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An immediate effect of custom-made ankle foot orthoses on postural stability in older adults

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ABSTRACT

Background: Foot and ankle problems are highly prevalent fall risks in the elderly. Ankle foot orthoses designed to stabilize the foot and ankles have been studied within specific patient groups, but their efficacy with a less restrictive elderly population is unknown. This study investigated if custom-made ankle foot orthoses improve postural stability in older adults.
Methods: Thirty ambulatory older adults averaged 73 (standard deviation = 6.5) years completed Romberg's balance (eyes-open/eyes-closed), functional reach, and Timed Up and Go tests while wearing validated kinematic sensors. Each test was completed in standardized shoes with and without bilateral orthoses. Additionally, barefoot trials were conducted for the Romberg's and functional reach tests.
Findings: Compared to the barefoot and 'shoes alone' conditions, the orthoses reduced center of mass sway on average by 49.0% ($P = 0.087$) and 40.7% ($P = 0.005$) during eyes-open balance trials. The reduction was amplified during the eyes-closed trials with average reductions of 65.9% ($P = 0.000$) and 47.8% ($P = 0.004$), compared to barefoot and 'shoes alone' conditions. The orthoses did not limit functional reach distance nor timed-up and go completion times. However, the medial-lateral postural coordination while reaching was improved significantly with orthoses compared to barefoot (14.3%; $P = 0.030$) and 'shoes alone' (13.5%; $P = 0.039$) conditions.
Interpretation: Ankle foot orthoses reduced postural sway and improved lower extremity coordination in the elderly participants without limiting their ability to perform a standard activity of daily living. Additional studies are required to determine if these benefits are retained and subsequently translate into fewer falls.

1. Introduction

Falls are a major health concern for the rapidly growing older adult population (above 65 years of age). Estimates of the proportion of elderly that fall each year have ranged from 22.1% to almost 40% (Hausdorff et al., 2001; Shumway-Cook et al., 2009). Miller et al. found that 8.3% of seniors treated for a fall at an emergency department, returned for treatment of a secondary fall within 6 months of the initial fall (Miller et al., 2009). The cost of treating a fall requiring any medical care averages $4100 for Medicare patients (Shumway-Cook et al., 2009). Falls by older adults treated in an emergency department are reported to average $11,408 in costs and increase to $29,363 if hospitalization is required (Woolcott et al., 2012).

While falls are often multifactoral in cause and subsequently their prevention will require interprofessional interventions, podiatry is one area of medicine that has recently been increasing its efforts to better understand and prevent falls (Najafi et al., 2013a). Prospective research has shown foot and ankle problems which are highly prevalent in older adults (Dunn et al., 2004), increase the risk of falls (Menz et al., 2006a). This relationship has implications for quality of life and occurrence of depression (Downton and Andrews, 1991; Quach et al., 2013). The contribution of footwear to falls has in part been demonstrated by work that showed an association between indoor falls of older adults and lack of shoe use indoors, suggesting that shoes may help prevent falls (Menz et al., 2006b). Previous research has shown that a multifaceted podiatric intervention utilizing home based foot and ankle exercises, assistance with the purchase of safe footwear, and provision of prefabricated foot orthoses can reduce the rate of falls in older people with disabling foot pain (Spink et al., 2011).

Foot problems, loss of proprioception and decreases in ankle strength and range of motion associated with aging have been tied to deteriorations in balance and increased fall risk (Anon, 2011b; Bok et al., 2013). Ankle foot orthoses (AFO) are intended to keep the foot and ankle in optimal positions and are commonly prescribed with the intent of improving gait and balance. Previous work with nonpathologic samples has suggested that AFO can facilitate proprioception via stimulation of cutaneous mechanoreceptors (Feuerbach et al., 1994)

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and mitigate the impact of fatigued ankle muscles upon stability (Vuillerme and Pinsault, 2007). In the case of peripheral neuropathy patients, AFO reduced gait variability while walking on uneven surfaces by stabilizing the ankle (Richardson et al., 2004; Son et al., 2010). In 2006, there were 75,240 AFO prescribed under Medicare alone (HCPCS/Alpha-Numeric, 2008). While there is a large volume of studies that have shown the benefits of AFO for individuals that have suffered a stroke, multiple sclerosis, Charcot, or non-progressive brain lesions (Geboers et al., 2002; Menotti et al., 2014; Tyson and Kent, 2009), research involving a less restrictive sample of the older adult population is lacking (Hijmans et al., 2007).

Although a direct objective predictor of fall risk has not been discovered yet, several studies have determined a strong association between poor postural balance and increased risk of falling. Abnormal postural sway measured by the range of sway, for example, has been introduced as a significant independent predictor of recurrent falls (Maki et al., 1994; Thapa et al., 1996), or as a distinguishable factor among fallers and non-fallers (Lajoie and Gallagher, 2004; Maki et al., 1994).

