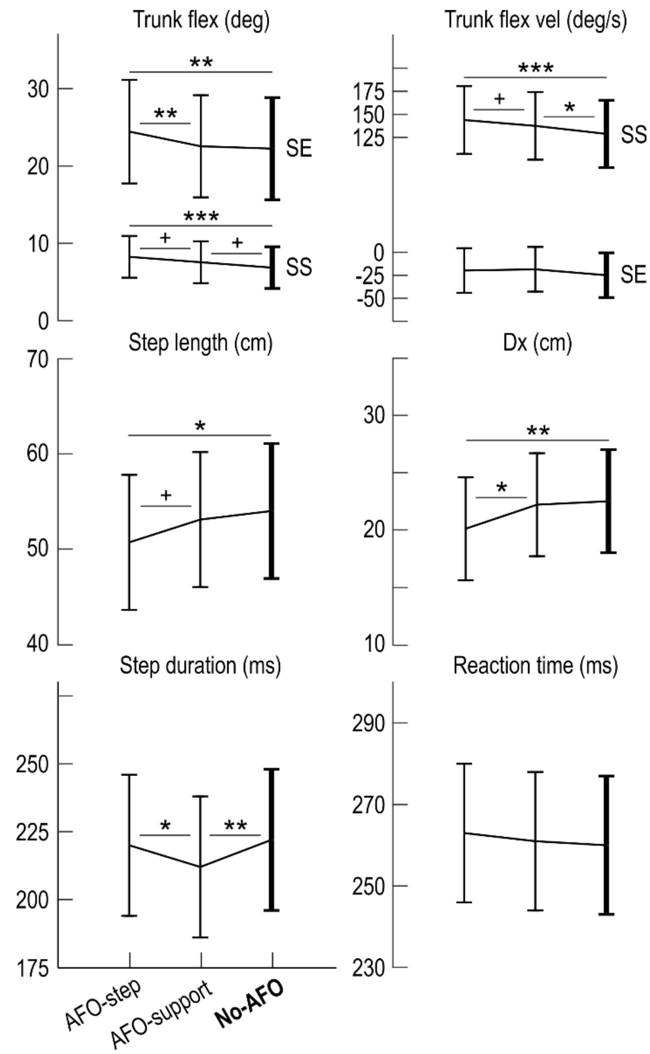

*Figure 2.3. Comparison of the compensatory stepping response kinematics between conditions. The figure depicts comparison of the Trunk flexion and velocity, Step length, Dx, Step duration, and Reaction time during AFO-step, AFO-support, and No-AFO conditions. Error bars represent ± standard error. Abbreviations: AFO-step = AFO on the stepping leg, AFO-support = AFO on the support leg, flex = flexion, vel = velocity, SS = Step Start, SE = Step End. Note: + ≤ P-value < 0.1, * = P-value < 0.05, ** = P-value < 0.01, *** = P-value < 0.001.*

AFO-support and No-AFO were not different in all the aforementioned measures (all *P*> 0.06) except Trunk flexion velocity at SS, which was 6.8% larger during AFO-support (*P*=0.02), and Step duration which was 4.5% smaller during AFO-support (*P*=0.008).

AFO on the stepping leg (AFO-step) decreased ankle motion, Foot progression, and Propulsive impulse of the step (Fig. 2.4). Propulsive impulse during AFO-step was 22.1% smaller compared to No-AFO (*P*<0.0001). Ankle flexion angle at SS and SE during AFO-step were 78.8% and 58.5% smaller compared to No-AFO respectively (both *P*<0.0001). Ankle flexion velocity at SS (plantarflexion) and SE (dorsiflexion) during AFO-step were smaller by 36.0% and 50.8% compared to No-AFO (both: *P*<0.0001). Foot progression angle and velocity at SS during AFO-step were 9.9% and 18.7% smaller compared to No-AFO respectively (both *P*<0.0001). Foot progression angle at SE was 212.5% smaller during AFO-step compared to No-AFO (*P*<0.0001). Importantly, Foot progression angle at SE was negative during AFO-step (i.e. heel strike: landing foot on the treadmill with heel), while it was positive during No-AFO (i.e. forefoot strike – landing with toes). Foot progression velocity at SE during AFO-step was 187.0% larger (and positive) compared to No-AFO (negative direction) (*P*<0.0001).

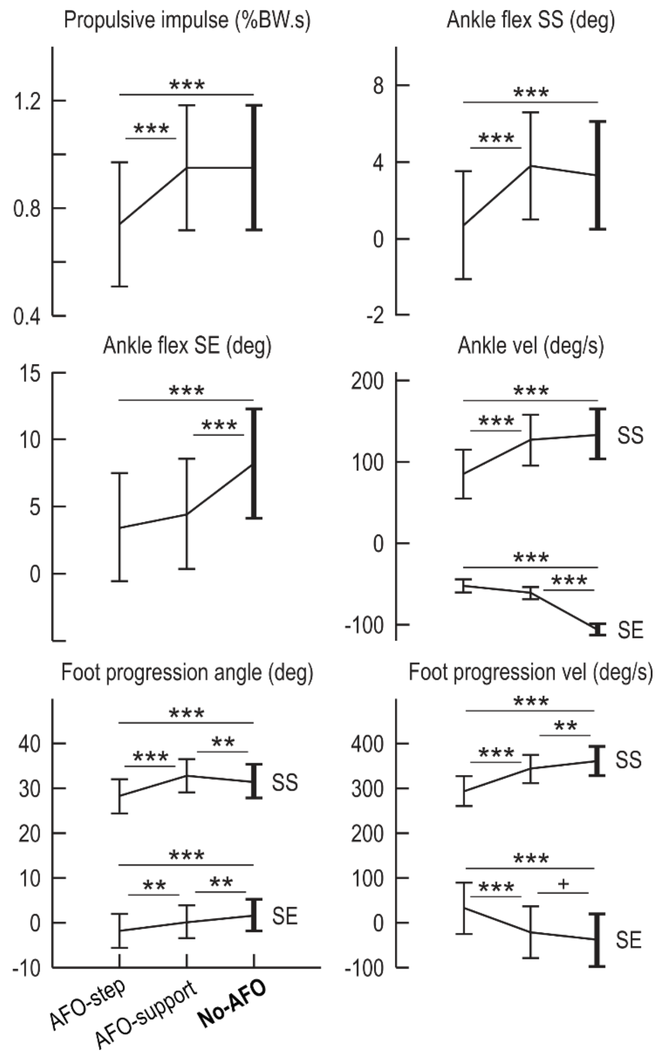

*Figure 2.4. Comparison of the Propulsive impulse, Ankle kinematics, and Foot progression kinematics between conditions. Propulsive impulse of the stepping leg, Ankle flexion and velocity, and Foot progression angle and angular velocity are compared between AFO-step, AFO-support, and No-AFO. Error bars represent ± standard error. Abbreviations: AFO-step = AFO on the stepping leg, AFO-support = AFO on the support leg, flex = flexion, vel = velocity, SS = Step Start, SE = Step End, BW = Body Weight. Note: + ≤ P-value < 0.1, * = P-value < 0.05, ** = P-value < 0.01, *** = P-value < 0.001.*

AFO on the support leg (AFO-support) did not affect the Propulsive impulse of the step but several differences were found in stepping ankle and foot kinematics. Propulsive impulse, Ankle flexion angle and velocity at SS were not different between AFO-support and No-AFO (all *P*>0.16). Ankle flexion angle at SE was 46.3% smaller during AFO-support compared to No-AFO (*P*<0.0001) and Ankle flexion velocity (dorsiflexion) at SE was 42.9% smaller in magnitude (i.e.

less negative) during AFO-support compared to No-AFO (P=0.0001). Foot progression angle at SS during AFO-support was 4.5% larger compared to No-AFO (P=0.006). Foot progression velocity at SS was 4.7% smaller during AFO-support compared to Non-AFO (P=0.008). Foot progression angle at SE was 93.8% smaller during AFO-support compared to No-AFO (P=0.009). Foot progression velocity at SE was not different between AFO-support and No-AFO (P=0.07).

Propulsive impulse was linearly correlated with Step length, Trunk flexion at SS and SE, Trunk flexion velocity at SS, and dynamic stability (Dx) in all subjects and conditions (Fig. 2.5). Propulsive impulse was positively correlated with Step length and Dx (both P<0.0001) while it was negatively correlated with Trunk flexion and velocity at SS and Trunk flexion at SE (all P<0.0001). No correlation was found between Propulsive impulse and Trunk flexion velocity at SE (P=0.17).

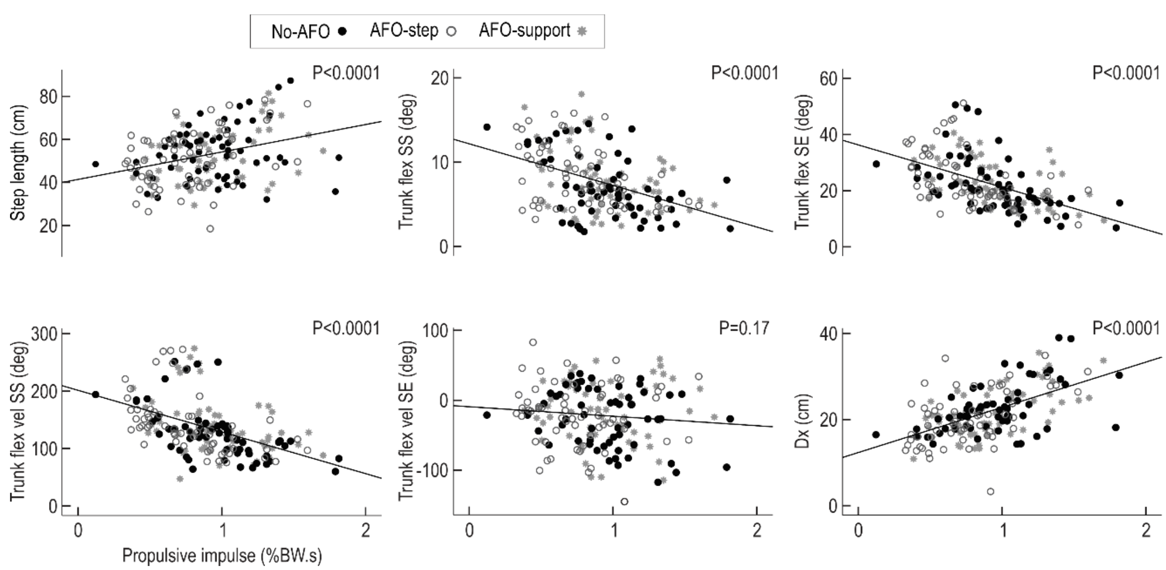

Figure 2.5. Propulsive impulse vs. Step length, trunk kinematics, and Dx. The figure depicts linear regression plots with Propulsive impulse as the independent variable and Step length, trunk kinematics, and Dx as dependent variables. Abbreviations: AFO-step = AFO on the stepping leg, AFO-support = AFO on the support leg, flex = flexion, vel = velocity, SS = Step Start, SE = Step End, BW = Body Weight.

2.5. Discussion

2.5.1. Summary

The objective of this study was to evaluate the impact of a semi-rigid thermoplastic AFO on the compensatory stepping response in young healthy individuals following trip-like treadmill perturbations. We found that the AFO on the stepping leg (AFO-step) negatively affected the compensatory stepping response by decreasing trunk stability (increased Trunk flexion and velocity), shortening the step, and reducing dynamic stability (smaller Dx). However, the AFO on the support leg (AFO-support) was only marginally different from the No-AFO condition. Notably, the impact on the compensatory stepping response was correlated to diminished Propulsive impulse of the step. In summary, AFO-use on the stepping leg is associated with decreased Propulsive impulse and impaired compensatory stepping response (e.g. reduced trunk stability) in young adults.

There are numerous causes and circumstances of falls and thus it is important to note that AFOs enhance important metrics (e.g. static stability, reaching distance) that decrease falls under these circumstances (e.g. transfers). Moreover, AFOs decrease the probability of a trip/stumble occurring by increasing toe clearance during gait [146,147]. The results here suggest that AFO-use may impair the compensatory stepping response *after* a trip/stumble has occurred. Additionally, though requiring further study, the correlation between propulsive impulse and trunk stability suggests that individuals with stroke that have residual capability to generate plantarflexion forces might perform better with AFO designs that allow plantarflexion expression (e.g. peroneal nerve stimulators, articulated AFOs). Regardless, given AFO-users already impaired compensatory stepping response [35,37] and its correlation with increased fall rate [28], further study of these devices and how they affect the compensatory stepping response in fall-prone individuals is warranted.

2.5.2. AFO use and falls

AFO-use is beneficial – increasing walking speed [52,61,62] and joint control [130], decreasing asymmetrical gait patterns [129], enhancing Berg Balance scores [131,132] and static postural stability [131]. Additionally, dorsiflexion support (of any kind) is critical to reestablishing gait and avoiding stumbles/trips in the community. Many individuals with stroke fall while they are *not* walking (e.g. transfers, pivots). AFO-use enhances static balance which is suggested to decrease falls under these conditions [131]. The results from this study provide insight on how AFO-use impacts the biomechanics of the reactive response *after* a trip/stumble has occurred.

Falls in individuals with stroke are characterized by poor compensatory stepping responses quantified by reduced trunk control, shorter step length, and reduced dynamic stability [30,142,148]. This study indicates that AFO-use leads to similar deficits in young healthy adults during a trip. While the differences may appear small in young subjects (i.e. none of our subjects fell as a result of AFO-use), clinical AFO users already have a diminished capacity to generate effective compensatory steps and even a small decrease in trunk stability and step length may increase the incidence of falls in these populations. Therefore, further study of these devices and how they perform during dynamic fall scenarios in fall-prone individuals is warranted.

This study, to our knowledge, is the first to demonstrate the correlation of forward propulsion of the stepping leg to the effectiveness of the compensatory stepping response following a trip-like perturbation. The importance of propulsion in driving dynamic stability and controlling whole-body angular momentum during locomotion is well established [50,76,80,140,149]. Moreover, a recent study shows that propulsion of the support limb after a trip contributes to control of whole-body angular momentum thereby allowing successful recovery [150,151]. Correspondingly, we found that diminished forward propulsion of the stepping limb due to AFO-use negatively impacts the compensatory stepping response which might increase trip-related fall risk in fall-prone populations. This study adds to the literature highlighting the crucial role of plantarflexors in dynamic balance control not only during gait [76,79,138–140] but also during a balance perturbation such as trip.

2.5.3. AFO prescription and future design

Foot drop is caused by dysfunction of dorsiflexor muscles [152] but many patients have intact (or residual) plantarflexor muscles. Using a rigid AFO addresses dorsiflexion deficit but also compromises the plantarflexion function. As our results indicate that propulsion is critical to initiate an effective compensatory stepping response, an ideal AFO design might address dysfunction of dorsiflexors during the swing phase of gait but either allow or support plantarflexion function during the push off phase of gait. Future studies should also evaluate other types of AFOs that do not restrict plantarflexion expression (e.g. peroneal nerve functional electrical stimulators, hinged/articulated AFOs) to determine how these devices perform during a dynamic fall response.

Finally, our results suggest it might be advisable for clinicians and orthotists to carefully consider plantarflexion strength when prescribing AFOs. AFOs can completely restrict ankle movement but they can also be articulated to allow movement of the ankle. While significantly more research is warranted, particularly in fall-prone individuals (e.g. stroke), our results suggest that some consideration for the residual capacity of an individual with foot drop to generate plantarflexion might be important during AFO prescription/fitting. Future studies should aim to develop a quantifiable prescription method that ensures each individual receives the best AFO design matched to their specific impairments [153–155].

2.5.4. Limitations and future directions

The present study provides insight on mechanical impacts of an AFO during trip-like treadmill perturbations; however, this study only evaluates the immediate mechanical effects of AFO on young adults without neurological impairment. Long-term AFO users with chronic stroke should be rigorously studied to investigate how using an AFO affects their fall outcomes. Long-term users likely have developed altered muscle activation patterns, ankle/knee/hip kinematics, static/dynamic postural control, and compensatory stepping strategies that will interact with AFO-use.

The present work studies laboratory trip-like perturbations which provide valuable preliminary kinematic/kinetic data for designers to improve current AFO design leading to improved dynamic fall response and potentially less falls. The impact of AFO use on community fall outcomes of individuals with stroke is not well evaluated. To our knowledge, only two studies have evaluated the fall outcomes in AFO-users with stroke [94,133]. Bethoux et al. 2015 compares AFO users to individuals who use functional electrical estimulators and reports the fall rate nearly 40% in both groups over a 12-months follow-up period. While this study indicates the high fall rate in AFO users, it does not answer if AFO reduced or increased falls because it does not evaluate the subjects in No-AFO condition. Nikamp et al. 2019 only studies the individuals with acute stroke. This study reports that individuals who use an AFO early after stroke (1 week) fall more often than individuals who need an AFO but do not use it until 8 weeks after stroke. These results raise questions about whether AFOs increase falls. However, they report that 63.6% of the falls in early (1 week) group occurred while the subject was not wearing the prescribed AFO. Therefore, it remains unclear how AFO affected the fall outcome. Morever, this study only evaluates the short-term effect of the AFO (8 weeks). In conclusion, a large prospective study evaluating the actual impact of an AFO on fall outcomes of individuals with stroke (including their circumstances and causes) is necessary.

2.6. Conclusion

A semi-rigid AFO negatively impacts the compensatory stepping response of young healthy individuals by decreasing trunk control, shortening step length, and reducing dynamic stability. Further, diminished propulsive impulse due to AFO-use is correlated to these impairments suggesting an important role for plantarflexion in the generation of an effective compensatory stepping response. This study highlights that future studies should carefully examine the impact of AFO-use on fall outcomes. Further, AFOs/devices which allow plantarflexion (e.g. functional electrical stimulators, articulated AFOs) should be evaluated to determine if they are better alternatives to rigid designs with respect to falls.

CHAPTER 3

THE IMPACT OF ANKLE-FOOT-ORTHOSES AND FUNCTIONAL ELECTRICAL STIMULATORS ON FALL OUTCOMES AND COMPENSATORY STEPPING RESPONSE IN INDIVIDUALS WITH STROKE

3.1. Abstract

Between 20% to 30% of individuals with stroke have foot drop which increases risk of stumbling and falling. Ankle-foot-orthoses (AFOs) and functional electrical stimulators (FES) are commonly prescribed to treat foot drop. Despite well-established positive impacts of AFOs and FES devices on balance and gait, AFO and FES users still fall at a high rate. The objective of this study was to investigate the underlying biomechanical mechanisms leading to high risk of falling in long-term AFO and FES users with chronic stroke. Forty-two individuals with chronic stroke (14 AFO users, 10 FES users, 18 Non-users) were evaluated during a series of trip-like treadmill perturbations. Fall outcomes and compensatory stepping response kinematics were quantified. It was found that AFO and FES users fall 2.50 and 2.77 times more than Non-users – despite having Berg Balance Scale, Timed Up & Go, and 10 m walk test scores similar to the Non-users. AFO and FES users demonstrated a more impaired compensatory stepping response characterized by increased trunk flexion velocity at the end of the first step and increased inability to generate a second step with paretic leg where a second step was required to regain balance. Interestingly, removing the AFO/FES had no significant impact on fall outcomes and compensatory stepping response of AFO and FES users. No differences in fall rate and compensatory stepping response were found between AFO and FES users. AFO and FES users had a more impaired lower limb characterized by smaller Fugl-Meyer score, weaker dorsi- and plantarflexor, and more spastic plantarflexor. These results suggest that AFO and FES users' higher fall rate and more impaired compensatory stepping response do not relate to AFO/FES use, rather it is the severe lower limb impairment that is not fully addressed by AFO/FES putting them at a higher risk of falling. AFO and FES devices likely prevent community falls by preventing trips however once a trip occurs, they may not assist recovery of balance.

3.2. Introduction

Foot drop is a neuromuscular deficit causing an inability to dorsiflex the ankle and lift the forefoot during the swing phase of gait [43]. Between 20% to 30% of individuals with stroke have persistent foot drop [156] increasing the risk of stumbling and falling [27,43]. In addition to falling, foot drop can result in abnormal movement patterns (e.g. circumduction) [43], pain, discomfort [43,157], decreased step length [158,159], decreased walking speed [159,160], and increased energy cost of walking [158,159,161]. Given the major risk of falling in stroke population [8], it is of great importance to fully address this neuromuscular impairment.

Ankle-foot-orthoses (AFOs) and functional electrical stimulators (FES) are commonly prescribed to treat foot drop. While there are several different AFO types (e.g., rigid, semi-rigid, articulated), the most common AFO is the thermoplastic model [52,53]. Thermoplastic AFOs restrict ankle movement thereby preventing foot drop or plantarflexion. FES devices (e.g. Bioness L300) prevent foot drop by assisting dorsiflexion by stimulating the peroneal nerve during the swing phase of gait [52]. Both AFOs and FES devices have been shown to enhance walking speed [13,52,55,57,58,159,162], foot clearance [146,147,163], cadence [55,159], and step length [57]. Further, Both AFOs and FES devices improve functional balance and mobility measured by berg balance scale (BBS) [13,58,163] and Timed Up & Go (TUG) test [58,65]. Despite well-established positive impacts of AFOs on gait and balance, their impact on fall outcomes of individuals with stroke is not well evaluated [8]. To our knowledge, only three groups have studied fall outcomes of AFO or FES users [26,94,133]. Hausdroff et al., 2008 showed that FES reduced fall frequency in individuals with stroke by 92% during 2 months after prescription [26]. Though the results from this short-term study are very promising, Bethoux et al., 2015 [94] in a more long-term 12 months follow-up study showed that both AFO and FES users had a high falling rate of 40% after prescription. More concerning is Nikamp et al., 2019 [133] that showed early prescription of an AFO in individuals with acute stroke was associated with 2.75 times more falls compared to the individuals who were prescribed an AFO with an 8-week delay. These results suggest that despite many beneficial impacts of AFOs on static balance and gait, AFO users are still at a very high risk of falling and AFO use has not adequately addressed this risk. These studies provide valuable data on prospective community falls but do not provide any information about the fundamental mechanisms leading to high risk of falling in AFO users. To discover why AFO users still fall at a high rate, it is critical to study the mechanics and mechanisms of their falls in the laboratory. Most falls occur due to an external balance perturbation such as trip or slip [25,92,134–137] followed by an unsuccessful compensatory stepping response [28,29,31–34]. Thus, to have a clear understanding of why AFO users fall at a high rate, it is important to study the impact of AFOs on mechanics of compensatory stepping response and associated fall outcomes during a balance perturbation such as trip.

Falls in individuals with stroke are linked with an impaired compensatory stepping response characterized by decreased trunk movement control [30,38,142], shorter step length [30,40], reduced center of mass (COM) stability [30,38,40,164], and inability to generate compensatory steps with paretic leg [29,35]. Ankle propulsive forces mainly generated by plantarflexors are critical contributors to initiate an effective compensatory step and control whole-body angular momentum [76,140]. Therefore, restricting plantarflexion by a rigid AFO may negatively impact the compensatory stepping response. Our preliminary results in chapter 2 demonstrated that a semi-rigid AFO decreases propulsion. Decreased propulsion compromised the compensatory stepping response of young healthy adults by reducing trunk motion control, step length, and center of mass (COM) stability following a trip-like perturbation. Moreover, the results from the literature show that AFOs' mechanical effects deteriorate propulsion and dynamic balance in young healthy adults [76,83] and children with hemiplegia [84] during walking. These results raise an important concern about AFO usage and its probable detrimental impact on stroke survivors' compensatory stepping response. In addition to foot drop and risk of stumbling [27,43], AFO users might have weak calf muscles [46,47] that lead to reduced push-off [8,44] and knee flexion [8,49] during walking. Reduced push-off and knee flexion likely compromise paretic stepping and whole-body angular momentum control, therefore put them at higher risk of falling. To decrease fall risk, it is necessary to fully address these deficits. However, there is a concern that the inhibitory effects of conventional rigid AFOs might further deteriorate these deficits [76].

Unlike AFOs that restrict plantarflexion, FES devices provide dorsiflexion assistance during walking without constraining the ankle plantarflexion and inhibiting propulsion. Therefore, theoretically, FES devices do not impede compensatory stepping response and may be a better alternative to rigid bulky AFOs for individuals with more functional plantarflexors. However, neither AFOs nor FES devices assist plantarflexion during walking or a balance perturbation. Therefore, they likely do not compensate for decreased push-off and impaired compensatory stepping response in individuals with a severely impaired ankle. It is important to note that AFOs and FES devices likely prevent a considerable percentage of trip-related falls by preventing the occurrence of trips. However, the ability of these devices to assist *during* a fall has not been evaluated. To our knowledge, no studies have evaluated the effects of AFOs and FES devices on compensatory stepping response of individuals with stroke. It is important to study the impact of AFOs and FES devices on compensatory stepping response and investigate whether FES devices perform better than AFOs during a balance perturbation such as trip.

The objective of this study was to investigate the underlying biomechanical mechanisms leading to high risk of falling in long-term AFO and FES users with chronic stroke. Therefore, we evaluated the fall outcomes and compensatory stepping response of individuals with stroke (AFO users, FES users, and Non-users) during treadmill perturbations that mimic over-ground trips [93]. Posteriorly-directed treadmill perturbations that evoke forward stepping responses (similar to a trip-like response) were used because they allow us to quantify the mechanics of the compensatory stepping response under multiple conditions and repeatedly. Further, to determine the impact of AFO and FES devices on the compensatory stepping response and fall outcomes, subjects were tested without the presence of AFO/FES as well. We hypothesized that both AFO and FES users would fall more often than Non-users and have a more impaired compensatory stepping response characterized by decreased trunk movement control and reduced capability to generate a step with the paretic leg. Also, we expected that AFO users would fall more often and have more impaired compensatory stepping response compared to FES users. Finally, we hypothesized that AFO and FES use would not enhance the compensatory stepping response.

3.3. Methods

Forty-two individuals with unilateral chronic stroke (18 Non-users, 14 AFO users, 10 FES users) participated in this study (Table 3.1). Eligibility criteria were 1) ability to walk 5 minutes without assistance, 2) no spinal/lower extremity injury/surgery in the past year, 3) no history of fainting in the past year, 4) at least a month of AFO/FES use on a daily basis. This study was performed at Arizona State University (ASU) under the IRB approved protocol STUDY00002970. All subjects provided written informed consent.

Subjects' age, height, weight, and stroke type were recorded. Lower extremity impairment was assessed by lower extremity Fugl-Meyer test. Spasticity of the ankle plantarflexors (lateral Gastrocnemius and Soleus) and dorsiflexor (Tibialis Anterior) was assessed using Modified Modified Ashworth Scale [165,166]. Maximum voluntary isometric contraction (MVIC) of plantarflexion and dorsiflexion was measured using a Biodex System 3 (Biodex, New York, USA). Normalized MVICs are reported as the ratio of the paretic leg MVIC to the non-paretic leg MVIC (%) (Table 3.1). Functional balance and mobility were evaluated by Berg Balance Scale (BBS), Timed Up & Go (TUG), and 10 m walk test. AFO/FES users performed clinical tests while wearing their own orthosis/device.

Groups were matched through an independent samples t-test for age, height, and weight. Further, groups were matched by stroke type and gender using a chi-squared test. Fugl-Meyer score, normalized MVIC for plantar- and dorsiflexion, Modified Modified Ashworth Scale (for Gastrocnemius, Soleus, and Tibialis Anterior), and clinical scores of balance and mobility (BBS, TUG, 10 m walk test) were compared between the groups using an independent samples t-test.

Table 3.1. Subject characteristics, lower extremity impairment, and spasticity.

Variable	AFO users (N=14)	FES users (N=10)	Non-users (N=18)	P-values		
Gender (M/F)	7/7	4/6	12/6	Pearson Chi-square P-values = 0.36		
Stroke type (ischemic/hemorrhagic/unknown)	8/6/0	7/3/0	9/7/2	Pearson Chi-square P-values = 0.50		
Variable				**P-values** *AFO vs Non*	*FES vs Non*	*AFO vs FES*
Age (yrs)	54.7 ±10.5	45.9 ±15.2	54.8 ±12.0	0.97	0.10	0.11
Height (cm)	168.4 ±10.2	164.8 ±12.7	169.8 ±7.6	0.68	0.21	0.45
Weight (kg)	79.7 ±15.8	70.4 ±25.3	83.6 ±17.7	0.53	0.12	0.28
Normalized MVIC - plantarflexion (%)	36.9 ±23.8	43.1 ±25.4	66.7 ±49.6	0.047 *	0.17	0.54
Normalized MVIC - dorsiflexion (%)	44.7 ±30.4	52.8 ±36.8	90.2 ±32.0	0.0003 ***	0.009 **	0.56
Lower extremity Fugl-Meyer score (maximum score = 86)	72.7 ±5.9	72.9 ±6.5	79.7 ±5.4	0.002 **	0.008 **	0.94
Modified Modified Ashworth Scale – lateral Gastrocnemius	1.1 ±1.2	1.2 ±0.9	0.3 ±0.5	0.015 *	0.001 **	0.78
Modified Modified Ashworth Scale – Soleus	1.0 ±1.0	1.1 ±1.1	0.3 ±0.5	0.009 **	0.01 *	0.82
Modified Modified Ashworth Scale – Tibialis Anterior	0.3 ±1.1	0 ±0	0.1 ±0.2	0.38	0.47	0.41

Abbreviations: M=male, F=female, MVIC=maximum voluntary isometric contraction. Note: Normalized MVICs are reported as the ratio (%) of the MVIC of the paretic leg to the non-paretic leg. Data is reported as mean ± standard deviation or numbers. * = P-value < 0.05, ** = P-value < 0.01, *** = P-value < 0.001.

After clinical assessments, subjects were fitted in a safety harness and received treadmill balance perturbations that required single or multiple steps to prevent falling. Subjects were asked to stand quietly on the treadmill before perturbations in posterior and anterior directions evoking forward and backward stepping respectively were delivered. This study focused on posteriorly-directed perturbations but anteriorly-directed perturbations were delivered randomly to eliminate direction anticipation. AFO/FES users received perturbations under two conditions 1) with and 2) without their AFO/FES. For consistency of the experiment, Non-users performed the experiment in two conditions as well 1) No-AFO and 2) wearing a pre-fabricated semi-rigid AFO. Conditions were randomized for all subjects. Prior to perturbations, subjects walked on our dual-belt treadmill (GRAIL, Motek Medical BV, Amsterdam, The Netherlands) with a self-selected comfortable speed for 2 minutes with the purpose of warming up and acclimation to each condition. Subjects were asked to stand upright on the treadmill at their self-selected comfortable stance width. Floor projection light was adjusted based on their self-selected stance width. Subjects stood at the same position with the same stance width (using the floor projection light) before every perturbation. The instruction prior to balance perturbations was: “stand upright and look straight ahead. Try to do what is necessary (including taking steps) to regain your balance and not fall as the treadmill moves in some direction at some time during the next 20 seconds.”.

Posterior perturbations were delivered in 3 levels of intensity (level 1: small, level 2: medium, level 3: large). Based on a previous study on stepping thresholds following these type of perturbations [167], level 1 was designed such that subject could recover with a single step. Level 2 and 3 required at least 2 steps to recover. Perturbations had a trapezoidal velocity profile similar to previously published studies in older adults [143] and individuals with stroke [30,142]. Displacement, constant velocity, acceleration, and deceleration of the posterior perturbations' velocity profiles were as follows: small: 17% of body height (m), 1.00 m/s, 10.0 m/s^2, -10.0 m/s^2, medium: 32% of body height (m), 1.26 m/s, 12.6 m/s^2, -12.6 m/s^2, and large: 47.5% of body height (m), 1.26 m/s, 12.6 m/s^2, -12.6 m/s^2. Anterior perturbations were delivered in 2 intensities. The displacement, constant velocity, acceleration, and deceleration of anterior perturbations were as follows: small: 10% of body height (m), -0.9 m/s, -9.0 m/s^2, 9.0 m/s^2, medium: 20% of body height (m), -1.1 m/s, -11.0 m/s^2, 11.0 m/s^2.

At each condition, subjects received an initial round of 3 posterior and 2 anterior perturbations, randomized in direction but in an increasing order of intensity – for safety reasons. Two more rounds of the same perturbations were delivered in a complete randomized fashion. However, if the subject fell (i.e. unambiguously caught by the harness) on a perturbation level during the initial round, same perturbation was repeated up to 3 times and if the subject fell on all 3 trials, no more perturbation of that level or larger was delivered throughout that condition (i.e. that level and larger ones were removed from round 2 and 3).

Passive reflective markers were attached to the subject's body according to the modified Helen Hayes marker set [144] and markers trajectory data were recorded using a 10-camera motion capture system (Vicon, Oxford, UK) at 250 Hz sampling rate. A 4^{th} order Butterworth filter with a 6 Hz cutoff frequency was applied to the markers kinematic data using Vicon Nexus 2.6.1 (Vicon, Oxford, UK). Kinematic variables during the first compensatory step were calculated using filtered markers data and MATLAB software (Mathworks, Natick, MA). Ground Reaction Forces (GRFs) were recorded through the embedded force plates (Bertec, Columbus, OH) under each belt of the instrumented dual-belt treadmill at 2000 Hz sampling rate.

Kinematic variables to evaluate the effectiveness of the first compensatory step were as follows: Trunk flexion and velocity, Step length (normalized to body height), COM-BOS (normalized to body height), Reaction time, Step duration. Moreover, failure rate to initiate a second step was calculated – as it was required to recover on medium and large perturbations. All these variables are defined and demonstrated in Table 3.2 and Figure 3.1. Trunk flexion and velocity were calculated at the initiation (SS: step_start) and completion (SE: step_end) of the first compensatory step. SS and SE were detected using the GRF of the stepping leg with a 20 N threshold. A custom build MATLAB code was used to detect SS and SE and the experimenter manually verified those.

Table 3.2. Definition of the dependent variables.

Dependent variables	**Definition**
Trunk flexion	The angle between the trunk and vertical line in the sagittal plane relative to the initial angle of the trunk at perturbation onset. Anterior trunk inclination is considered positive direction.
Trunk flexion velocity	First derivative of Trunk flexion with respect to time.
Step length	The anterior-posterior displacement between stepping and support foot centers at SE.
COM-BOS (Dx)	The anterior-posterior displacement between the center of mass (COM) and the boundary of base of support (i.e. stepping leg toe marker) at SE. Positive values represent COM within (i.e. posterior to) the base of support.
Reaction time	The time from perturbation onset to toe-off (i.e. SS).
Step duration	The time from step initiation (SS) to completion (SE).
Second step failure rate	Percentage of times that subject is required to take a second step but fails to do that. Note: stroke survivors often initiate the first step with the non-paretic leg. A second step is required in any trial except the ones that subject recovers from the perturbation with a single step. A second step is counted only when the foot is lifted from the treadmill (verified by GRFs) and lands anterior to the other foot (manually verified by anterior-posterior position of the toe markers by the experimenter). Failure to initiate/complete a second step with the paretic leg is followed by a fall or alternatively using the non-paretic leg to take that step (i.e. pivot/hopping strategy) [30].