Therefore if an AFO were able to improve postural stability while avoiding limiting the ankle range of motion, it may subsequently reduce fall risk in the general older adult population. Hence, the purpose of this investigation was to determine the immediate effect of a custom-made flexible AFO on balance and functional reach distance in a less restrictive sample of older adults than has been utilized in previous AFO research. We hypothesize that an open gauntlet style custom made AFO could improve postural stability. Secondarily, we hypothesize that such an AFO might influence ankle function in the anterior posterior direction as well as tasks of daily living. To validate the later hypothesis, we examined the immediate impact of AFO on forward reach distance, a common household activity, as well as timed-up and go (TUG) completion times as a surrogate of motor function performance during activities of daily living.

2. Methods

2.1. Participants

Thirty participants were recruited over a six-month period (Table 1) by flyers, word of mouth and from an outpatient podiatry clinic in North Chicago, IL. Inclusion criterion included being aged 65 years or older and the ability to walk 20 m without an assistive device. Individuals with hemiplegia and with excessive lymphedema or edema that would prohibit appropriate fit of the AFO were excluded. All potential participants read and signed a local institutional review board approved consent form prior to completing any study procedures.

Table 1
Subjects' demographics.

Number of participants	N = 30
Age (years)	73 (6.5)
BMI (kg/m^2)	30 (5.2)
Gender	Female: n = 23; 76.7% Male: n = 7; 23.3%
Diabetes mellitus	n = 14; 46.7%
Diabetes mellitus with peripheral neuropathy	n = 13; 43.3% Average VPT left foot = 51.9 (23.2) Average VPT right foot = 53.3 (27.2)
Geriatric Depression Scale	Average score: 2.59 (3.21) No depression: n = 24; 80.0% Mild depression: n = 4; 13.3% Server depression: n = 2; 6.7%
Fall Efficacy Scale International	Average score: 30.6 (8.5) No concern for fall: n = 4; 13.3% Moderate concern for fall: n = 7; 23.3% High concern for fall: n = 19; 63.3%
Self reported history of one or more falls in the past 12 months	No fall: n = 14; 46.7% One fall: n = 10; 33.3% Multiple falls: n = 6; 20.0%

2.2. Procedures

During the initial visit, eligibility was confirmed and shoe size was measured for requisition of standardized athletic shoes (OrthoFeet, Northvale, NJ, USA). The participants were casted with their feet on a contoured footboard and knees at 90° in order to produce the custom-made AFO (Moore Balance Brace, Langer Biomechanics, Ronkonkoma, NY, USA) which had flexible, open ankle posterior leaf style gauntlet design which is intended to allow ankle stabilization without inhibiting sagittal plane motion. The participants reported previous history of falls in the past one year and completed a fear of falling questionnaire, Fall Efficacy Scale International (FES-I) (Delbaere et al., 2010; Yardley et al., 2005). Based on the FES-I scores, the participants were further classified as having low (16–19), moderate (20–27), or high (FES-I score ≥28) concern for falling (Delbaere et al., 2010). The Geriatric Depression Scale (GDS-15) (Almeida and Almeida, 1999; de Craen et al., 2003) was also administered with GDS-15 score of 5 or greater selected as cutoff for the identification of signs of moderate or severe depression (Marc et al., 2008). Finally, subject demography characteristics (e.g. age, gender, height, and weight) and medical history (e.g. presence of diabetes) were collected. Peripheral neuropathy (loss of plantar sensation) was assessed via vibration perception threshold score (VPT) as described by Young (Young et al., 1993) for the participants who were diabetic as the prevalence of peripheral neuropathy is approximately 35% in this population (Gregg et al., 2004). The presence of moderate to severe neuropathy was determined by VPT score ≥25 V, whereas those with a VPT <25 V were classified as having only mild or no neuropathy. With the participants in a seated position with their eyes closed, VPT was assessed by asking the participants to identify when they perceived vibratory sensation on the great toe using a biothesiometer (Xilas Medical, San Antonio, TX, USA). VPT scores were recorded as continuous variables within a range of 1–100 V. The highest value obtained at the right and left great toe was used for analysis (Armstrong et al., 1998).

The second and final visit was completed once the custom-made AFO had been manufactured. Subjects had no experience using the AFO prior to this visit. Each of the AFO had a custom-made footplate and arch support with flexibility for plantar/dorsi flexion as shown in Fig. 1a. The AFO was placed inside the shoe (Fig. 1b) and the participants slid their feet into the shoe. The appropriate fit was determined after each patient walked approximately 30 ft and the shoe size, straps and laces were adjusted by the researcher. Balance and functional reach (FR) bilateral assessments were conducted in three conditions: 'barefoot', standardized shoes ('shoe alone'), and with AFO in standardized shoes ('shoe + AFO'). TUG tests were limited to the 'shoe alone' and 'shoe + AFO' conditions. With the exception of barefoot assessments, all assessments were performed while the subjects wore knee high athletic socks and the standardized shoes. To prevent any learning or practice bias, the order of 'shoe alone' and 'shoe + AFO' conditions was randomized for each subject.