Abbreviations: SS=step start, SE=step end.

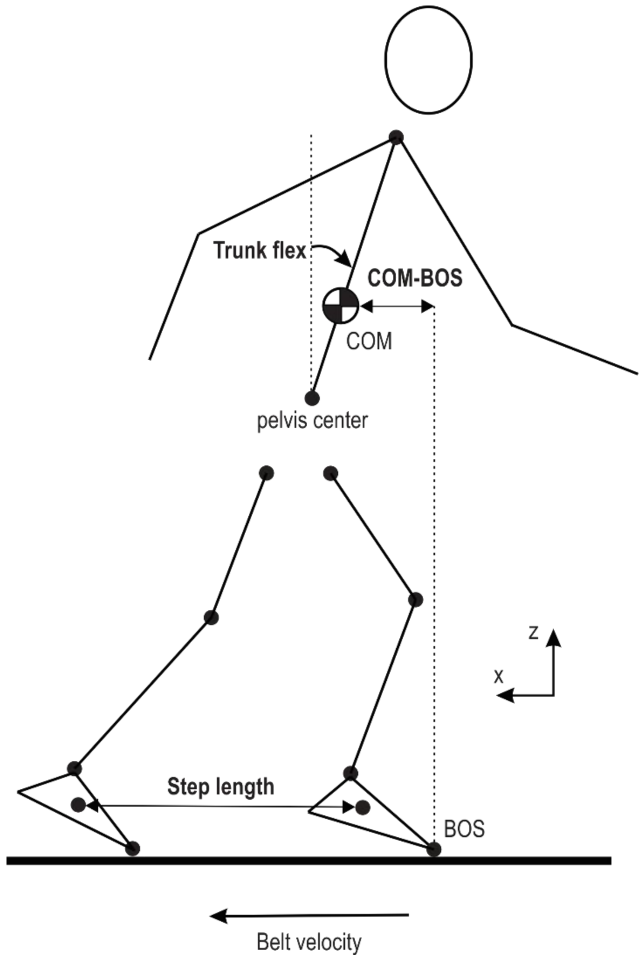

Figure 3.1. Schematic of the subject's body configuration at completion of the first compensatory step with kinematic variables. All variables are depicted in positive orientation/direction. Abbreviations: flex = flexion.

Fall rate at each perturbation level was measured as the ratio of the number of falls (i.e. getting unambiguously caught by the harness) to the total number of perturbations delivered on that level. At each condition, 3 of each perturbation were delivered unless subject fell all 3 times on a specific perturbation and did not receive the larger perturbations for safety reasons in which case fall rate on larger perturbations was considered 100%. Further, total fall rate across all levels was calculated.

Total fall rate and fall rate at each level were compared between AFO users, FES users, and Non-users at their natural condition (i.e. AFO and FES users wearing their orthosis/device and Non-users not wearing any AFOs). Moreover, the total fall rate and fall rate at each level were compared for AFO and FES users with and without their orthosis/device. It was hypothesized that 1) AFO and FES users would fall more often than Non-users and 2) AFO users would fall more often than FES users. An ANOVA using Linear Mixed Effects Model was performed with groups (AFO user, FES user, Non-user), conditions (with and without AFO/FES) and levels (1,2,3) as independent variables and fall rate at each perturbation level as the dependent variable. Subjects were treated as a random factor. Tukey HSD was used for all post-hoc comparisons. Statistical analyses were performed using R (R Development Core Team, 2006). Significance level was considered as $p<0.05$.

First compensatory step kinematics and failure rate to initiate a second step (Table 3.2) were compared between the groups at their natural conditions. Further, these metrics were compared between conditions (with and without AFO/FES) for AFO users and FES users. It was hypothesized that AFO and FES users would have more impaired compensatory stepping response compared to the Non-users characterized by decreased trunk movement control and reduced capability to generate a step with the paretic leg. Further, it was expected that AFO users would have a more impaired compensatory stepping response compared to FES users. Also, it was hypothesized that AFO/FES would not enhance the compensatory stepping response. Same statistical analyses described above were performed with the same independent variables and the variables described in Table 3.2 as dependent variables.

3.4. Results

Despite having matched clinical scores of balance and mobility (Fig. 3.2), AFO users' and FES users' total fall rate were 2.5 and 2.77 times larger than Non-users respectively (AFO users = 42.9 ± 8.4 %, FES users = 47.8 ± 9.6 %, Non-users = 17.2 ± 8.2 %, P=0.03, P=0.02 respectively) (Fig. 3.3). Total fall rate of AFO and FES users were not different (P=0.64). Largest differences in fall rates were found at level 3. AFO users' and FES users' fall rate at level 3 were 2.53 and 3.25

times larger than Non-users respectively (AFO users = 48.0 ± 9.9 %, FES users = 61.7 ± 11.6 %, Non-users = 19.0 ± 9.7 %, *P*=0.04, *P*=0.006 respectively). At level 2, FES users' fall rate was 2.23 times larger than Non-users (FES users = 58.0 ± 11.1 %, Non-users = 26.0 ± 9.5 %, *P*=0.03). AFO users' fall rate at level 2 was 1.89 times larger than Non-users, however the difference did not reach significance (AFO users = 49.1 ± 9.8 %, Non-users = 26.0 ± 9.5 %, *P*=0.09). No differences in fall rate were found between the groups at level 1 (all *P*>0.05). Fall rate of AFO users and FES users were not different at any level (all *P*>0.05). No differences were found in fall rates between the conditions (with and without device) (all *P*>0.05) (Fig 3.4).

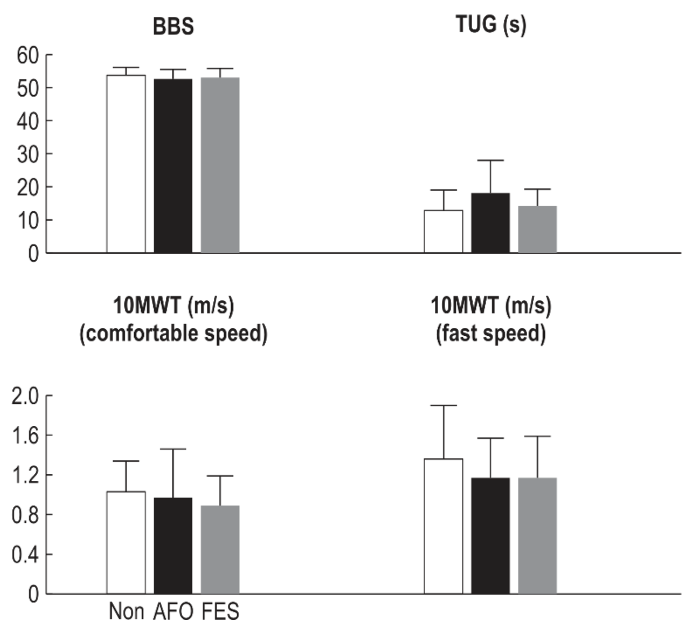

Figure 3.2. Comparison of the clinical scores between the groups. Note: each group was tested in their natural condition (i.e. AFO and FES users wearing their orthosis/device and Non-users without any AFOs).

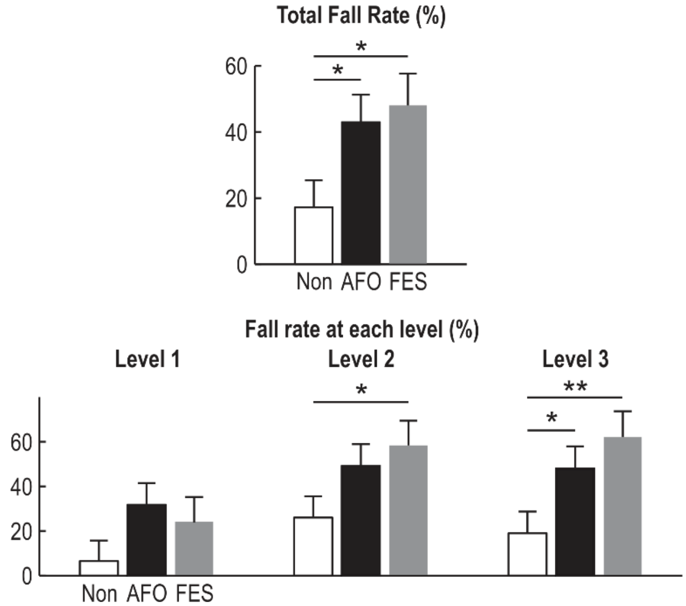

*Figure 3.3. Comparison of total fall rate and fall rate at each level between the groups. Note: each group was tested in their natural condition (i.e. AFO and FES users wearing their orthosis/device and Non-users without any AFOs). * = P-value < 0.05, ** = P-value < 0.01, *** = P-value < 0.001.*

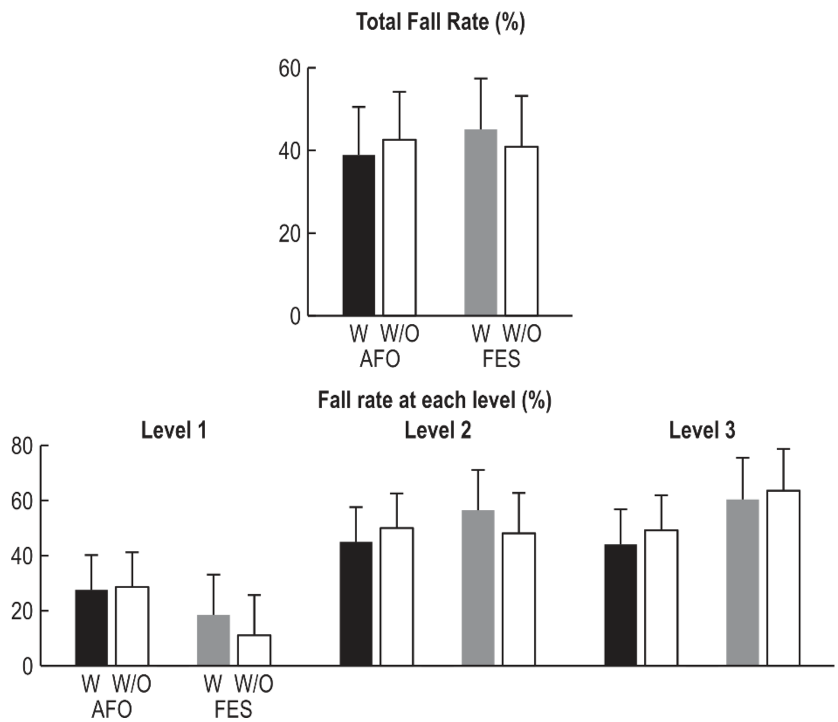

Figure 3.4. Comparison of total fall rate and fall rate at each level between with and without AFO/FES conditions. Abbreviations: W=with, W/O=without.

Despite the increased fall rate of AFO and FES users, their compensatory stepping response kinematics were similar to the Non-users except Trunk flexion velocity at SE that was larger for AFO and FES users compared to the No-users. No differences in any of the variables at level 1 were found between the groups (all $P>0.05$) (Fig. 3.5). At level 2, AFO users' and FES users' Trunk flexion velocity at SE were 1.78 and 1.86 times larger than Non-users (AFO users = 111.4 ± 17.4, FES users = 116.4 ± 18.4, Non-users = 62.6 ± 17.6, $P=0.049$, $P=0.04$ respectively) (Fig. 3.6). AFO users' and FES users' Trunk flexion at SE were larger than Non-users although the differences did not reach significance (AFO users = 43.9 ± 2.3, FES users = 43.2 ± 2.4, Non-users = 37.5 ±2.3, $P=0.05$, $P=0.09$ respectively). Second step failure rate of AFO users and FES users at level 2 were larger than Non-users but the differences did not reach significance (AFO users = 47.2 ± 9.4 %, FES users = 54.7 ± 10.3 %, Non-users = 31.3 ± 8.8 %, $P=0.21$, $P=0.08$ respectively). At level 3, AFO users' and FES users' Trunk flexion velocity at SE were 2.27 and 2.69 times larger than Non-users (AFO users = 95.5 ± 18.1, FES users = 113.2 ±20.5, Non-users = 42.1 ± 17.9, $P=0.04$, $P=0.0095$ respectively) (Fig. 3.7). Second step failure rate of AFO users and FES users at level 3, were 3.39 and 2.76 times larger than Non-users respectively (AFO users = 72.2 ± 10.2 %, FES users = 58.8 ± 12.4 %, Non-users = 21.3 ± 9.2 %, $P=0.0002$, $P=0.02$ respectively). Trunk flexion at SS and SE, Trunk flexion velocity at SS, Step length, COM-BOS, Reaction time, and Step duration were not different between the groups at level 2 and 3 (all $P>0.05$).

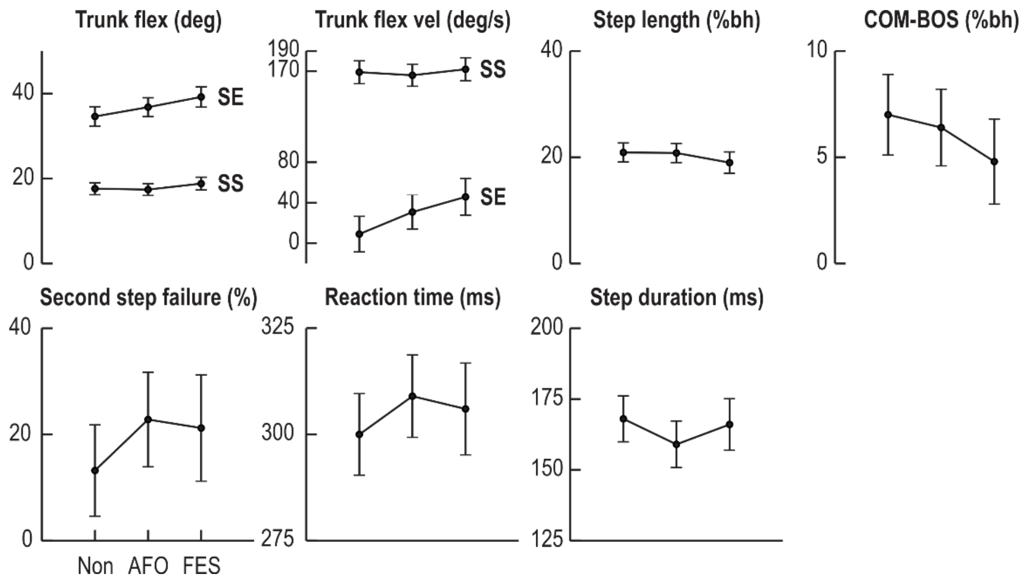

*Figure 3.5. Comparison of the compensatory stepping response of groups at level 1. Note: each group was tested in their natural condition (i.e. AFO and FES users wearing their orthosis/device and Non-users without any AFOs). Abbreviations: flex=flexion, vel=velocity, SS=step start, SE=step end, bh=body height, COM=center of mass, BOS=base of support. * = P-value < 0.05, ** = P-value < 0.01, *** = P-value < 0.001.*

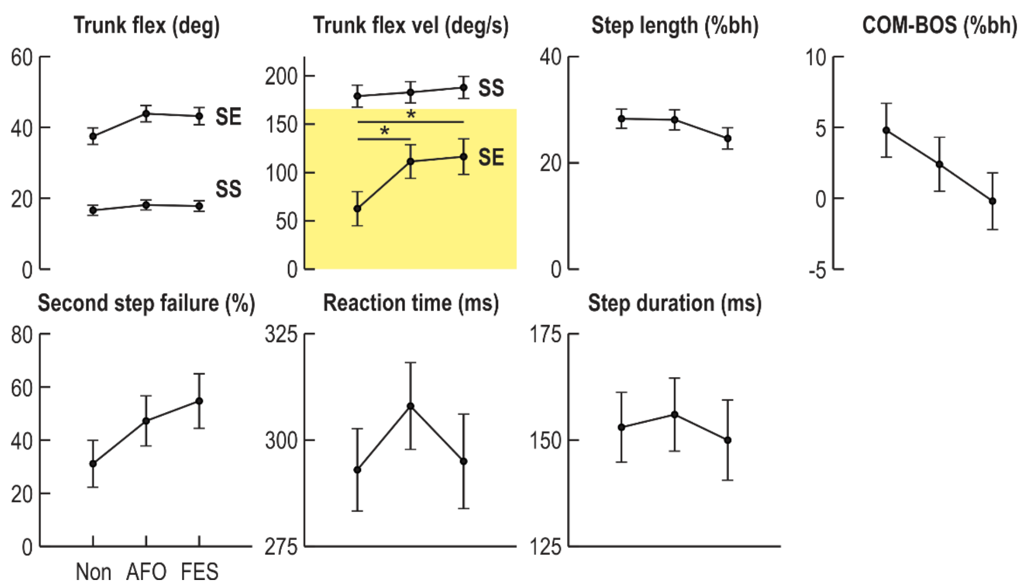

*Figure 3.6. Comparison of the compensatory stepping response of groups at level 2. Note: each group was tested in their natural condition (i.e. AFO and FES users wearing their orthosis/device and Non-users without any AFOs). Abbreviations: flex=flexion, vel=velocity, SS=step start, SE=step end, bh=body height, COM=center of mass, BOS=base of support. * = P-value < 0.05, ** = P-value < 0.01, *** = P-value < 0.001.*

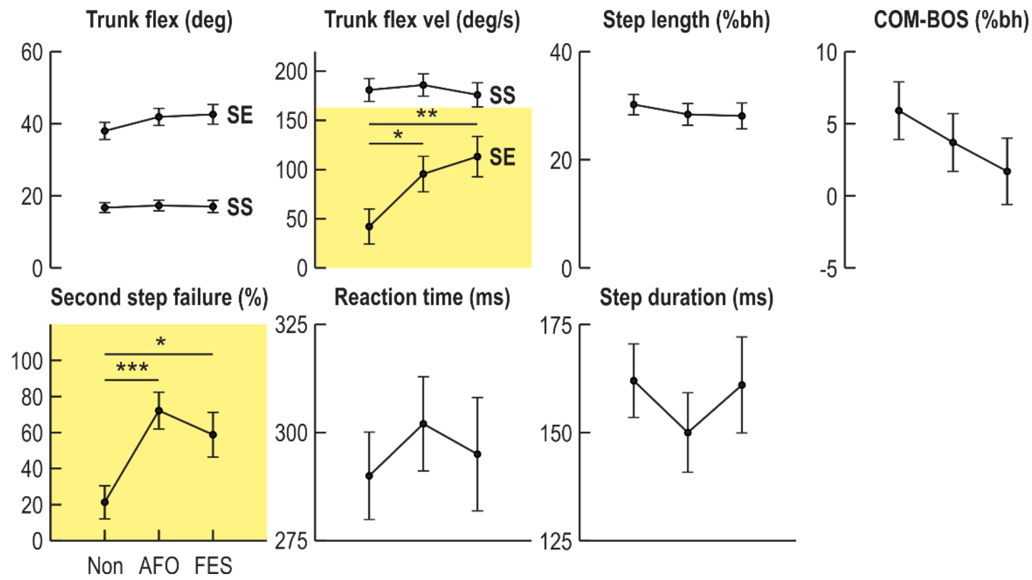

*Figure 3.7. Comparison of the compensatory stepping response of groups at level 3. Note: each group was tested in their natural condition (i.e. AFO and FES users wearing their orthosis/device and Non-users without any AFOs). Abbreviations: flex=flexion, vel=velocity, SS=step start, SE=step end, bh=body height, COM=center of mass, BOS=base of support. * = P-value < 0.05, ** = P-value < 0.01, *** = P-value < 0.001.*

Individuals with stroke often initiate their compensatory step with their non-paretic leg [30]. AFO and FES users used their non-paretic leg to initiate the compensatory step more often than the Non-users (total rate: AFO users = 92.4 ± 7.5 %, FES users = 91.9 ± 8.0 %, Non-users = 66.8 ± 7.8 %, *P*=0.02, *P*=0.03 respectively). At level 1, AFO and FES users initiated their compensatory step with the non-paretic leg at a larger rate compared to the Non-users (AFO users = 91.4 ± 7.8 %, FES users = 92.4 ± 8.4 %, Non-users = 63.4 ± 8.0 %, *P*=0.01, *P*=0.01 respectively). At level 2, AFO and FES users initiated their compensatory step with the non-paretic leg at a larger rate compared to the Non-users, though the difference between AFO users and Non-users was not significant (AFO users = 89.7 ± 8.1 %, FES users = 91.1 ± 8.5 %, Non-users = 67.9 ± 8.1 %, *P*=0.06, *P*=0.049 respectively). At level 3, AFO and FES users initiated their compensatory step with the non-paretic leg at a larger rate compared to the Non-users, though the difference between FES users and Non-users was not significant (AFO users = 96.2 ± 8.4 %, FES users = 92.3 ± 9.6 %, Non-users = 69.1 ± 8.3 %, *P*=0.02, *P*=0.07 respectively).

Kinematic variables of the first compensatory stepping response did not differ when AFO users were tested without the AFO (Fig. 3.8, Fig. 3.9, Fig. 3.10). The only variable that was different between AFO and No-AFO condition was the Second step failure rate at level 2 which was 1.86 times larger without AFO compared to the AFO condition (AFO = 41.5 ± 11.4 %, No-AFO = 77.0 ± 11.6 %, *P*=0.0001) (Fig.3.9). However, at level 3 Second step failure rate was not different between the conditions (*P*=0.29) (Fig. 3.10). At level 3, Trunk flexion velocity at SE was 1.37 times larger at AFO condition compared to No-AFO condition although it did not reach significance (AFO = 96.9 ± 22.2, No-AFO = 70.5 ± 22.6, *P*=0.06). No differences were found in any other variables at any level.

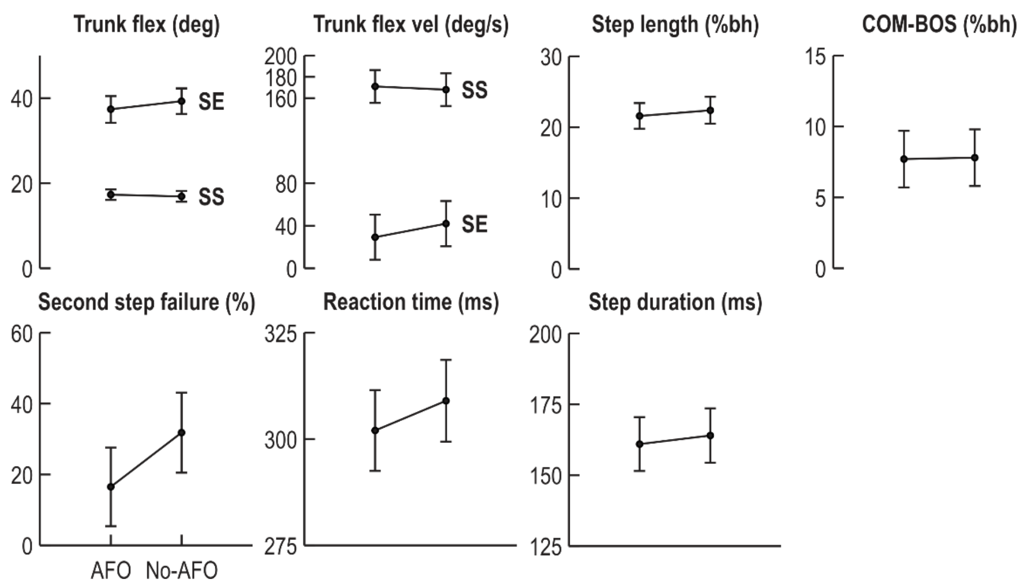

*Figure 3.8. Comparison of the compensatory stepping response of AFO users between AFO and No-AFO conditions at level 1. Abbreviations: flex=flexion, vel=velocity, SS=step start, SE=step end, bh=body height, COM=center of mass, BOS=base of support. * = P-value < 0.05, ** = P-value < 0.01, *** = P-value < 0.001.*

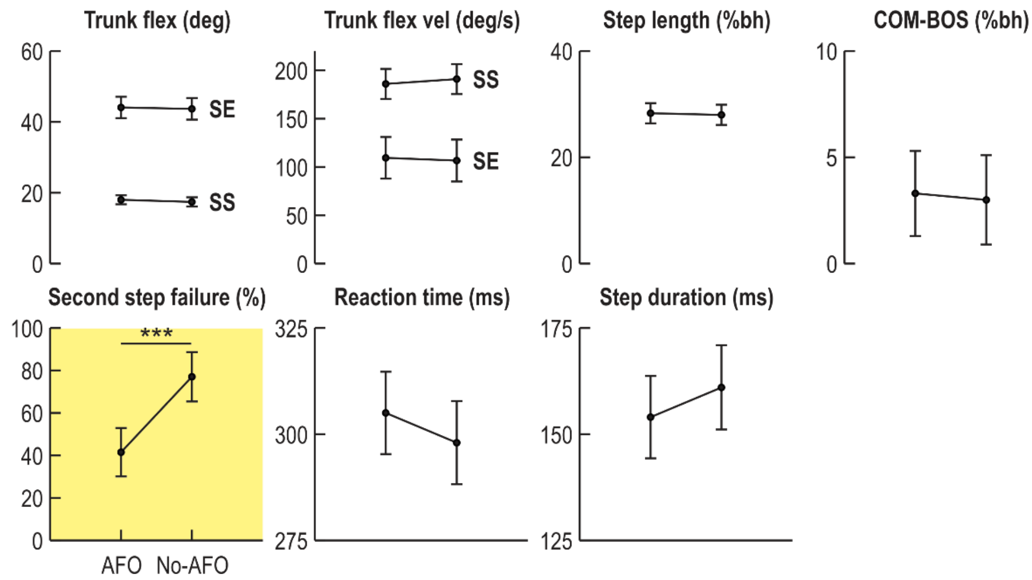

*Figure 3.9. Comparison of the compensatory stepping response of AFO users between AFO and No-AFO conditions at level 2. Abbreviations: flex=flexion, vel=velocity, SS=step start, SE=step end, bh=body height, COM=center of mass, BOS=base of support. * = P-value < 0.05, ** = P-value < 0.01, *** = P-value < 0.001.*

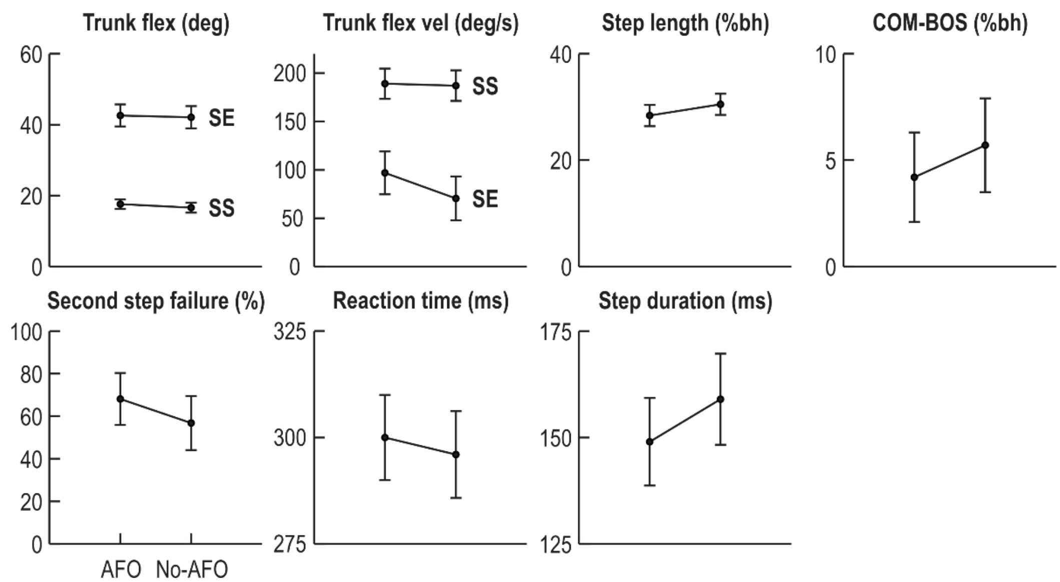

*Figure 3.10. Comparison of the compensatory stepping response of AFO users between AFO and No-AFO conditions at level 3. Abbreviations: flex=flexion, vel=velocity, SS=step start, SE=step end, bh=body height, COM=center of mass, BOS=base of support. * = P-value < 0.05, ** = P-value < 0.01, *** = P-value < 0.001.*

None of the kinematic variables were different between FES and No-FES conditions at any levels except Trunk flexion velocity at SS at level 2 which was larger at FES condition (FES = 190.0 ± 13.3, No-FES = 180.0 ± 13.3, *P*=0.04) (Fig. 3.11, Fig. 3.12, Fig. 3.13).

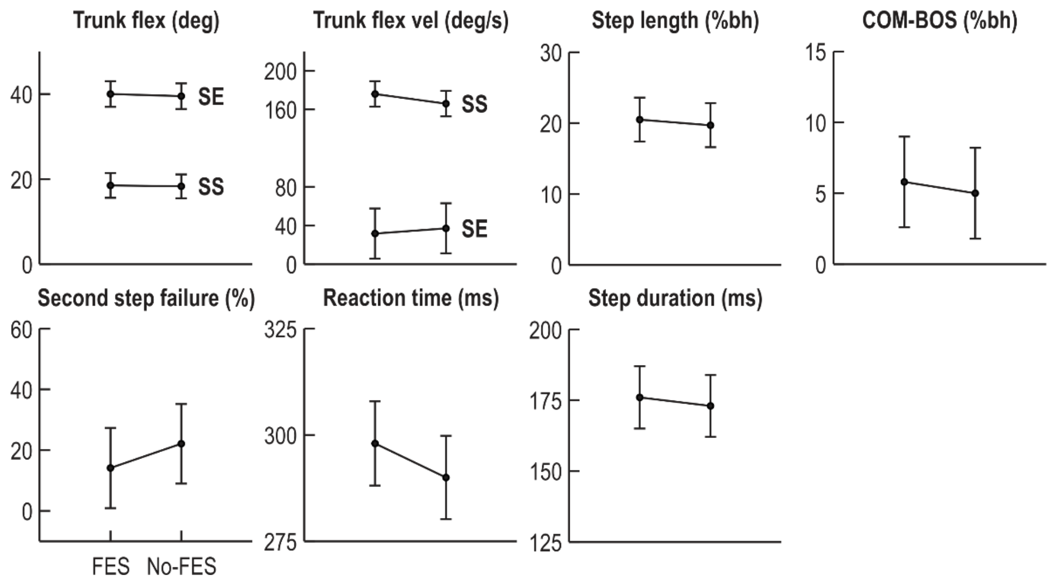

*Figure 3.11. Comparison of the compensatory stepping response of FES users between FES and No-FES conditions at level 1. Abbreviations: flex=flexion, vel=velocity, SS=step start, SE=step end, bh=body height, COM=center of mass, BOS=base of support. * = P-value < 0.05, ** = P-value < 0.01, *** = P-value < 0.001.*

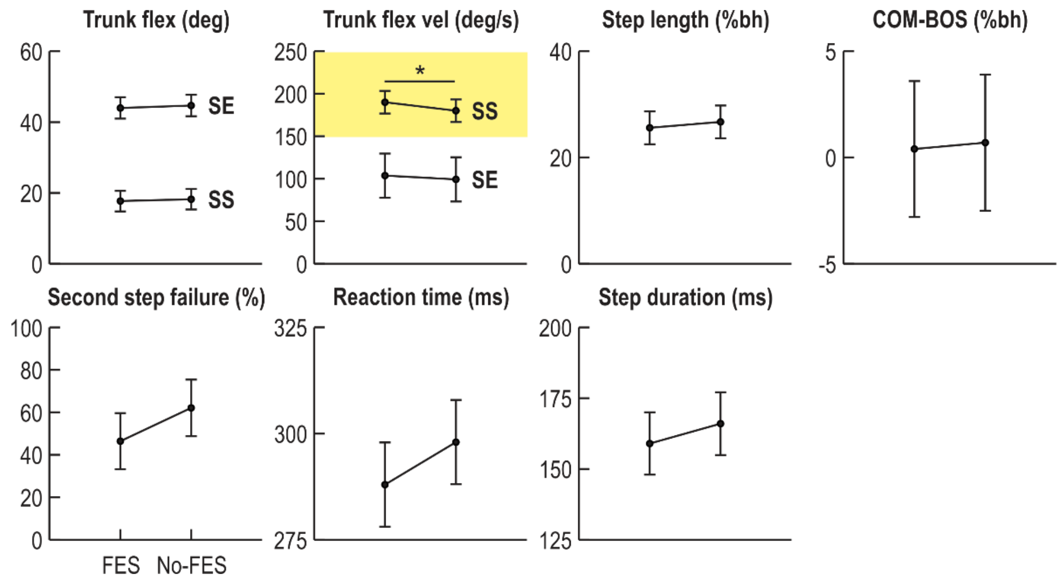

*Figure 3.12. Comparison of the compensatory stepping response of FES users between FES and No-FES conditions at level 2. Abbreviations: flex=flexion, vel=velocity, SS=step start, SE=step end, bh=body height, COM=center of mass, BOS=base of support. * = P-value < 0.05, ** = P-value < 0.01, *** = P-value < 0.001.*

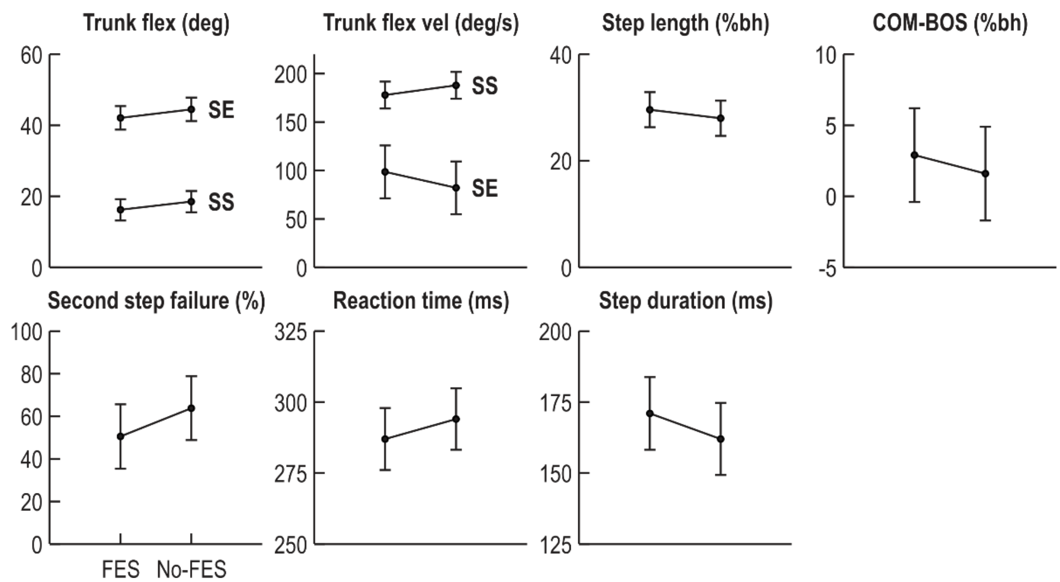

*Figure 3.13. Comparison of the compensatory stepping response of FES users between FES and No-FES conditions at level 3. Abbreviations: flex=flexion, vel=velocity, SS=step start, SE=step end, bh=body height, COM=center of mass, BOS=base of support. * = P-value < 0.05, ** = P-value < 0.01, *** = P-value < 0.001.*

3.5. Discussion

3.5.1. Summary

The objective of this study was to investigate the underlying biomechanical mechanisms leading to high risk of falling in long-term AFO and FES users with chronic stroke. We found that chronic AFO and FES users fell more often than Non-users by 2.5 and 2.77 times respectively following trip-like perturbations despite their clinical scores of balance and mobility (BBS, TUG, 10 m walk test) being matched to the Non-users. AFO and FES users' fall rate and compensatory stepping response kinematics did not differ. Despite increased falls in AFO and FES user groups, kinematics of the first compensatory step surprisingly were not different between the groups except the trunk velocity control at the end of the first step which was diminished for AFO and FES users compared to the Non-users. That is likely because AFO and FES users initiated their first step with the non-paretic leg over 90% of the time. The differences in fall outcomes appeared at level 2 and level 3 perturbations where a second step with paretic leg was required to recover. AFO and FES users showed an increased inability to generate a second step with the paretic leg. Thus, the two metrics likely leading to their higher fall rate are 1) inability to generate compensatory steps with paretic leg and 2) reduced trunk motion control – both previously shown to be linked with falls in individuals with stroke [28–30,35,38,39]. Surprisingly, removing the AFO/FES had no significant impact on fall outcomes and the compensatory stepping response. Therefore, the impaired compensatory stepping response of AFO and FES users is likely not related to AFO/FES use, but to the severe ankle impairments that AFO and FES do not fully address. AFO and FES users' ankle impairment was characterized by smaller Fugl-Meyer score, more spastic plantarflexors, and weaker plantarflexors and dorsiflexors.