2.3. Assessment protocols

2.3.1. Balance assessment

Each participant performed six 30-second trials (two for each footwear condition during eyes-open and eyes-closed) standing upright (bipedal) with their arms crossed, feet positioned close to each other without being in contact. During eyes-open trials, the participants were instructed to keep their eyes open and focused straight ahead with no visual target being specified. During eyes-closed condition, the participants were instructed to close their eyes while standing till any instruction was heard from the examiner. Talking was not allowed during the assessments. The order of footwear conditions was randomized across subjects, however, within each condition eyes open trials were administered first and then eyes closed trials followed. One of

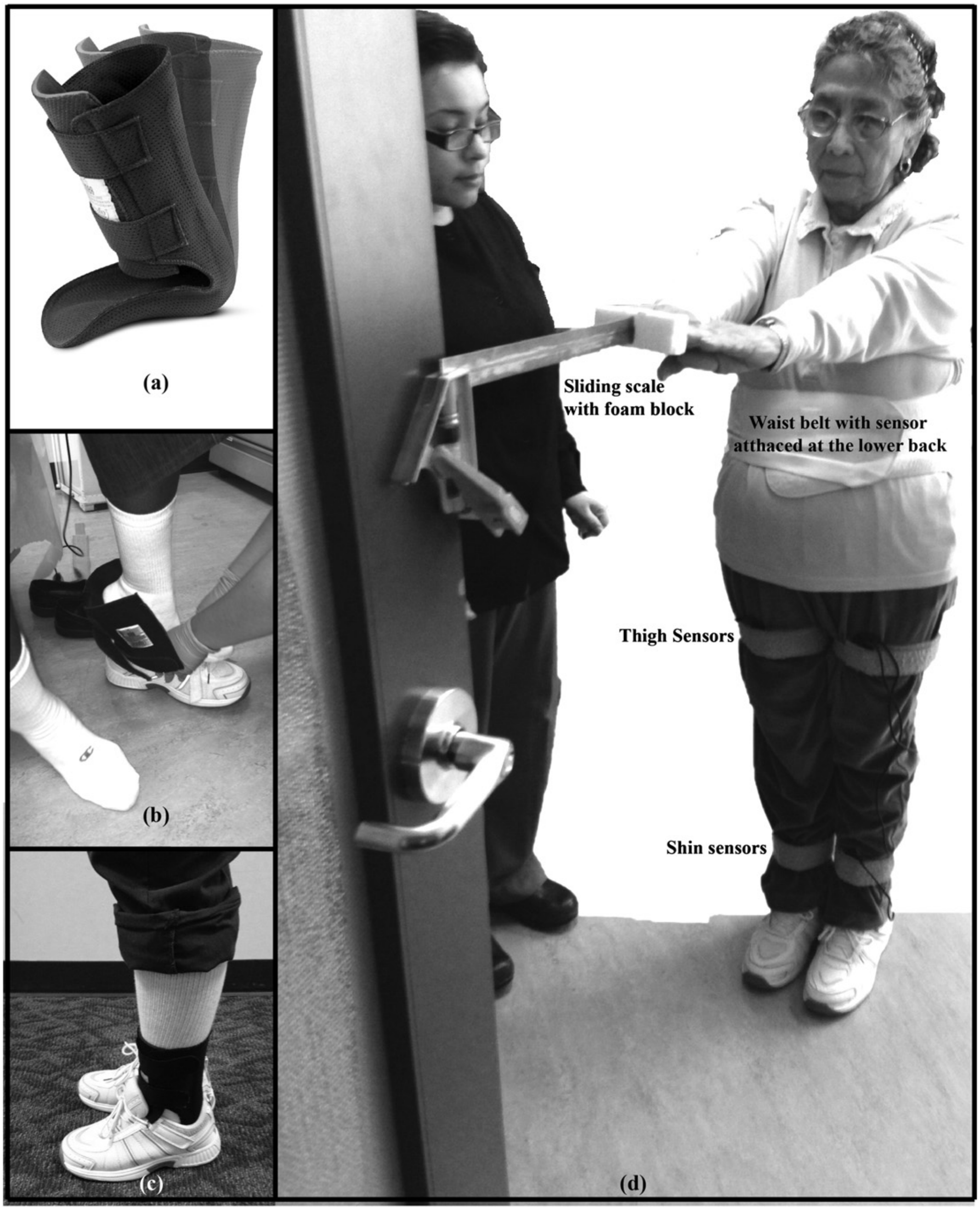

Fig. 1. (a) Open posterior leaf gauntlet style custom-made AFO (b) Participants sliding in their feet into the standard shoes (c) AFO placed inside the standard shoes (d) Functional reach task with sliding scale arrangement and body worn inertial sensors attached to the shin, thigh and the lower back.

the research team members served as a spotter during the balance trials in order to stabilize a subject if they completely lost their balance.