AFOs and FES devices have demonstrated well-established positive impacts on static balance [13,58,163] and gait [13,52,55,57,58,159,162] and likely decrease community falls by increasing toe clearance [146,147,163] and preventing trips/stumbles. However, our results suggest that once a trip occurs, these devices may not assist recovery of balance. An ideal future AFO should be designed to assist dorsiflexion during the swing phase and plantarflexion during the push-off phase of gait. Plantarflexion assistance enhances propulsion which is a critical contributor to step initiation [50] and whole-body angular momentum control [76,79,138–140]. Therefore, a future AFO that assists plantarflexion is suggested to reduce more falls by enhancing trunk control and paretic leg use for compensatory stepping. Rigid/soft powered ankle-foot orthotic systems that provide plantarflexion assistance and enhance propulsion [168–170] are suggested as a potential alternative for rigid AFOs if the design is portable, lightweight, and suitable for daily wear use. Another promising strategy that has shown to enhance trunk motion control following trip-like perturbations [116,142] (see chapter 4) is a trip-specific training program. Using a future powered AFO with plantarflexion assistance complemented by a trip-specific training program is suggested to enhance the compensatory stepping response and decrease falls in individuals with stroke.

3.5.2. Why do AFO and FES users fall more?

AFO and FES users showed more impaired ankle characterized by smaller Fugl-Meyer score, more spasticity, and weaker plantarflexors and dorsiflexors (Table 3.1). Plantarflexor weakness and spasticity can reduce paretic step propulsion [8] and negatively impact whole-body angular momentum control [76,140]. AFO and FES users' compensatory stepping response was characterized by 1) increased inability to generate a compensatory step with paretic leg and 2) decreased trunk motion control. Rigid AFOs and FES devices do not compensate for the plantarflexor weakness, spasticity, and reduced propulsion. Therefore, they are unable to compensate for the ineffective compensatory stepping response and reduce laboratory falls. However, our results showed only few differences in the kinematics of the first compensatory step between the groups. The only measure found to be different was the trunk velocity control at the end of the first step which was diminished for AFO and FES users compared to the Non-users. That is likely because AFO and FES users initiated their first step with the non-paretic leg over 90% of the time. These results are in agreement with chapter 2 results, where AFO on the support (non-stepping) leg did not impair the kinematics of the first compensatory step. The differences in fall outcomes appeared at level 2 and 3 perturbations where a second step with the paretic leg was required to recover. AFO and FES users showed an increased inability to generate a second step with the paretic leg which led to a fall unless the subject used an alternative strategy such as pivoting or hopping [30] using the non-paretic leg effectively. In other words, the subject used the non-paretic leg for both first and second steps (and more steps if required). The inability to generate compensatory steps with the paretic leg and reduced trunk control have both shown to be linked with falls in individuals with stroke [28–30,35,38,39]. These impairments in the compensatory stepping response can be related to a combination of AFO's mechanical impact on the ankle, ankle impairment (e.g. spasticity, weakness), altered muscle activation patterns, and alternative strategies (e.g. increased hip power, lateral pelvic tilt, pivoting) [8,30,48,88]. To investigate the AFO/FES effect, subjects were tested without the AFO/FES as well. Interestingly, removing the AFO/FES had no significant impact on fall outcomes and the compensatory stepping response. These results suggest that the impaired compensatory stepping response of AFO users is likely not related to AFO's inhibitory mechanical effects but to the severe ankle impairments and the other aforementioned factors. It is important to note that AFOs and FES devices likely decrease community falls by increasing toe clearance [146,147,163] and preventing trips/stumbles. However, our results suggest that once a trip occurs, these devices may not assist recovery of balance because they do not address the present impairments.

3.5.3. Role of propulsion in fall prevention

Ankle propulsion primarily generated by plantarflexors [76–80], has a critical role in fall prevention because 1) it provides the kinetic energy to initiate a compensatory step [50], and 2) it contributes to whole-body angular momentum control [76,79,138–140]. Therefore, enhancing propulsion through plantarflexion assistance is suggested to address the impaired compensatory stepping response characterized by increased inability to initiate a paretic compensatory step and decreased trunk movement control. The results from chapter 2 highlighted the critical role of propulsion in generating a long compensatory step as well as controlling the trunk movements following trip-like perturbations. A semi-rigid AFO decreased propulsion, step length, trunk movement control, and COM stability of young healthy adults following trip-like perturbations.

Moreover, decreased propulsion by the provision of a rigid AFO has shown to deteriorate dynamic balance in young healthy adults [76,83] and children with hemiplegia [84] during walking. The mechanical effects of a rigid AFO combined with the ankle impairments can significantly compromise the ankle propulsion of individuals with stroke. A future AFO that provides plantarflexion assistance is suggested to reduce more falls by enhancing propulsion, trunk control, and paretic leg use during balance perturbations.

Enhancing plantarflexion forces can benefit the AFO users in several other ways that decrease risk of falling. For example, it increases knee flexion during the swing phase which enhances toe clearance thus reduce risk of stumbling [8,49]. Further, it can decrease the abnormal walking patterns and strategies (e.g. circumduction, pelvic tilt, increased hip flexion) [8], the energy cost of walking [171,172], and risk of muscle disuse atrophy and weakness [129]. Long-term AFO use – especially during the early stages of stroke recovery – might lead to decreased plantarflexors activity, muscle disuse atrophy [171,173], loss of strength [8], delayed recovery [171], reduced knee flexion associated with decreased toe clearance [8,49], and difficulties in paretic stepping. Therefore, a future AFO that assists plantarflexion not only enhances propulsion, walking, and fall prevention capability but is less likely to weaken the ankle joint muscles and delay recovery.

3.5.4. Future interventions to decrease falls

An ideal AFO that assists dorsiflexion during the swing phase and plantarflexion during the push-off phase of gait may decrease more falls. Several powered ankle-foot orthotic systems have been designed in university laboratories to provide power to the ankle joint for both dorsiflexion and plantarflexion [88,170,174]. These devices which are soft/rigid exoskeleton robots have shown to effectively increase propulsion [168,169], toe clearance [168,169], and walking speed [170] as well as reduce the energy cost of walking [169] using different types of actuators (e.g. hydraulic actuator, series elastic actuator). These devices can be used as an alternative for conventional rigid AFOs to enhance compensatory stepping response and prevent more falls. However, they are not commercially available due to several challenges. Most of these devices are tethered and used only in the laboratory for rehabilitation not as a daily wear assistive device.

An untethered device is suitable for daily use, but the common challenges are heavy weight and power supply for these devices. A future portable lightweight powered AFO with enough output torque assistance is suggested to reduce more falls in individuals with stroke. Future studies should evaluate the impact of these devices not only on walking but on the compensatory stepping response of individuals with stroke to determine if trunk control and paretic leg use can be effectively enhanced.

Another promising strategy that has shown to enhance trunk motion control [116,142] and reduce falls following trip-like perturbations [116] is a trip-specific training program (see chapter 4). Trip-specific training is a targeted training program that exposes individuals to trip-like treadmill perturbations repeatedly. This training program enhances the compensatory stepping response required to prevent a fall by evoking it repeatedly. Using a future powered AFO with plantarflexion assistance complemented by a trip-specific training program is suggested to enhance the compensatory stepping response and decrease falls in individuals with stroke.

3.5.5. Limitations and future directions

The present work evaluated fall outcomes and compensatory stepping response of AFO and FES users following trip-like treadmill perturbations where the subject was free to choose the leg to start stepping with. However, during an over-ground trip, the individual can get tripped on either leg. There are conditions in which one leg is blocked by an obstacle and it is required to initiate the compensatory step with the other leg. In the present study, AFO and FES users chose to initiate their step with the non-paretic leg over 90% of the time similar to our previously published work [30]. Further, when a second step with the paretic leg was required, some subjects used an alternative strategy (pivot and hopping) [30] using the non-paretic leg for the second step as well. While these strategies can help the individual recover from the treadmill perturbation, they may not be practical during an actual trip where the non-paretic leg is blocked. Therefore AFO/FES users may fall at even a higher rate due to decreased capability to use the paretic leg. If they initiate the step with the paretic leg, more differences in the kinematics of the compensatory step may appear (e.g. reduced step length, reduced COM stability). Future studies should evaluate falls and compensatory stepping response of AFO/FES users following trips on both paretic and non-paretic legs. Additional important questions being raised are 1) does blocking the non-paretic leg result in using the paretic leg more frequently? 2) does initiating the compensatory step with the paretic leg increase fall rate? 3) what other kinematic variables (e.g. step length, reaction time) characterize AFO/FES users' falls when the first compensatory step is generated by the paretic leg?

In the present study, we found that AFO and FES do not increase falls or impair the compensatory stepping response since removing them did not make a significant difference. However, we tested the subjects shortly after removing the AFO/FES possibly not allowing for sufficient acclimation time. Subjects are accustomed to using their AFO/FES daily. Removing the AFO/FES may increase fear of falling which might have affected our data. Moreover, AFO users might have developed impaired compensatory stepping response due to long-term AFO use, especially during the early stages of stroke recovery. Specifically, AFO use may have caused plantarflexion weakness [171,173], alternative strategies (e.g. increased hip power/flexion) [48,88], and reduced knee flexion during walking [8] leading to an impaired compensatory stepping response. Participants of this study were at the chronic phase of stroke. It is unclear how long-term AFO use has affected their compensatory stepping response from the time of prescription. Future studies should investigate how the possible impacts of long-term AFO use on muscle use and movement patterns affect the compensatory stepping response and fall risk. Nikamp et al., 2019 [133] showed that delayed provision of AFOs are associated with less falls compared to early provision. Future studies should find the best time for provision of AFOs to minimize the possible detrimental impacts on recovery process. Also, it is questionable if FES devices are better for recovery phase because they do not inhibit the activation of ankle muscles as AFO does.

3.6. Conclusion

Long-term AFO and FES users fall more often than Non-users because they have a more impaired ankle (i.e. weaker, more spastic, less functional) that is not fully addressed by AFO/FES.

AFO and FES users have a more impaired compensatory stepping response characterized by increased inability to generate a compensatory step with the paretic leg and decreased trunk movement control. AFOs and FES devices likely prevent community falls by preventing trips however once a trip occurs, they may not assist recovery of balance. Future AFOs that provide plantarflexion assistance are suggested to reduce falls because plantarflexion forces are critical for initiation of a compensatory step and trunk movement control.

CHAPTER 4

A SINGLE SESSION OF TRIP-SPECIFIC TRAINING MODIFIES TRUNK CONTROL OF INDIVIDUALS WITH STROKE FOLLOWING BALANCE PERTURBATIONS

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4.1. Abstract

Individuals with stroke are at significant risk of falling. Trip-specific training is a targeted training approach that has been shown to reduce falls in older adults and amputees by enhancing the compensatory stepping response required to prevent a fall. Still, individuals with stroke have unique deficits (e.g. spasticity) which draws into question if this type of training will be effective for this population. The objective of this study was to evaluate if a single session of trip-specific training could modify the compensatory stepping response (trunk movement, step length/duration, reaction time) of individuals with chronic stroke. Sixteen individuals with unilateral chronic stroke participated in a single session of trip-specific training consisting of 15 treadmill perturbations. A falls assessment consisting of 3 perturbations was completed before and after training. Recovery step kinematics measured during the pre- and post-test were compared using a repeated measures design. Furthermore, Fallers (those who experienced at least one fall during the pre- or post-test) were compared to Non-fallers. Trip-specific training decreased trunk movement post perturbation. Specifically following training, Trunk flexion was 48 and 19 percent smaller on the small and medium perturbations at the end of the first compensatory step. Fallers (9 out of 16 subjects) post-training resembled Non-Fallers pre-training. Specifically, Trunk flexion at the completion of the first step during small and medium perturbations was not different between Fallers post-training and Non-Fallers pre-training. Still enthusiasm was tempered because Trunk flexion at the largest perturbation (where most falls occurred) was not changed and therefore total falls were not reduced as a result of this training.Our results indicate that trip-specific training modifies the dynamic falls response immediately following trip-like treadmill perturbations. However, the incidence of falls was not reduced with a single training session. Further study of the implications and length of the observed intervention effect are warranted.

4.2. Introduction

In 2000, falls among older adults cost the US healthcare system 19 billion dollars [175]. This number ballooned 63% to 31 billion dollars in only 15 years [176]. From 2001 to 2008, falls increased 50% [177] and with a growing elderly population [176] so too are associated health care costs [137,178]. Individuals with stroke are 1.77 times more likely to fall compared to unimpaired older adults [16] making falls the most common medical complication after stroke [8]. There is a clear need for effective fall prevention programs for this vulnerable population.

Trip-specific training is a targeted training approach that reduces falls in older adults and amputees [116,179,180]. During trip-specific training, trainees are exposed to treadmill perturbations in a controlled setting where injuries are not possible. Treadmill perturbations simulate over-ground trips [93] allowing trainees to practice responding to conditions that occur during community trips. Trips are targeted because they represent one of the most significant causes of falls in older adults and individuals with stroke [25,91]. Trip-specific training reduces the fall-risk of older women in the laboratory by 83.2% [116] and in the community by 50% compared to control groups [108]. Trip-specific training accomplishes this rapidly in 4 hours over 2 weeks [108].

Contrast trip-specific training with exercise fall prevention programs. Exercise-based interventions (e.g. tai chi) have garnered attention in recent years due to their success in decreasing falls in older adults [96]. In group exercise programs, individuals attend one-hour sessions, 2-3 times a week, for at least 12 weeks [16,181,182]. Exercise-based interventions work by targeting factors associated with falls (e.g. muscle strength) [96]. These programs are effective at fall reduction, reducing falls 17% [96] *but* these programs are not as effective in individuals with stroke [100,101]. This raises the question if trip-specific training will be effective in individuals with stroke.

The ability to arrest and reverse the motion of the trunk after a trip is one of the most sensitive measurements to predict fall outcomes in the laboratory in young adults, older adults, and individuals with stroke [30,93,116,180,183]. For example, Fallers have significantly larger trunk flexion and velocity compared to Non-Fallers at the completion of the first recovery step [30,116]. Individuals with stroke are distinctive from older adults *but* they fall for similar reasons [30]. Falls in individuals with stroke can be characterized by larger trunk flexion velocities [30]. The objective of this study was to evaluate if a single session of trip-specific training can modify the compensatory stepping response (trunk movement, step length/duration, reaction time) of individuals with chronic stroke. We hypothesized that a single session of trip-specific training would modify the compensatory stepping response by reducing trunk flexion and velocity at the completion of the first recovery step similar to our previous results in older women [8].

Only two groups have investigated the efficacy of a training program that included perturbations (i.e. subjects being pushed/pulled in a controlled manner) delivered to individuals with stroke [117–119]. We extend their results by 1) evaluating the independent effects of trip-specific training on kinematic quantification of compensatory stepping responses (e.g. trunk kinematics, step length) of individuals with chronic stroke, 2) evaluating the effects of trip-specific training on center of mass (COM) stability measures, and 3) evaluating the effects of trip-specific training on subjects classified as Fallers and Non-fallers to determine whether falling prior to training influenced the results of the training.

4.3. Methods

4.3.1. Participants

Sixteen subjects with unilateral chronic stroke participated in this study (Table 4.1). Eligibility criteria were: 1) ability to stand and walk independently for 5 minutes, 2) no musculoskeletal injury or surgery in the past year and 3) no history of dizziness or fainting in the past year. This study was approved by Rehabilitation Institute of Chicago (RIC), Northwestern University, and University of Illinois at Chicago's (UIC) Institutional Review Boards. All subjects provided written informed consent.