Postural sway during each trial was quantified by center of mass (COM), ankle, and hip area of sway following identical procedures reported and validated in our earlier study using wearable sensors (Najafi et al., 2010a, 2012). Briefly, five inertial sensors, each including a triaxial accelerometer, triaxial gyroscope, and a triaxial magnetometer (BalanSens™, BioSensics LLC, Boston, USA), were attached respectively, to subject's shin, thigh, and lower back (close to sacrum) using comfortable Velcro bands as shown in Fig. 1d. The wearable sensors allowed estimating three-dimensional (3D) angles of the ankle and hip joints with a sampling frequency of 100 Hz. A two-link model of the human body was then used to calculate the COM stabilogram from estimated angles and subject's anthropometry (i.e. height and weight) data. The ranges of sway in medial–lateral and anterior–posterior directions were then estimated for COM, ankle and hip using the stabilogram data, after excluding outliers as described in a previous study (Najafi et al., 2010a). The total sway was then calculated by multiplying the range of motion in anterior–posterior and medial–lateral directions.

2.3.2. Functional reach assessment

We assumed that the custom-made AFO might restrict ankle function in the anterior–posterior direction. To examine this hypothesis, a Functional Reach (FR) task similar to the one described by Duncan et al., (Duncan et al., 1990) was modified to objectively assess reach distance and postural stability in all the three footwear conditions. The task required the subject to stand erect with arms stretched forward and one hand placed on top of the other (Fig. 1d). A slide ruler was attached to a door approximately at shoulder height in front of the subject. A foam block was affixed to the end of the ruler to ease finger contact with the ruler. The subject was then instructed to push the foam block as far forward as possible by leaning forward without bending knees. The subjects were also not allowed to step forward and were instructed to stop if they felt like they were losing balance or if they felt they would need to take a step in order to push the ruler further. Each trial was repeated twice with randomized order of footwear conditions and the average of the two trials was considered for final statistical analysis. As it was plausible that the AFO might also influence the time required to get to the maximum reach distance by challenging ankle function, time taken to reach the maximum distance was measured by utilizing the acceleration readings of the lower back inertial sensor (Fig. 1) of the BalanSens™ system (BioSensics LLC, Boston, MA, USA).

To quantify, functional reach ability, the maximum reach distance was measured using the slide ruler. In addition, postural coordination (reduction in COM sway through coordination of hip and ankle motion) was quantified using reciprocal compensatory index (RCI) (Najafi et al., 2010a). Briefly, using wearable sensors described earlier, ankle, hip, and COM sway were estimated. RCI was calculated according to the following formula:

$$\mathrm{RCI} = \sqrt{\frac{var(COM)}{k1^2 var(\sin(\theta a)) + k2^2 var(\sin(\theta h))}}$$

Where, 'var' denotes variance, and θ_a and θ_h denote, respectively, ankle and hip angles in any given time. K1 and K2 are constants and are estimated using subject's anthropometry data as described in Najafi et al. (Najafi et al., 2010a). RCI values close to zero indicate good coordination between the hip and ankle and values close to or greater than one are indicative of poor coordination. In this study, RCI was estimated in medial–lateral directions, assuming that a minimum COM motion in medial–lateral direction indicated an optimum functional reach task in anterior–posterior direction.

2.3.3. TUG assessment

To examine whether AFO restrict subjects' mobility performance, we examined the impact of AFO on TUG completion times (Podsiadlo and Richardson, 1991; Shumway-Cook et al., 2000). The test includes major motor tasks such as rising from a chair, walking, turning, and sitting on a chair. Assuming that AFO will not restrict major daily motor performance, we hypothesized that there would be a difference in TUG completion times with and without wearing the AFO. The standard TUG test was performed by all the participants in 'shoe alone' and 'shoe + AFO' conditions. Similar to the extraction of time taken to reach the maximum FR distance, the lower back inertial sensor of the BalanSens™ system (BioSensics LLC, Boston, MA, USA) was used to extract the exact TUG completion times in all trials. The normal time required to finish the test is between 7 and 10 s (Podsiadlo and Richardson, 1991).

2.3.4. Subjects' perception assessment

After all measurements were completed, the subject's perception of wearing AFO was assessed using a 10-point Likert scale questionnaire, which included the following statements:

Question 1: The AFO make me feel less likely to fall when standing.

Question 2: The AFO rubs or hurts my ankle when I walk.
Question 3: I am likely to continue to wear the AFO daily.

The subjects were asked to mark on a 10-point Likert scale with anchor descriptors of strongly disagree at 0 and strongly agree at 10 for each item of the questionnaire.

2.4. Statistical analysis

Sample size of 30 was determined based on a previous study using the same sensors (Najafi et al., 2010b). Based on a previous study, considering a power = .80, $P < .05$, 19 patients were required to observe significant variations in COM sway area. In order to study the effect of AFO on postural stability, comparisons across foot conditions ('barefoot', 'shoe alone', 'shoe + AFO') for all measurable parameters were made using repeated measures ANOVA. Cohen's d values were calculated to measure the effect size between groups. When the normality assumption was satisfied and a significant difference ($P < 0.05$) was found, the Least Significant Difference (LSD) post-hoc test was used for pairwise comparisons. Age and BMI were used as covariates. Multivariate ANOVA test was used to evaluate the effect of the subject's history (e.g. presence of diabetes, presence of neuropathy, history of fall, fear of falling, depression, and medication use) on magnitude of postural sway changes after wearing AFO compared to 'shoe alone' condition.

To identify independent predictors for change in postural stability after wearing an AFO when compared to 'shoe alone' condition, a multiple linear regression backwards model was used. The subjects' age, BMI, FES-I, and baseline balance (postural sway during 'shoe alone' trial) were assumed as independent variables. Pearson's correlation coefficient was calculated for examining the correlation between dependent variables (e.g. changes in COM sway during eyes-closed after wearing AFO compared to 'shoe alone' condition) and independent variables identified using regression model.

Categorical data have been reported as absolute numbers, and its relative percentage and parametric data as mean and standard deviation in parentheses (SD). Postural balance results have been adjusted by BMI and age. Additionally, in Fig. 2, the error bar represents the SE values. The resultant P-value was represented for each test up to three decimal points. For all tests an alpha level of 0.05 was considered statistically significant. When group differences achieved statistical significance, 95% confidential interval (95%CI) was also reported. All calculations were made using SPSS, v.21.

3. Results

3.1. Effect of AFO on postural sway

During eyes-open trials (Table 2), wearing AFO reduced COM sway by an average of 49% compared to 'shoe alone' ($P = 0.005$, 95%CI = −0.058 to −0.012 cm^2) and 40.7% compared to 'barefoot' ($P = 0.087$, 95%CI = −0.106 to 0.008 cm^2). While no between group difference was observed for hip sway ($P > 0.685$), ankle sway on

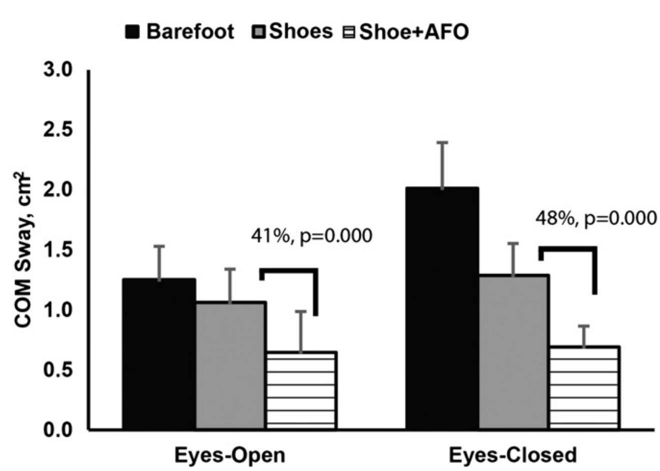

Fig. 2. Standing balance postural sway assessment results. Center of Mass (COM) sway area during Barefoot, Shoes alone and AFO's in Standard shoe conditions with error bars representing standard error.

Table 2
Standing balance during eyes-open tests.

	Barefoot G1	Shoe alone G2	Shoe + AFO G3	*P* value	Groups	Difference*	Pairwise *P*-value	95% Confidence interval for difference	
								Lower bound	Upper bound
COM sway, cm^2	1.231 (1.408)	1.055 (1.411)	0.630 (1.734)	0.000	G2–G1	−0.176 (1.565) 14.0%	0.544	−0.062	0.034
					G3–G1	−0.601 (1.812) 49.0%	0.087	−0.106	0.008
					G3–G2	−0.425 (0.734) 40.7%	0.005	−0.058	−0.012
Ankle sway, deg^2	0.646 (0.617)	0.557 (0.619)	0.254 (0.414)	0.000	G2–G1	−0.089 (0.119) 13.8%	0.458	−0.333	0.154
					G3–G1	−0.393 (0.106) 60.8%	0.001	−0.611	−0.175
					G3–G2	−0.303 (0.054) 54.4%	0.000	−0.414	−0.192
Hip sway, deg^2	0.542 (0.350)	0.480 (0.378)	0.580 (1.560)	0.000	G2–G1	−0.062 (0.068) 11.4%	0.370	−0.201	0.077
					G3–G1	0.038 (0.276) 7.0%	0.892	−0.528	0.603
					G3–G2	0.099 (0.242) 20.6%	0.685	−0.398	0.596

All results have been adjusted by age and BMI of participant.
* SD values were reported in parenthesis.

average was significantly reduced after wearing AFO by 60.8% ($P = 0.001$, 95%CI = −0.611 to −0.175 deg^2) and 54.4% ($P = 0.000$, 95%CI = −0.414 to −0.192 deg^2) compared to 'barefoot' and 'shoes alone' conditions respectively. Although, wearing shoes moderately reduced COM sway compared to 'barefoot' by 14% on average, the enhancement was not statistically significant in our sample ($P = 0.544$). On the same note, no significant difference was observed for ankle and hip sway by wearing shoes alone compared to barefoot condition.