Table 4.1. Subject characteristics and clinical scores for Fallers vs. Non-fallers. Fallers: those who experienced at least one fall (unambiguously supported by the harness) following a perturbation during pre- or post-test. Non-fallers: those who never fell during the experiment.

Variable	**Faller (n=9) mean (SD) or n**	**Non-faller (n=7) mean (SD) or n**	**P-value**
Subject characteristics			
Gender (M/F)	6/3	7/0	
Age (year)	60.8 (11.1)	57.7 (6.5)	0.53
BMI (kg/m2)	28.9 (4.0)	28.0 (6.3)	0.73
Hemiparetic side (R/L)	8/1	5/2	
Dominant leg before stroke (R/L/unknown)	6/3/0	6/0/1	
Time since stroke (year)	9.7 (6.1)	7.0 (3.3)	0.32
Stroke type (ischemic/hemorrhagic/unknown)	5/4/0	5/1/1	
Clinical scores			
Berg balance	49.6 (4.5)	52.9 (2.8)	0.11
5 times sit to stand (s)	23.5 (12.7)	22.1 (11.7)	0.82
10 m walk (comfortable pace) (s)	7.0 (1.0)	6.8 (2.2)	0.81
10 m walk (fast) (s)	5.0 (1.3)	5.0 (1.2)	0.97
PASE	134.1 (61.7)	156.2 (78.2)	0.54
Fall Efficacy Scale - International (FES-I)	29.4 (8.9)	23.6 (6.6)	0.17
Stance Asymmetry	1.15 (0.53)	1.00 (0.21)	0.50

Abbreviations: PASE Physical Activity Scale for the Elderly, M male, F female, R right, L left

4.3.2. Protocol

Subject characteristics and stroke information were recorded. PASE (Physical Activity Scale for the Elderly) [184], Fall Efficacy Scale – International (FES-I) [11], and Fall history questionnaires were completed. Balance and functional mobility were assessed using Berg Balance Scale, 10 m walk test, and 5 times sit-to-stand (Table 4.1). Stance Asymmetry was represented as the ratio of the weight borne on the non-paretic leg to the weight borne on the paretic leg over a 20-second period during which the subject stood quietly with a self-selected stance width and each foot on separate force plates (AMTI, Watertown, MA).

During the experiment, subjects received perturbations while standing on a dual-belt, stepper motor driven, and computer-controlled treadmill (ActiveStep™, Simbex, Lebanon, NH). Perturbations of varying amplitude were delivered in both anterior and posterior directions whereby a stepping response was required to prevent a fall. Subjects were instructed to stand with self-selected stance width on the treadmill and “do what is necessary to prevent falling” as the treadmill belt rapidly moves in an unexpected direction. Subjects were fitted with a ceiling-mounted safety harness to prevent their hands and knees from contacting the treadmill belts if they were unsuccessful to regain balance following a perturbation.

Subjects completed both a pre- and post-test as well as a single session of perturbation training. Training consisted of 15 posteriorly-directed perturbations (relative to the direction the subject was facing) during which the treadmill belts followed a trapezoidal velocity profile of moderate magnitude (displacement: 0.22 m, constant velocity: 0.56 m/s, acceleration and deceleration: 13.89 and -13.89 m/s^2). Posteriorly-directed perturbations elicit recovery kinematics that closely mimic those following an over-ground trip [93]. Posteriorly-directed perturbations require a forward stepping response to avoid a fall. The pre- and post-tests consisted of the same 6 perturbations – 3 posteriorly-directed and 3 anteriorly-directed perturbations. The direction of the perturbation was randomized to reduce the likelihood of anticipating the perturbation. Posteriorly-directed perturbations were designed using three different trapezoidal kinematic profiles (Small (level 1): 0.22m, 0.26 m/s, 6.5 and -6.5 m/s^2 ; Medium (level 2): 0.29 m, 0.64 m/s, 15.9 and -15.9 m/s^2; Large (level 3): 0.76 m, 1.3 m/s, 12.9 and -12.9 m/s^2). Displacement, constant velocity, acceleration and deceleration of anteriorly-directed perturbations ranged from 0.04 to 0.14 m, -0.6 to -1.2 m/s, -10 and 10 m/s^2. The direction of the perturbation was randomized but the magnitude was sequenced from small to large.

4.3.3. Data collection and analysis

Twenty-two passive-reflective markers were placed over specific upper and lower extremity and trunk landmarks using a modified Helen Hayes marker set [144]. The three-dimensional positions of markers were tracked by an 8-camera motion capture system (Motion Analysis Co., Santa Rosa, CA) operating at 120 Hz. Markers trajectories were filtered using a 4th order Butterworth with a cutoff frequency 6Hz (Cortex 2.5.2, Motion Analysis Co., Santa Rosa, CA). Kinematics were calculated from markers position using custom software (MATLAB, Mathworks, Natick, MA).

Dependent variables were Reaction time, Step duration, Step length, Trunk flexion and velocity, Dx, and Margin of stability (MOS). All variables are defined in Table 4.2 (Fig. 4.1). Variables were calculated at initiation (step_start: SS) and completion (step_end: SE) of the first recovery step. SS (i.e. toe off) was detected by visually detecting the first movement of the toe marker in the vertical direction. SE (foot contact) was detected by visually detecting the moment when either toe or heel marker vertical velocity reaches to zero (i.e. foot has contacted the treadmill). Whichever marker (i.e. toe or heel marker) that reaches zero velocity first is used to determine the SE.

All pre- and post-test trials were classified as either a “fall” or “recovery”. If the subject became unambiguously supported by the harness following a perturbation, the trial was considered a fall.

Table 4.2. Dependent variables and their definitions. The limb that initiated the first recovery step was labeled as the stepping limb and the contralateral limb was labeled as the base limb. Margin of stability (MOS) was adopted from Hof et al., 2005 [185].

Dependent variables	**Definition**
Reaction time	Time from perturbation onset to SS.
Step duration	Time from SS to SE.
Step length	Anteroposterior distance between the centers of stepping foot segment and base foot at SE.
Trunk flexion	Sagittal plane angle of the line connecting the center of the pelvis to the midpoint of the line connecting the shoulder markers relative to the initial position of the trunk at perturbation onset. Positive values representing a forward trunk tilt.
Trunk flexion velocity	Time derivative of the Trunk flexion.
Dx	Anteroposterior distance between vertical projection of center of mass (COM) position and the edge of the base of support (stepping leg toe marker) with positive values indicating COM to be within the boundary of the base of support (dynamically stable).
Margin of stability (MOS)	A dynamic stability measure calculated using both anteroposterior position and velocity of COM relative to the edge of the base of support with positive values representing dynamically stable and negative values indicating dynamically unstable conditions.

Abbreviations: SS: step_start, SE: step_end, COM: center of mass, MOS: Margin of stability.

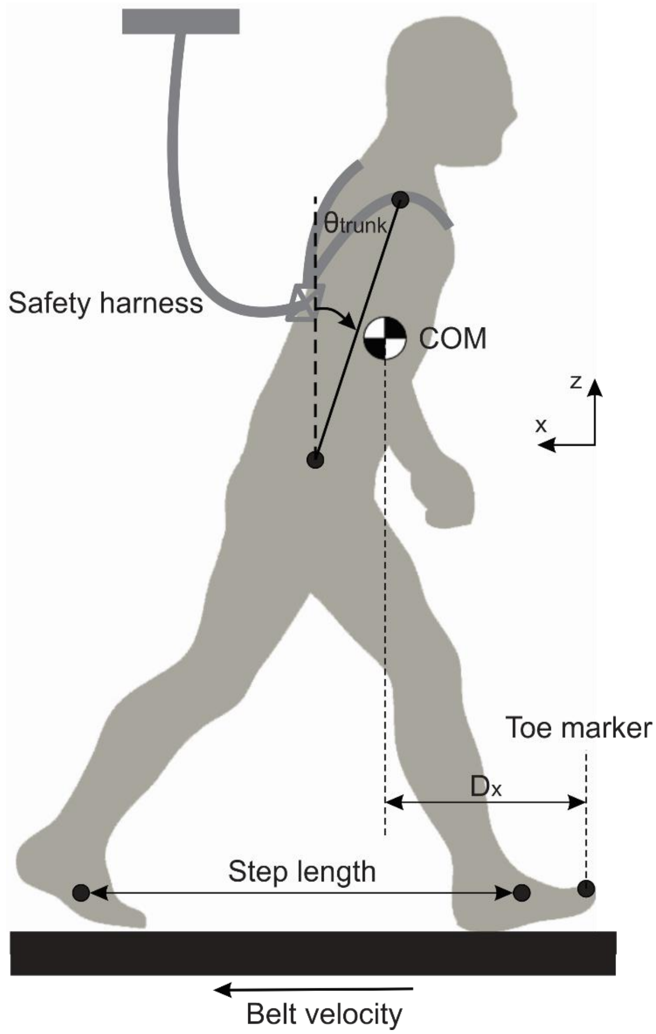

Figure 4.1. Kinematic and stability measures. Figure depicts a positive Trunk flexion angle, Center of mass (COM) position, positive Dx, and Step length.

4.3.4. Statistics

To evaluate the influences of a single-session trip-specific training on the effectiveness of recovery attempts following treadmill perturbations, a pre- and post-test comparison of all the dependent variables was conducted. Based on our hypothesis, we expected that trunk flexion angle and velocity would be significantly reduced after training similar to our previous results in older women [116]. A generalized linear mixed-effects model (GLMM) [145] was used with condition (pre-test/post-test) and perturbation level (1-3) as the independent variables and the aforementioned dependent variables (e.g. trunk kinematics). Subjects were treated as a random factor. Post-hoc comparisons were conducted using Tukey HSD test.

In a secondary analysis, Fallers (i.e. those who experienced at least one fall during the pre- or post-test) and Non-fallers (i.e. subjects who never fell during the experiment) were compared. Pre-test trials of Fallers and Non-fallers were compared to post-test trials. Furthermore, post-test trials for Fallers were compared to pre-test trials for Non-fallers. The same statistical analyses described above were conducted with pre-test and post-test, perturbation level (1-3) and Faller/Non-faller as the independent variables and the same dependent variables.

Fallers and Non-fallers were compared in subject characteristics and clinical scores (Table 4.1) using independent t-tests. All statistical analyses were conducted using R (R Development Core Team, 2006) with a significance level of $p \leq 0.05$.

4.4. Results

A total of 17 falls were recorded of which 15 occurred following the level 3 perturbation. Nine subjects who fell at least once were classified as Fallers. Nine falls occurred during the pre-test and 8 falls occurred during the post-test. Seven of the 9 Fallers fell during both pre- and post-test. Only 2 Fallers who fell in pre-test avoided falling in post-test. Differences of subject characteristics and clinical scores between Fallers and Non-fallers were not significant (all $P>0.05$; Table 4.1).

A majority of subjects used the non-paretic limb consistently through the experiment, but a handful of subjects used the paretic limb or modified their strategy during the training. Thirteen subjects always initiated recovery steps with their non-paretic limb. Three subjects (2 Fallers and 1 Non-faller) used both the paretic and non-paretic legs to initiate recovery steps across different levels and conditions. During pre-training on levels 1 and 2, none of the subjects initiated a stepping response with paretic leg. During post-training, 2 (level 1) and 3 (level 2) subjects initiated the recovery step with their paretic limb. Finally, at level 3, 2 subjects used the paretic limb during both pre- and post-tests.

4.4.1. Pre-test vs. post-test for all subjects

The trip-specific training was associated with reduced post-perturbation Trunk flexion following level 1 and level 2 perturbations (Fig. 4.2). At level 1, post-test Trunk flexion at SS was 34 percent smaller than that of the pretest ($F_{1,73}$=6.03, P=0.016). Post-test Trunk flexion at SE was 48 percent smaller than that of the pretest ($F_{1,73}$=19.91, P<0.0001). At level 2, the post-test Trunk flexion velocity at SS decreased 20 percent compared to pre-test ($F_{1,73}$=8.05, P=0.006). Finally, post-test Trunk flexion at SE decreased 19 percent compared to the pre-test ($F_{1,73}$=9.33, P=0.003). The post-training differences in Trunk flexion velocity at SE, Reaction time, Step duration, Step length, Dx and MOS were not significant (all levels; all P>0.05).

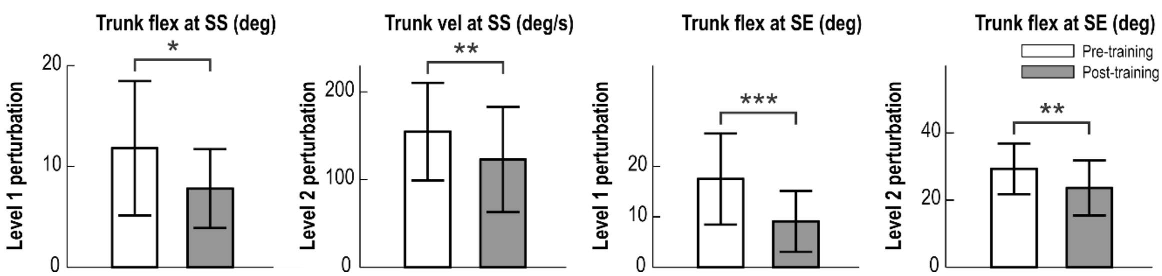

*Figure 4.2. Pre-test vs. post-test trials comparisons for all subjects. Figure represents significant differences between pre-test and post-test trials on different levels of perturbation. Subjects showed modified trunk control by showing reduced Trunk flexion and velocity at level 1 and 2 after trip-specific training. Error bars represent ± standard deviation. * = P-value < 0.05, ** = P-value < 0.01, *** = P-value < 0.001.*

4.4.2. Pre-test vs. post-test within Faller and Non-faller groups

Fallers showed more differences pre and post-test than Non-fallers (Fig. 4.3). At level 1 post-test, Fallers showed a reduction of 38 percent in Trunk flexion at SS compared to the pre-test ($F_{1,68}$=5.92, P=0.017). Fallers post-test Trunk flexion at SE decreased 54 percent compared to the pretest ($F_{1,68}$=20.90, P<0.0001). Moreover, the post-test Dx at SS increased more than 100 percent ($F_{1,68}$=11.15, P=0.0013). At level 2, Fallers post-test Trunk flexion at SE decreased 20 percent ($F_{1,68}$=7.01, P=0.0097) and Step duration was 33 percent larger in post-test trials compared to the pretest ($F_{1,68}$=4.04, P=0.048). The post-training differences in Trunk flexion velocity, reaction time, Dx at SE, MOS, and step length for Fallers were not significant (all levels; all $P>0.05$).

The only significant difference found between pre- and post-tests of Non-fallers was a 24 percent reduction in post-test Trunk flexion velocity at SS at level 2 trials ($F_{1,68}=5.17$, $P=0.026$). Non-fallers demonstrated trends toward smaller Trunk flexion at SE in post-test trials at level 1 ($F_{1,68}=2.84$, $P=0.096$) and level 2 ($F_{1,68}=3.13$, $P=0.08$) that did not reach significance. No differences were observed in Reaction time, Step duration, Step length, Trunk flexion velocity at SE, Dx and MOS at any levels (all $P>0.05$).

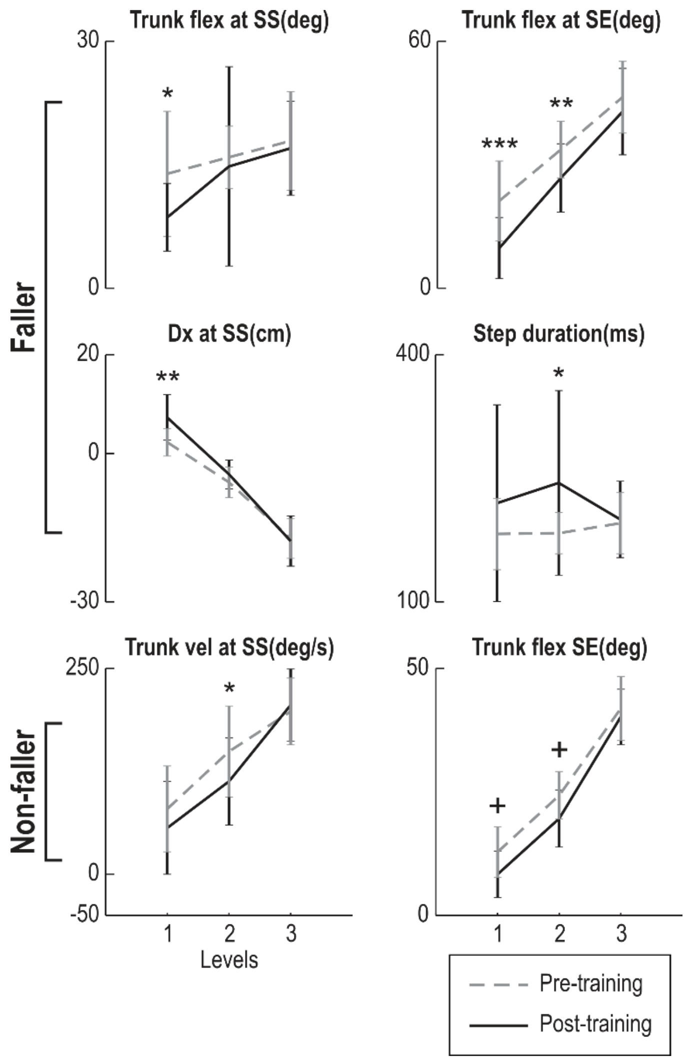

*Figure 4.3. Pre-test vs. post-test trials comparisons for Fallers and Non-fallers. Pre-test and post-test trials were compared across all different levels of perturbation in Faller and Non-faller groups separately. Recovery attempts of Fallers showed to be influenced by trip-specific training to a greater extent. Error bars represent ± standard deviation. + = P-value < 0.1; * = P-value < 0.05, ** = P-value < 0.01, *** = P-value < 0.001.*

4.4.3. Non-fallers vs. Fallers before and after training

Fallers exhibited a 65 percent larger level 1 ($F_{1,68}$=4.99, *P*=0.028) and a 38 percent larger level 2 ($F_{1,68}$=5.38, *P*=0.023) Trunk flexion at SE compared to Non-fallers (Fig. 4.4). Fallers also had a 290 percent larger level 2 ($F_{1,68}$=6.38, *P*=0.014) and a 434 percent larger level 3 Trunk flexion velocity at SE compared to Non-Fallers. Finally at level 3, Fallers showed 184 percent smaller Dx at SE ($F_{1,68}$=12.06, P=0.0008) and 34 percent smaller Step length ($F_{1,68}$=10.24, P=0.002) compared to Non-fallers during the pre-test.