Eyes-closed trials show (Table 3) that 'shoes alone' and 'shoe + AFO' conditions significantly reduced body sway compared to 'barefoot' in particular for COM and ankle sway. However, between group difference effect size for 'shoe + AFO' was almost double that of the 'shoes alone' condition for COM sway (d = 0.407 for 'shoe alone' v. 'barefoot'; d = 0.793 for 'shoe + AFO' v. 'barefoot') and for ankle sway (d = 0.334 for 'shoe alone' v. 'barefoot'; d = 1.013 for 'shoe + AFO' v. 'barefoot'). In addition, 'shoes + AFO' significantly reduced COM and ankle sway compared to 'shoe alone' condition, on average by 47.8% ($P = 0.000$, 95%CI = −0.156 to −0.064 cm^2) and 50.8% ($P = 0.000$, 95%CI = −0.555 to −0.253 deg2), respectively. In addition, 'shoe + AFO' significantly reduced hip sway compared to 'barefoot' on average by 36.2% ($P = 0.001$), but the reduction in sway was not significant compared to 'shoe alone' ($P = 0.502$).

Multivariate analysis, suggested that variations in COM and ankle sway between 'shoe alone' and 'shoe + AFO' conditions during both eyes-open and eyes-closed trials are independent of BMI, history of falls, fear of falling, gender, presence of diabetes, and presence of neuropathy, ($P > 0.05$). However, multiple linear regression analysis suggests that for the eyes closed condition the decline in COM sway when going from the 'shoe alone' to the 'shoe + AFO' condition was dependent on barefoot COM sway (B = −0.599(0.096); $P = 0.000$, 95%CI = −0.796 to −0.402, r-square = 0.581). Also for the eyes closed condition, a similar relationship was found with greater 'shoe alone' COM sway being associated with a greater decline in COM sway when going from 'shoe alone' to 'shoe + AFO' (Fig. 3). Hence, those subjects that exhibited the greatest sway in the 'barefoot' and 'shoes alone' conditions, saw the greatest reduction in sway in the 'shoes + AFO' condition. The correlation was increased by selecting the subjects with the presence of neuropathy (r = −0.968, p = 0.000). However, during eyes-open, the change in body sway was independent of barefoot body sway as well as the participants' characteristics (e.g. age, BMI, FES-I, GDS).

3.2. Effect of AFO on functional reach task

The maximum reach distance was not dependent on footwear condition and no between group differences were observed using a pairwise comparison (Table 4). While no statistical significance was observed for the time required to complete the task within the ANOVA ($P > 0.05$) test, pairwise comparisons showed a decrease of time with 'shoe alone' and 'shoe + AFO' conditions when compared to 'barefoot' condition (Table 4).

Although AFO did not limit the reach distance, the results revealed that when wearing AFO, postural coordination in the medial–lateral direction is significantly enhanced (RCI was reduced). Specifically, RCI during 'shoe + AFO' was significantly reduced on average by 14.3% ($P = 0.030$; 95%CI = −0.215 to −0.012) and 13.5% ($P = 0.030$, 95%CI = −0.105 to −0.006) compared to 'barefoot' and 'shoe alone', respectively. The results also suggest that the 'shoe alone' condition did not enhance postural coordination during the functional reach task compared to barefoot condition.

Table 3
Balance assessment cross footwear conditions during eyes-closed test.

	Barefoot G1	Shoe alone G2	Shoe + AFO G3	*P* value	Groups	Difference*	Pairwise *P*-value	95% Confidence interval for difference	
								Lower bound	Upper bound
COM sway, cm^2	2.045 (1.966)	1.337 (1.379)	0.695 (0.894)	0.086	G2–G1	−0.708 (1.642) 34.7%	0.026	−0.108	−0.007
					G3–G1	−1.350 (1.480) 65.9%	0.000	−0.156	−0.064
					G3–G2	−0.642 (1.084) 47.8%	0.004	−0.086	−0.018
Ankle sway, deg^2	1.010 (0.704)	0.796 (0.551)	0.392 (0.362)	0.021	G2–G1	−0.214 (0.120) 21.1%	0.000	−0.461	0.033
					G3–G1	−0.618 (0.109) 61.2%	0.000	−0.842	−0.0394
					G3–G2	−0.404 (0.074) 50.8%	0.000	−0.555	−0.253
Hip sway, deg^2	0.942 (0.892)	0.669 (0.404)	0.601 (0.638)	0.000	G2–G1	−0.273 (0.161) 29.0%	0.101	−0.603	0.057
					G3–G1	−0.341 (0.095) 36.2%	0.001	−0.536	−0.146
					G3–G2	−0.068 (0.099) 10.2%	0.502	−0.272	0.136

All results have been adjusted by age and BMI of participant.
* SD values were reported in parenthesis.