While Fallers showed differences prior to training, after training Fallers resembled pre-test Non-Fallers. Trunk flexion at SE did not differ between post-test Fallers and pre-test Non-Fallers at level 1 ($F_{1,68}$=0.50, P=0.48) and level 2 ($F_{1,68}$=0.41, P=0.52). No differences were found between the groups in Trunk flexion velocity at SE at level 2 ($F_{1,68}$=1.54, P=0.22). No differences were found between the groups in Step duration, Reaction time and any other variables at SS (all levels; all P>0.05). Still, differences between the groups emerged at level 3. Trunk flexion velocity of Fallers was larger ($F_{1,68}$=6.10, P=0.016), Dx at SE was smaller ($F_{1,68}$=7.18, P=0.009), and Step length was smaller ($F_{1,68}$=7.56, P=0.007) compared to Non-fallers at level 3.

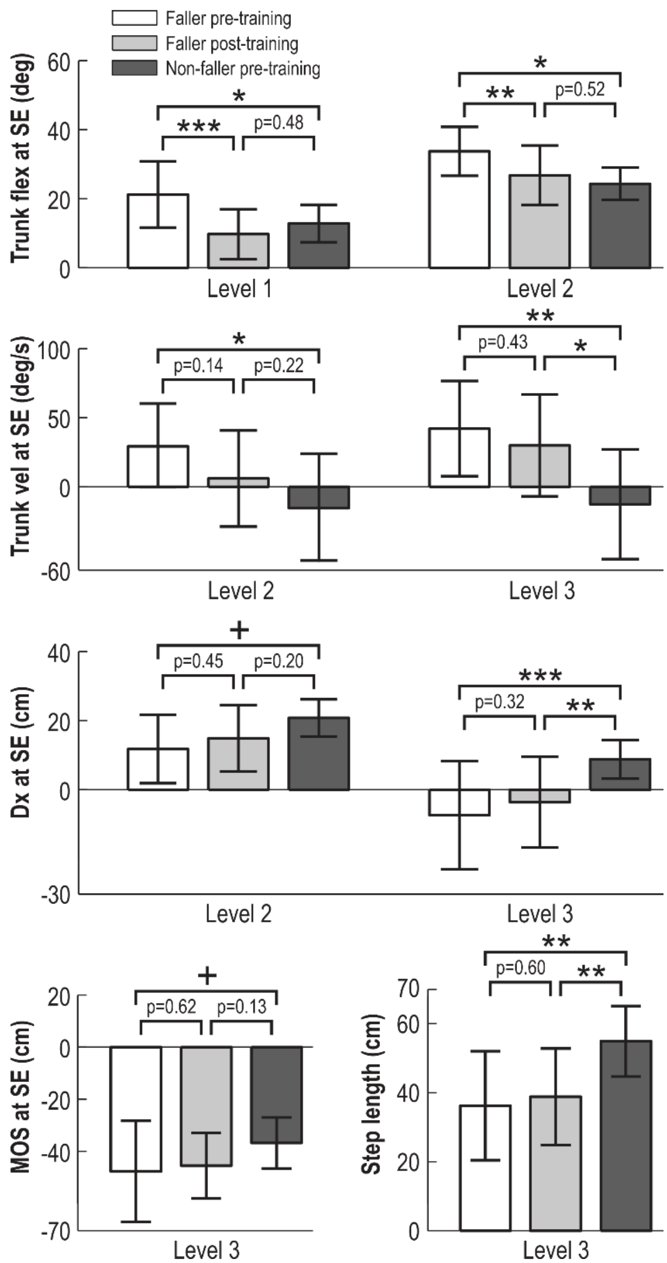

*Figure 4.4. Post-test trials for Fallers vs. pre-test trials for Non-fallers Comparisons. Before training, there were several differences in kinematics of the recovery attempts of Fallers and Non-fallers across all different levels. Recovery attempts of Fallers after training at level 1 and 2 were not different from the recovery attempts of Non-fallers before training. At level 3, recovery attempts of Fallers were not significantly influenced by the training and remained different from Non-fallers' recovery attempts prior to training. Error bars represent ± standard deviation. + = P-value < 0.1; * = P-value < 0.05, ** = P-value < 0.01, *** = P-value < 0.001.*

4.5. Discussion

The objective of this study was to evaluate if a single session of trip-specific training can modify the compensatory stepping response (trunk movement, step length/duration, reaction time) of individuals with chronic stroke. We hypothesized that a single session of trip-specific training would modify the compensatory stepping response by reducing trunk flexion and velocity at the completion of the first recovery step similar to our previous results in older women [8]. We found that the single-session trip-specific training protocol modified trunk control in all subjects with Fallers showing the most changes with their kinematics after training resembling those of Non-fallers pre-test. Despite these notable changes, no significant differences were found at the largest perturbation (level 3) – where most falls occurred. Further, only 22 percent (2 out of 9) of Fallers fell less often on the post-test compared to the pre-test. Thus, while significant modifications were found in a single session, indicating that this may be a viable option in individuals with stroke, additional questions are now raised. For example, what is the upper limit of perturbation from which an individual with stroke can learn to recover? For how long is the modified performance retained? Are falls in the community reduced by this training? Perhaps of greatest immediate interest is the extent to which the presently reported results are reproducible.

A single session of trip-specific training modified trunk control as measured by trunk flexion; however, trunk flexion velocity was less sensitive to trip-specific training. While no differences in trunk flexion velocity were reported pre- and post-training, trunk flexion velocity was modified when Fallers post-training were compared to Non-fallers pre-training suggesting this metric is being modified in Fallers but may not reach statistical significance due to 1) the short duration of training and 2) small sample size of this pilot study. Our previous work in older women showed both trunk flexion and velocity improvements [116]. However, these studies were larger (52 subjects) and each subject received at least 120 perturbations over 4-10 sessions. With this in mind, it is of significance that this study demonstrated modifications in trunk control in only a single session of 15 trials in a more challenging population. Still, future work should extend and replicate this work in a larger pool of subjects to determine if trunk flexion velocity and other important dependent variables (e.g. Reaction time, Step length, Step duration, Dx) can be modified.

4.5.1. Trip-specific training as a viable fall-prevention strategy

While previous work has demonstrated the potential of trip-specific training in healthy older adults, the present work aimed to assess the efficacy of trip-specific training in individuals with stroke. Previous work indicates trip-specific training [108,116] and slip-specific training [114] are viable fall-prevention interventions that can effectively reduce fall-risk in older adults even in a single session and in individuals with Parkinson's disease [110]. Moreover, the effectiveness of compensatory stepping response required to recover from falling, as measured by trunk control, is enhanced by trip-specific training [116]. Still, individuals with stroke may have neuromuscular deficits such as muscle weakness, spasticity/flaccidity, and abnormal muscle synergies [121] as well as diminished capacity for motor learning [126] that may limit the effectiveness of trip-specific training unless those deficits are addressed by the training. To our knowledge, only two groups have evaluated the effects of a training program that included postural perturbations on falls and stepping response of individuals with stroke [117–119]. Mansfield et al., 2018 engaged individuals with stroke in a 6-week trip-specific training protocol. They found that fall outcomes in the community were not statistically different between individuals exposed to trip-specific training and the control group. Still, differences were observed in reactive balance clinical testing (BEST-reactive) which were still present 12 months post-training. Our results support this report in that we see modification of the compensatory stepping response (decreased trunk movement) but not a decrease in laboratory-induced falls. This indicates that the traditional dosing of trip-specific training may need to be modified, lengthened, or used in conjunction with other fall prevention strategies to yield a decrease in fall outcomes. Still, Mansfield et al., 2018 and this report indicate that the reactive response during a fall can be modified in individuals with stroke and in relatively short duration (1 session/6 weeks) warranting further evaluation.

In summary, we have shown that 1) a single-session trip-specific training can modify trunk control in individuals with stroke following large postural perturbations that simulate a trip during locomotion 2) Fallers are particularly responsive to this type of training – even resembling Non-fallers' pre-test results.

4.5.2. Limitations and future directions

The present work represents a preliminary study that requires further study to determine its reproducibility and validate its use. First, we only evaluated short-term effects of training. Additional training is needed to modify responses to their natural limit as well as enhance retention, which we did not evaluate. Second, our subjects were ambulatory individuals with stroke with high Berg balance scores (Table 4.1). Future work should evaluate the safety and efficacy of this type of training in more severely impaired individuals. Third, no modifications were found on level 3 perturbations, where most experimental falls occurred. It is unclear if this lack of effectiveness is due to 1) limitations related to individuals with stroke (e.g. muscle weakness), 2) our specific protocol (e.g. training occurred on medium-sized perturbations of a single level), and/or 3) a combination of both. We found modifications on level 1 and 2, which is the similar size we trained the subjects. In the future, larger perturbations should be utilized to determine if further modifications can be seen during more challenging fall protocols. Alternatively, further practice on mid-size perturbations may prove effective given a longer, multiple-session protocol. Future work should probe how protocol shifts enhance the effectiveness of trip-specific training. Finally, our current study evaluated only anterior-posterior perturbations and did not consider upper extremity movements. We chose posteriorly-directed perturbations because they have been shown to resemble the mechanics of over-ground trips [93]. However, individuals with stroke can fall due to numerous reasons and other types of perturbations should be evaluated. In addition, upper extremity reaching movements are an important strategy used by older adults and patient populations [186,187]. Therefore, future studies should also evaluate if training affects these movements.

4.6. Conclusion

A single session (15 trials) of trip-specific training modifies trunk control in individuals with stroke. While dynamic falls response required to prevent a fall following a trip-like perturbation was modified, the incidence of falls was not reduced in a single training session. Replication and further study with an extended version of the presently described trip-specific training protocol is warranted to investigate whether the trunk control modifications can lead to reduced incidence of falls in stroke population.

CHAPTER 5

CONCLUSIONS

This dissertation aimed to evaluate the effectiveness and drawbacks of promising fall prevention strategies in individuals with stroke by rigorously analyzing the biomechanics of laboratory falls and compensatory movements required to prevent a fall with the ultimate goal of decreasing falls in stroke population. In chapter 2 and 3, ankle-foot-orthoses (AFOs) – the most commonly used orthotic device in the US [53] – and functional electrical stimulators (FES) that are commonly prescribed to treat foot drop in individuals with stroke were studied. The impacts of AFOs and FES devices on biomechanical mechanisms leading to falls in long-term AFO and FES users with chronic stroke as well as young healthy individuals were evaluated. Furthermore, these two chapters provide specific information about the factors and metrics that are required to be addressed in the future AFO design to decrease more falls. In chapter 4, trip-specific training which is a novel targeted training program recently raised as a potential solution to reduce trip-related falls was studied. In this training program, individuals are repeatedly exposed to trip-like perturbations that evoke the compensatory stepping response required to prevent a fall following a trip. The impacts of a single session training on the compensatory stepping response of individuals with stroke were studied to investigate whether trip-specific training is a viable training protocol to effectively reduce falls in stroke population. In summary, this dissertation provides very important specific information for clinicians, orthotists, and powered device engineers/researchers on how to improve the current AFO design and training programs to decrease more falls in individuals with stroke.

AFOs and FES devices are commonly prescribed to treat foot drop and decrease stumbling and falling in individuals with stroke. Despite well-established beneficial impacts of these devices on walking and static balance, their impact on fall outcomes of individuals with stroke is not well evaluated. In a recent study [94], both AFO and FES users showed a 40% fall rate 12 months after prescription. Although AFOs and FES devices likely prevent a percentage of community falls by preventing trips, the results from this study raise very important questions. Why do AFO/FES users still fall at a very high rate? Do AFOs and FES devices possibly increase falls in long-term? or is it because AFO and FES users have a more impaired ankle and compensatory stepping response that AFO/FES does not fully address? Rigid AFOs restrict plantarflexion which is a critical contributor to generate forward propulsion [76–80], initiate a fast compensatory stepping response, and control whole-body angular momentum [76,140]. AFO use has shown to deteriorate forward propulsion and dynamic balance in young healthy adults and children with hemiplegia [76,83–85]. Therefore, there is a concern that AFO use might negatively impact the compensatory stepping response required to prevent a fall. Thus, it is necessary to study the underlying mechanisms leading to falls in these individuals.

AFO users' compensatory stepping response might be affected by a combination of several important factors 1) mechanical inhibitory impacts of the AFO on the ankle, 2) ankle impairments (e.g. calf muscle weakness, spasticity), and 3) abnormal movement strategies developed to compensate the ankle weakness (e.g. circumduction, increased hip torque/flexion, increased non-paretic ankle power) [48,88]. Therefore, the results of the study on AFO users might reflect not only the AFO's impact but a combination of all these factors. Therefore, as a preliminary analysis and also to solely study the mechanical effects of the AFO on the ankle and compensatory stepping response, young healthy individuals were fitted with a semi-rigid AFO and studied in chapter 2. The results from young healthy adults are important because they have shown to fall for similar reasons as older adults and individuals with stroke (i.e. reduced trunk control, shorter step length, and reduced COM stability).

The objective of chapter 2 was to evaluate the impact of a semi-rigid thermoplastic AFO on the compensatory stepping response in young healthy individuals following trip-like treadmill perturbations. It was found that a semi-rigid AFO on the stepping leg diminished the propulsive impulse of the compensatory step which led to a decreased trunk movement control, shorter step length, and reduced COM stability. These results highlight the critical role of plantarflexors in generating an effective compensatory stepping response. However, AFO on the support leg (non-stepping leg) did not significantly impact the compensatory step kinematics. These results suggest that the mechanical effects of an AFO on the stepping leg might negatively affect the compensatory stepping response. However, AFO's impact on individuals with stroke could be different because the AFO's mechanical effects are mixed with the ankle impairment effect, altered muscle activation patterns, and alternative movement/fall prevention strategies. For example, individuals with stroke mostly initiate their compensatory stepping response with the non-paretic leg and if a second step is required they may use an alternative strategy (e.g. pivoting around the non-paretic leg) to avoid using the paretic leg.

The objective of chapter 3 was to investigate the underlying biomechanical mechanisms leading to high risk of falling in long-term AFO and FES users with chronic stroke. It was found that long-term AFO and FES users fall more often than Non-users following trip-like perturbations although their clinical scores of balance and mobility (BBS, TUG, 10 m walk test) were similar to the Non-users. However, the kinematics of the first compensatory step were not different between AFO users, FES users, and Non-users except the trunk velocity control at the completion of the first step which was diminished in both AFO and FES users. That is likely because AFO and FES users initiated their first step with the non-paretic leg 92.4% and 91.9% of the time respectively. These results are in agreement with the results from chapter 2, where AFO on the support leg did not significantly impact the kinematics of the first compensatory step. The differences in fall outcomes appeared at level 2 and level 3 perturbations where a second step with the paretic leg was required to recover. AFO and FES users showed an increased inability to generate a second step with the paretic leg. The inability to generate a second step with the paretic leg led to a fall unless the subject used an alternative strategy such as pivoting or hopping using the non-paretic leg effectively. In other words, the subject used the non-paretic leg for both first and second steps (and the following steps if required). The inability to generate compensatory steps with the paretic leg and reduced trunk control have shown to be linked with falls in individuals with stroke. These results suggest that 1) AFO and FES users might be at a higher risk of falling despite having clinical scores of balance and mobility similar to the Non-users, and 2) inability to generate a compensatory step with paretic leg and decreased trunk motion control are the two metrics that likely cause their higher fall rate. These impairments in the compensatory stepping response can be related to a combination of AFO's mechanical impact on the ankle, ankle impairments (e.g. spasticity, weakness), altered muscle activation patterns, and alternative strategies (e.g. increased hip power, pivoting) [48,88]. To investigate the AFO/FES effect, subjects were tested without the AFO/FES as well. Removing the AFO/FES had no significant impact on fall outcomes and the compensatory stepping response. Thus, our results suggest that the impaired compensatory stepping response of AFO users is likely not related to AFO's inhibitory mechanical effects but to the severe ankle impairments and other aforementioned factors. Specifically, AFO and FES users had a more impaired lower extremity (measured by Fugl-Meyer test), more spastic plantarflexors, and weaker dorsiflexors and plantarflexors compared to the Non-users. Finally, it is suggested that the AFOs and FES devices do not address the present impairments to assist preventing a fall once a trip occurs. It is important to note that the present study only evaluates non-paretic stepping in AFO/FES users. In a dynamic condition where the non-paretic leg is blocked and a paretic step initiation is critical for balance recovery, more differences in the kinematics of the compensatory step may appear (e.g. reduced step length, reduced COM stability). Still, future studies should investigate if the mechanical impacts of an AFO impede the compensatory stepping response when initiated with the paretic leg similar to the results from young healthy adults (chapter 2).