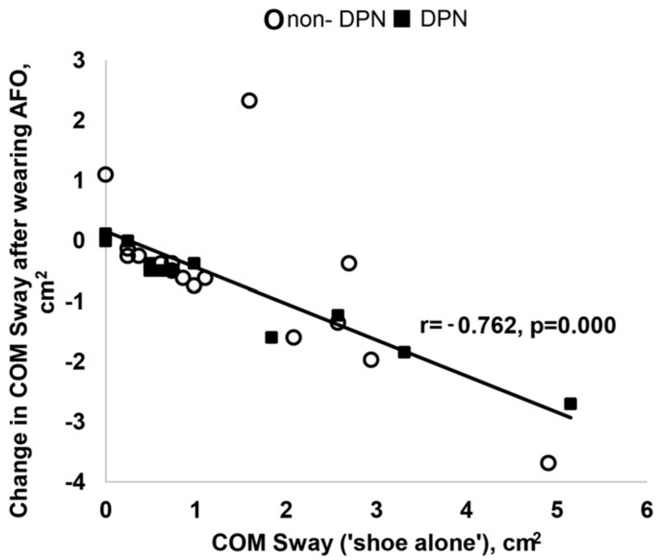

Fig. 3. Change in center of mass sway between 'shoes alone' versus 'shoes + AFO' conditions. Participants were categorized with respect to either presence of Diabetic Peripheral Neuropathy (DPN) or not which includes participants with and without Diabetic Mellitus (DM).

3.3. Effect of AFO on TUG assessments

The AFO did not significantly impact TUG completion times ($P = 0.359$, 95%CI = 0.121 to −0.779). The TUG completion times for the 'shoe alone' condition was 13.75(SD = 0.63) seconds on average and during 'shoe + AFO', the completion time was 14.08(SD = 0.65) seconds on average.

3.4. Subjects' perception of assessment

The subjects generally felt that they were less likely to fall when using the AFO while standing (average score: 7.59(2.04) range: strongly disagree = 0 to strongly agree = 10). They also generally reported that the AFO did not rub or hurt their ankles (average score: 2.33(2.73) range: 0–10). On average, the participants reported that they were more likely than not to continue wearing the AFO daily (average score: 6.28(2.86) range: 1–10).

4. Discussion

The main purpose of this study was to determine if bilateral custom-made AFO could improve bipedal balance in a general older adult population, and therefore likely improve postural stability, while not restricting mobility performance. Postural sway area has been widely observed to be a strong risk factor for falls in older adult populations (Lajoie and Gallagher, 2004; Muir et al., 2010; Najafi et al., 2012; Persad et al., 2010; Wrobel and Najafi, 2010). While postural sway area was mostly measured in terms of Center of Pressure (COP) (Piirtola and Era, 2006), use of innovative body worn sensors in this study helped detect COM sway. This methodology has not only been shown to have high agreement with COP sway (r = 0.92) but may better represent the postural compensatory mechanism than COP measurement (Najafi et al., 2010a).

Significant reductions in COM sway averaging 40% to 65% ($P < 0.05$) were observed with the use of the AFO during standing balance trials in comparison to the other footwear conditions. This suggests that the AFO reduced one of the primary risk factors for falls. Footwear in general seems to help with postural stability (Menz and Sherrington, 2000) and accordingly a reduction in COM sway by 21% during eyes-closed trials were observed in our results with the use of standardized shoes when compared to the barefoot condition. However, while shoes seem to reduce ankle sway area by 14–21% (Table 2, 3), the use of AFO in shoes significantly reduced ankle sway area 54% to 60% when compared to shoes and barefoot conditions during bipedal balance tests.

Sway area, especially during eyes-closed trials, has previously been found to be a primary indicator for falls (Hoang et al., 2014; Lajoie and Gallagher, 2004) in older adults. The participants in the present study with relatively higher sway area during eyes-closed trials benefited more than the others in terms of postural stability with use of AFO. The results from multivariate and multiple linear regression models suggest that the benefit of AFO in reducing postural sway is independent of the subject's characteristics (e.g. age, BMI, history of falls, fear of falling, diabetes, and peripheral neuropathy). However, it is dependent on the subject's baseline postural stability, suggesting that those with poor baseline stability may benefit more from AFO use than those with relatively good postural stability.

While increasing ankle stability and reducing postural sway may be associated with reduced risk of falling, ankle rigidity and reduced ankle range of motion could negatively impact the risk of falling (Menz et al., 2006a). In this study, to explore whether the custom-made AFO might restrict ankle function and daily motor performance, we examined the immediate effect of the AFO on functional reach and TUG tests, which surrogate dynamic balance and daily mobility performance respectively. Reach distance, which was a secondary outcome for our study, has also been associated with fall risk in the older adult population in the past (Behrman et al., 2002; Butler et al., 2011; Duncan et al., 1992; Persad et al., 2010). This study was the first to utilize the inertial sensors for FR test in conjunction with objective measurement of the reach distance using a sliding scale arrangement. This arrangement not only reduced observer bias but also provided the ability to track postural

Table 4
Between groups comparison for functional reach test.