The results from chapter 2 and 3 provide evidence that modifying AFOs to address the ankle impairments and enhance the dynamic fall response is an essential need. Based on the results, an ideal AFO should be designed to assist dorsiflexion during the swing phase and plantarflexion during the push-off phase of gait. Plantarflexion assistance is critical because it enhances propulsion which 1) propels the leg forward at the initiation of the step, and 2) is a critical contributor to whole-body/trunk angular momentum control. Therefore, a future AFO that provides plantarflexion assistance is suggested to reduce more falls by enhancing trunk control and paretic leg use for compensatory stepping. Moreover, Enhancing plantarflexion forces can benefit the AFO users in several other ways that decrease risk of falling. For example, it increases knee flexion during the swing phase which enhances toe clearance thus reduce risk of stumbling [8,49]. Further, it can decrease the abnormal walking patterns and strategies (e.g. circumduction, pelvic tilt, increased hip flexion) [8], the energy cost of walking [171,172], and risk of muscle disuse atrophy and weakness [129]. Several powered ankle-foot orthotic systems have been designed in university laboratories to provide power to the ankle joint for both dorsiflexion and plantarflexion [88,170,174]. These devices which are soft/rigid exoskeleton robots use different types of actuators (e.g. hydraulic actuator, series elastic actuators) and have shown to effectively increase propulsion [168,169], toe clearance [168,169], and walking speed [170] as well as reduce energy cost of walking [169]. The promising results suggest these devices as an alternative to conventional rigid AFOs to enhance compensatory stepping response and prevent more falls. However, these devices are not commercially available due to several challenges. Most of these devices are tethered and used only in the laboratory for rehabilitation, not as daily wear assistive device. An untethered device is suitable for daily use but the common challenges are heavy weight and power supply for these devices. A future portable lightweight powered AFO with enough output torque assistance is suggested to reduce more falls in individuals with stroke. Future studies should test the impact of these devices not only on walking but on the compensatory stepping response of individuals with stroke to determine if trunk control and paretic leg use can be effectively enhanced. Another promising strategy that may enhance trunk control and paretic leg use during balance perturbations is using a targeted perturbation-based training which was studied in chapter 4.

Trip-specific training is a targeted training program that reduces falls in older adults and amputees [116,179,180]. In this training program, individuals are repeatedly delivered trip-like treadmill perturbations that evoke forward stepping required to prevent a fall. After only 4 hours of trip-specific training for 2 weeks, older women showed 83.2% and 50% reduced laboratory and community falls (respectively) compared to the control groups [108,116]. Moreover, older women's trunk motion control was improved after training [116]. Current exercise-based training programs have shown to reduce falls in older adults, but not successful reducing falls in stroke population [96]. The promising results of trip-specific training raise the question if this training will be effective in individuals with stroke. As shown in our results from chapter 3 and previous studies [30,38,39], trunk control is a very critical metric to reduce falls following balance perturbations. Therefore, it is important to investigate if trip-specific training can enhance trunk control in individuals with stroke similar to the results in older women [116].

The objective of chapter 4 was to evaluate if a single session of trip-specific training can modify the compensatory stepping response (trunk movement, step length/duration, reaction time) of individuals with chronic stroke. It was found that a single-session trip-specific training modified trunk control of individuals with stroke. These results, in a single session, indicate that trip-specific training may be a viable training option to enhance compensatory stepping response and reduce falls in individuals with stroke. However, fall rate was not reduced in a single session likely because 1) the training consisted of smaller perturbations than pre- and post-test perturbations and most falls occurred on the largest perturbation in pre- and post-test, and 2) multiple sessions were required similar to other studies [116]. Future studies should answer important questions such as 1) what is the upper limit of perturbation from which an individual with stroke can learn to recover? 2) For how long is the modified performance retained? 3) Are falls in the community reduced by this training?

In summary, in this dissertation, biomechanics of falls from 58 individuals with stroke and 10 young healthy individuals were analyzed to answer very critical questions on how to reduce falls in individuals with stroke. First, trip-related fall outcomes of individuals with stroke were analyzed and it was found that AFO and FES users fell more often than the Non-users during trip-like perturbations. Second, the biomechanical mechanisms leading to their high risk of falling were investigated and found to be 1) inability to initiate a compensatory stepping response with the paretic leg and 2) decreased trunk motion control. Third, the impacts of the AFO/FES were investigated by testing the subjects without them and it was found that AFO/FES does not significantly impact fall outcomes and compensatory stepping response. Rather, it is the severe ankle impairments (e.g. plantarflexor weakness, spasticity) that are not fully addressed by the

AFO/FES and put them at a higher risk of falling. Fourth, a potential solution to compensate for the impairments and decrease falls is suggested. Future AFOs should be modified to provide push-off assistance which is a critical factor for paretic step initiation and trunk control. Soft and rigid robotic ankle-foot orthotic devices that have shown to increase push-off as well as prevent foot drop can be used as an alternative for conventional rigid AFOs if designed portable, lightweight, and suitable for daily use. Finally, as another potential solution to enhance trunk motion control, trip-specific training was investigated and found to be a viable training option to enhance trunk control in individuals with stroke. Using a future powered AFO with plantarflexion assistance complemented by a trip-specific training program is suggested to enhance the compensatory stepping response and decrease falls in individuals with stroke.

5.1. Future directions

Although the results from chapter 2 suggest that propulsion is linearly correlated to an effective compensatory stepping response in young healthy adults, the correlation of step propulsion with fall outcomes and compensatory step kinematics in individuals with stroke remains to be investigated. It is very important to study the propulsion of both paretic and non-paretic legs during balance perturbations. Individuals with stroke often initiate their first compensatory step with the non-paretic leg. The first step is the most critical step to prevent a fall since many falls can be prevented by a single compensatory step. Therefore, future work should verify if the propulsion of the non-paretic step is correlated to critical metrics such as trunk movement control, step length, and COM stability. Moreover, future work should investigate if AFO users have reduced non-paretic side propulsion. As chapter 2 results suggest, having an AFO on one leg is unlikely to mechanically affect the propulsion of the step taken by the other leg. However, AFO users have a severely impaired lower limb that might be associated with a more impaired and delayed lateral weight shifting which is an essential function for the initiation of a non-paretic step. Therefore, decreased stability and weight-bearing capability of the paretic stance leg may negatively impact the effectiveness of a non-paretic compensatory step. More importantly, it should be investigated whether AFO users' decreased capability to initiate a step with the paretic leg and reduced trunk control are correlated to diminished propulsion on the paretic side. A combination of plantarflexors weakness and the inhibitory effects of an AFO can reduce propulsion of the paretic step. Future work should investigate whether propulsion assistance can enhance AFO users' capability to initiate a step with their paretic leg. Further, the correlation of the trunk movement control and push-off forces of the paretic leg during the swing phase of the non-paretic leg should be investigated. During the swing phase of the non-paretic leg, paretic leg's GRFs contribute to control the whole-body angular momentum. Therefore, plantarflexion assistance not only during the push-off phase but also during the stance phase of the paretic leg may compensate for the impairments of the compensatory stepping response and decrease falls in AFO users.

Future studies should investigate if there is a correlation between the plantarflexion MVIC (maximum voluntary isometric contraction) and the compensatory step propulsion during a balance perturbation. Reduced MVIC of the plantarflexors may correlate to reduced propulsion during a balance perturbation. However, reduced propulsion might be compensated using other joints such as the hip. Moreover, reduced propulsion may be due to a slower rate of plantarflexion torque generation rather than the MVIC which is the maximum plantarflexion torque an individual can generate. Therefore, future studies should evaluate the isometric torque generation rate as well as the MVIC. Future studies should determine if these metrics have a strong correlation with propulsion and can be used as a clinical measure to assess the propulsion. These metrics can be measured in clinical settings using a dynamometer system (e.g. Biodex System) while the subject is seated. On the other side, calculation of the propulsion during treadmill perturbations is more challenging and requires embedded force plates in a dual-belt treadmill as well as a safety harness.

Future studies should determine the most sensitive fall predictors (e.g. clinical scores of balance, gait analysis results). As our results suggest, standard clinical scores of balance such as BBS may not be adequately sensitive to predict the fall outcomes following balance perturbations. A rigorous study of a variety of the current clinical scores of balance and mobility such as BBS, TUG, 10 m walk test, mini best, functional gait assessment, and 5 times sit-to-stand should be performed to establish the best protocol to predict falls. Among the aforementioned tests, mini best is the only one that evaluates reactive stepping responses required to prevent a fall similar to the ones elicited during treadmill perturbations. Though further study is required, it is suggested that the mini best score may have the strongest correlation with laboratory falls and compensatory stepping responses. Further, gait analysis variables such as step length, walking speed, cadence, anterior-posterior and medio-lateral sway measures, whole-body angular momentum, and hip/knee/ankle kinematics should be studied to determine if any of those variables have a strong correlation with fall outcomes and compensatory stepping responses. For example, an increased sway in the sagittal and frontal plane may indicate a higher risk of falling. An increased range of angular momentum in either sagittal or frontal planes indicates reduced dynamic stability [76] and might increase the risk of falling. Decreased hip and knee flexion may lead to reduced toe clearance during walking and a higher risk of stumbling and falling. Furthermore, reduced hip and knee flexion results in difficulties initiating a paretic compensatory step following a balance perturbation. Since the treadmill perturbations were delivered from stance, it is also important to determine if kinematic and kinetic variables of the stance such as stance width, weight-bearing asymmetry, and sway measures while standing on both legs and one leg (both paretic and non-paretic) with eyes open and closed have any correlation with fall outcomes and compensatory stepping response effectiveness. For example, larger weight-bearing asymmetry – often characterized by larger weight borne on the non-paretic leg – may lead to a delayed and less effective non-paretic step initiation since more weight is required to be offloaded and shifted to the paretic side prior to step initiation. The length of stance on the paretic leg, as well as the sway measures during one-legged stance test, can be used to assess instability of the paretic leg. These measures may correlate to the instability of the paretic stance leg during a balance perturbation. Instability of the paretic leg may lead to 1) an early foot strike of the non-paretic leg and 2) reduced control of the whole-body angular momentum during the swing phase of the non-paretic leg. Therefore, instability of the paretic leg during the swing phase of the non-paretic leg may increase risk of falling. It is important to determine if instability of the paretic leg during the one-legged stance test can predict fall outcomes during balance perturbations. Measuring the paretic leg instability while standing on that leg is more practical, easier, and safer to perform in a clinical setting because it only needs a force plate rather than a treadmill system. Furthermore, future studies should investigate if lower limb impairment assessment using tests such as Fugl-Meyer, Modified Ashowrth Scale, as well as isometric/isokinetic ankle, knee, and hip maximum voluntary contraction correlates to fall outcomes. For example, ankle plantarflexors weakness may lead to reduced propulsion and therefore impaired compensatory stepping response. Moreover, knee and hip flexors impairments may lead to an increased inability to initiate a paretic step because knee and hip flexion are required to lift off the foot from the treadmill and maintain sufficient toe clearance during the swing phase. In summary, clinical scores of balance and mobility, gait kinematics and kinetics, stance kinematics and kinetics, and lower limb impairment of the individuals with stroke should be rigorously evaluated using a multiple regression analysis to find the correlation of these measures with fall outcomes and the effectiveness of the compensatory stepping response. Among the measures that have a correlation with falls, the best and most sensitive predictors of falls should be determined using appropriate statistical tests such as discriminant analysis and a principal component analysis (PCA). These data contribute to a very more precise fall risk assessment in individuals with stroke. Moreover, the best protocol can be developed to be used instead of balance perturbations for fall risk assessment because balance perturbations are difficult to perform and less practical in clinical settings. The new protocol can be used in the future to predict the impacts of different interventions (e.g. AFOs, training programs) on fall outcomes of individuals with stroke.

Alternative strategies to avoid falling such as pivoting and hopping during balance perturbations [30] should be evaluated for their impacts on fall outcomes in future studies. These strategies are used as an alternative for when the individual is unable/reluctant to initiate a second step with the paretic leg. While these strategies help to prevent falls on the treadmill it is unclear if they can be as effective during actual trips. Specifically, during an actual trip, non-paretic leg might be blocked by an obstacle which does not allow using these strategies. Future work should investigate if these strategies should be encouraged and enhanced by training to be used by stroke survivors or stroke survivors should be trained to not rely on these strategies and use their paretic leg more often during a balance perturbation. Furthermore, these strategies can be evaluated as a predictor of fallers. Individuals who develop these strategies might be at a higher risk of falling because they likely have a more impaired leg that leads to a more impaired trunk control and inability to generate a paretic compensatory step.

Hip extensors contribute to generate propulsion as well as the plantarflexors. Individuals with stroke often use hip power to compensate for the lack of propulsion caused by weak plantarflexors. However, individuals with stroke often have impaired hip extensors as well [8]. Future studies should evaluate the contribution of hip power to the propulsion of the compensatory step. Moreover, AFO users' hip extensors strength should be measured to determine if the impairments in the compensatory stepping response are correlated to a weak hip extensor. Hip extensors strength can be evaluated using isometric and isokinetic maximum voluntary contraction. Future work should verify if hip extensors weakness measured by MVIC correlates to a reduced hip power during a balance perturbation. Moreover, future work should investigate if hip torque assistance by using a powered hip orthotic device can enhance propulsion and the compensatory stepping response.

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APPENDIX A

ARIZONA STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD APPROVAL

ASU Knowledge Enterprise Development

APPROVAL: EXPEDITED REVIEW

Claire Honeycutt
BHSE: Biological and Health Systems Engineering, School of
-
Claire.Honeycutt@asu.edu

Dear Claire Honeycutt:

On 8/3/2015 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Biomechanical Analysis of Laboratory Induced Balance disturbances
Investigator:	Claire Honeycutt
IRB ID:	STUDY00002970
Category of review:	(4) Noninvasive procedures, (7)(a) Behavioral research
Funding:	Name: HHS-National Institutes of Health (NIH), Funding Source ID: R00 HD073240
Grant Title:	
Grant ID:	
Documents Reviewed:	• Fall_lab_honeycutt_IRB.docx, Category: IRB Protocol; • Questionnaire_fall history_honeycutt.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Research Strategy, Category: Sponsor Attachment; • ConsentForm_Falllab.pdf, Category: Consent Form; • Questionnaire_bergbalance_honeycutt.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Specific Aims, Category: Sponsor Attachment; • Fall_Flyer_honeycutt.pdf, Category: Recruitment Materials; • Quesiontainne_ PASE.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Honeycutt Citi Training, Category: Non-ASU human subjects training (if taken within last 3 years to grandfather in); • Phone and email script_honeycutt.pdf, Category: Screening forms; • 1K99HD073240-A1_ HoneycuttR00.pdf, Category: Grant application;

The IRB approved the protocol from 8/3/2015 to 8/2/2016 inclusive. Three weeks before 8/2/2016 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 8/2/2016 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the “Documents” tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Masood Nevisipour
Nathaniel Kirkpatrick
Claire Honeycutt
Xi Zong
Nicholas Walker

APPENDIX B

NORTHWESTERN UNIVERSITY INSTITUTIONAL REVIEW BOARD APPROVAL

Institutional Review Board Office
Northwestern University
Biomedical IRB
750 North Lake Shore Drive
Suite 700
Chicago, Illinois 60611
312-503-9338
Social and Behavioral Sciences IRB
600 Foster Street
Chambers Hall, Second Floor
Evanston, Illinois 60208
847-467-1723

NORTHWESTERN UNIVERSITY

3/14/2014

Eric Perreault
Physical Medicine and Rehabilitation
e-perreault@northwestern.edu

IRB Project Number: STU00091601
Project Title: Mechanisms underlying impaired postural corrections following stroke
Project Sites:
Rehabilitation Institute of Chicago (RIC)
Northwestern University (NU)

Sponsor Information (Grant #, if applicable):

National Institute of Health K99 HD073240

Submission Considered: New Submission Submission Number: STU00091601
Study Review Type: Expedited
Review Date: 3/14/2014
Status: APPROVED Approval Period: (3/14/2014 - 3/13/2015)

Dear Perreault,

The IRB considered and approved your submission referenced above through 3/13/2015. As Principal Investigator (P.I.), you have ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of human subjects.

You are required to comply with all NU policies and procedures, as well as with all applicable Federal, State and local laws regarding the protection of human subjects in research including, but not limited to the following:

Not changing the approved protocol or consent form without prior IRB approval (except in an emergency, if necessary, to safeguard the well-being of human subjects).

Obtaining proper informed consent from human subjects or their legally responsible representative, using only the currently approved, stamped consent form.

Promptly reporting unanticipated problems involving risks to subjects or others, or promptly reportable non-compliance in accordance with IRB guidelines.

Submit a continuing review application 45 days prior to the expiration of IRB approval. If IRB reapproval is not obtained by the end of the approval period indicated above, all research related activities must stop and no new subjects may be enrolled.

IRB approval includes the following:
Waiver of Consent: A Waiver of Consent was granted for this project in accordance with section 45CFR46.116d(1-4)

Protocol Document:
Name
Protocol

Recruitment Materials (Note- the investigator is responsible for complying with applicable departmental or NU policies regarding use of bulk e-mail for recruitment purposes):

Name
email script
telephone script

Survey/Questionnaires:
Name

Berg Balance
Fall History
PACE