	Barefoot G1	Shoe alone G2	Shoe + AFO G3	*P* value	Groups	Difference*	Pairwise *P*-value	95% Confidence interval for difference	
								Lower bound	Upper bound
Reach distance, cm	9.16 (2.66)	9.31 (2.58)	9.51 (2.42)	0.998	G2–G1	0.152 (0.204) 1.6%	0.464	−0.267	0.267
					G3–G1	0.352 (0.311) 3.8%	0.269	−0.287	0.990
					G3–G2	0.200 (0.226) 2.1%	0.384	−0.264	0.663
Time taken, s	0.88 (0.46)	0.68 (0.37)	0.67 (0.36)	0.073	G2–G1	−0.203 (0.063) 22.9%	0.003	−0.079	−0.335
					G3–G1	−0.212 (0.063) 24.0%	0.002	−0.089	−0.335
					G3–G2	−0.010 (0.058) 1.4%	0.868	0.105	−0.124
RCI** during risk task	0.79 (0.16)	0.78 (0.23)	0.68 (0.22)	0.011	G2–G1	−0.009 (0.048) 1.1%	0.86	−0.108	0.091
					G3–G1	−0.113 (0.049) 14.3%	0.030	−0.215	−0.012
					G3–G2	−0.105 (0.048) 13.5%	0.039	−0.204	−0.006

All results have been adjusted by age and BMI of participant.
* SD values were reported in parenthesis.
** RCI: Reciprocal Compensatory Index.

stability in the medial–lateral direction and time taken for maximum reach distance. Our approach to evaluate postural coordination between hip and ankle motion using reciprocal compensatory index (RCI) allows evaluating the efficiency of coordination between ankle and hip joints to minimize jerkiness of movement in medial–lateral direction, while performing a reaching task in anterior–posterior direction.

Wearing AFO did not impact reach distance when compared to 'barefoot' or 'shoe alone' conditions. Time taken to achieve the maximum reach distance with AFO was similar to that of the 'shoe alone' condition. Moreover, immediate use of AFO significantly improved postural co-ordination by more than 13% compared to 'barefoot' and 'shoe alone'. As the reach was in the anterior–posterior direction, we assume that AFO flexible gauntlet design did not restrict forward reach, but improved the ankle hip co-ordination. Similar results of improved postural stability and walking (Arazpour et al., 2013; Menotti et al., 2014) were found in other older adult populations as well when using a flexible AFO design.

TUG assessments showed no differences in functional mobility with or without the use of AFO, which may suggest that the use of custom-made gauntlet design, will not limit mobility performance in older adults. AFO design did not limit the maximum functional reach, and hence does not restrict the functional movement in the anterior–posterior direction.

The reduction in postural sway and enhancement in postural coordination after wearing AFO might be explained by enhanced ankle postural stability as well as enhanced proprioception feedback. With a custom-made foot plate, gauntlet styling enabling plantar and dorsi flexion of the foot, the AFO might have improved proprioception (Hijmans et al., 2007) due to increased skin contact at the plantar aspect of the foot (Najafi et al., 2013b) as well as the shin area (Feuerbach et al., 1994) in contrast to the standard shoes.

The sample size of the current study is relatively small, however, the population represents a more "generic" sample of older adults than has been used in previous AFO research. Although a majority of the participants were recruited from a podiatric clinic, they were undergoing preventive foot care and had no significant foot pathologies during testing. These participants were variable in their concern for falls as shown in Table 1. The percentage of people with history of a fall (53.3%) in our sample was higher than a previously reported estimation of 33% for the general older population (Rubenstein, 2006). One primary limitation of our study and likely contributor to this difference was the high proportions of the participants with diabetes (46.7%) and peripheral neuropathy (43.3%) in the current study. The Centers for Disease Control and Prevention estimated that 26.9% of the adults in the US aged 65 or older had diabetes (Anon, 2011a). Individuals with diabetes have a higher risk of falling compared to aged matched healthy controls (Crews et al., 2013). Our study population also had a high percentage (77%) of female participants, however gender was not found to have any significant effect with our primary outcome variables. Moreover, recent studies (Bergland et al., 2003; Rossat et al., 2010) have also shown that older adult women are at more risk of falls and hence the current study population may represent a good sample of older subjects for which interventions are needed to reduce the risk of falling.

Another limitation of the study was the fact that all tests were conducted immediately after introducing the AFO. Therefore, the term implications for postural stability and actual fall incidence were not confirmed. However, studies on other specific populations have shown that prolonged use of AFO resulted in improved gait and balance outcomes (Cakar et al., 2010; Kluding et al., 2013; Zissimopoulos et al., 2014) while also not effecting the muscle activity (Geboers et al., 2002). While an assumption can be made that these immediate results of improved postural stability could be sustained with prolonged use of the AFO, further studies are warranted to examine the association between prolonged use and actual reduction in falls. In addition, the subject's adherence to AFO as well as perception of benefit, level of comfort, and ease of use during daily living activity need to be addressed in a longitudinal study. Finally, the results need to be confirmed in a randomized controlled trial in which long term benefit of AFO should be compared to control group.

5. Conclusion

This proof of concept study suggests that AFO enhance postural stability during standing and coordination in older adults without restriction of ankle motion in the anterior–posterior direction during a reaching task as well as TUG assessments. In addition, the results suggest that older adults perceived AFO to be beneficial for postural stability. In the long term, this may reduce their fear of falling and allow them to be more active. Should the initial improvements in balance be sustained with continued use of AFO, the device may be able to reduce fall risk in the elderly. However, longitudinal studies are required to confirm whether the observed reduction in postural control actually translates into fewer falls and enhancement of activities by older adult individuals that use the AFO long term.

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