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Effectiveness of Daily Use of Bilateral Custom-Made Ankle-Foot Orthoses on Balance, Fear of Falling, and Physical Activity in Older Adults: A Randomized Controlled Trial

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Keywords
Ankle-foot orthoses · Older adults · Balance · Fear of falling · Physical activity

Abstract
Background: Foot problems are prevalent in older adults, which may increase the risk and concern for falls. Ankle-foot orthoses (AFO) have been shown to be effective in the stabilization of lower extremities, but their long-term effectiveness in improving balance and their potential to encourage older adults to become more physically active are still debated. ***Objective:*** This randomized controlled trial investigated the effectiveness of daily use of a custom-made AFO on balance, fear of falling, and physical activity in older adults. ***Study Design:*** Forty-four older adults with concern about or at risk for falling were randomly allocated to either the control group (CG; 77.3% female, age 75.6 ± 6.5 years, BMI 29.3 ± 6.4) or the intervention group (IG; 63.6% female, age 73.7 ± 6.3 years, BMI = 27.8 ± 4.8). The IG received walking shoes and bilateral custom-made AFO. The CG received only walking shoes. At the baseline and 6-month follow-ups, balance and physical activity were assessed using validated wearable instrumentation and fear of falling was assessed using the Fall Efficacy Scale-International (FES-I). Adherence and acceptability toward wearing the AFO were assessed using self-reported questionnaires at the 6-month follow-up. ***Results:*** No significant between-group difference was observed at baseline (p = 0.144–0.882). Compared to baseline and the CG, hip, ankle, and center-of-mass (COM) sways were significantly reduced at the 6-month follow-up in the IG while standing with the feet together during the eyes-open condition (p = 0.005–0.040). Within the IG, the FES-I was reduced significantly (p = 0.036) and there was an increasing trend in the number of walking bouts with a medium effect size (d = 0.52, p = 0.440) compared to baseline. However, there were no significant changes in FES-I and physical activity measures in the CG (p = 0.122–0.894). The reduction in COM sway in the IG was moderately correlated with adherence (r = –0.484, p = 0.047) and strongly correlated with baseline COM sway (r = –0.903, p < 0.001). ***Conclusion:*** Results suggest that bilateral custom-made AFO plus walking

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shoes is effective in improving balance compared to walking shoes alone, and it significantly reduces the fear of falling, with a nonsignificant but noticeable positive trend in physical activity, compared to baseline. The results also suggest that older adults with poor balance at baseline and higher daily adherence to using the AFO will gain more benefit from the AFO intervention.

Introduction

Foot and ankle problems are common in older adults [1], and they have been shown to be associated with a decreased ability to undertake activities of daily living [2], deterioration in balance and gait [3], an increased risk of falls [4], and a poorer health-related quality of life [5]. The biomechanical, physiological, and functional declines with age in the lower extremities (e.g., dryness and hardness of plantar skin and soft tissues, reduction in joint range of motion, and loss of foot strength and plantar sensation) have been linked to a high plantar pressure, poor gait efficiency, foot deformity (e.g., hammer toes, overlapping toes, and hallux valgus), foot pain, impaired balance, and poor functional ability, ultimately leading to falls or a reduction in the level of physical activity [3, 6].

Ankle-foot orthoses (AFO) are commonly prescribed for pathological conditions affecting joint stability, positioning, pressure distribution, and neuromuscular insufficiencies [7]. They have been shown to be an effective intervention to improve postural stability for specific patients with hemiplegia and/or stroke [8, 9]. Stimulation of cutaneous mechanoreceptors is one way in which an AFO can facilitate proprioception and reduce the effect of fatigued ankle muscles upon stability [10]. However, the efficacy of daily use of AFO remains unclear and controversial [9]. Several studies have shown that a prefabricated AFO may increase the patient's risk of disuse atrophy in calf muscles [11]. Additionally, compliance with the daily use of prefabricated AFOs is reported to be low due to various reasons like foot pain, a lack of proper shoes to accommodate AFO or simply a lack of interest [12].

Recent evidence suggests that custom-made footplates (e.g., custom foot orthoses) could realign the foot and increase the surface area contact between the foot and the ground, enhancing tactile stimulation of the plantar surface of the foot and further improving postural stability [13]. Moreover, the use of custom foot orthoses can effectively reduce foot pain and increase spontaneous physical activity [14], potentially increasing older adults' adherence and acceptability to foot orthoses in their free-living environment. In the past, Yalla et al. [15] conducted a proof-of-concept study and showed that wearing bilateral AFO with a custom-made footplate can immediately improve the postural stability of older adults during balance assessments performed in a laboratory environment, but the benefits of the daily use of this custom-made AFO were not evaluated [15].

Therefore, this study aimed to evaluate the effectiveness of daily use of bilateral custom-made AFO on balance, fear of falling, and physical activity in older adults with concern about or at risk for falling. We hypothesized that daily use of custom-made AFO plus walking shoes would be acceptable among older adults and that it would lead to improvement in balance (e.g., reduction in postural sway) in comparison to walking shoes alone, which in turn may reduce the fear of falling and increase physical activity. We also anticipated that the degree of benefit would be dependent on baseline balance and daily adherence to wearing the AFO. We carried out a randomized controlled trial (RCT) to test these hypotheses.

Methods

Participants

Forty-four older adult participants were recruited from outpatient clinics, community-dwelling older adults, and Senior Education Centers in the Houston metropolitan area (TX, USA). Inclusion criteria included being ambulatory and age 65 years or older with a self-reported concern about falling or being at risk for falling (confirmed by either a fall in the past 6 months [16] or 13 s or more in the Timed Up and Go [TUG] test [17]). Use of walking-assistive devices (such as canes) in daily living was not a factor to exclude a potential participant. Participants were excluded if they: (1) had a wound on either of the feet or the ankles, (2) were taking any medication that might have an unstable (fluctuate over time) or temporary (<1 month) impact on balance and gait according to the judgment of the clinical investigator, (3) had any fractures of the foot or a major foot amputation, (4) had an acute medical condition which might be unstable (fluctuate over time) or temporarily have an impact on balance and gait according to the judgment of the clinical investigator, (5) had participated in an interventional study within the last 30 days or planned to participate in an interventional study during the period of this study, (6) were nonambulatory or unable to stand without help or walk a distance of at least 1.8 m (~6 feet) without assistance, (7) had cognitive impairment (score <24 on the Mini-Mental State Examination [18]), or (8) were unwilling or unable to participate in all of procedures and follow-up evaluations (e.g., long travel distance such as living >24 km away from the site of assessment). All of the participants signed a written consent form approved by the Institutional Review Board of the Baylor College of Medicine (Houston, TX, USA) (IRB No.: H-38050). The clinical trial is registered with ClinicalTrials.gov (identifier NCT02819011).

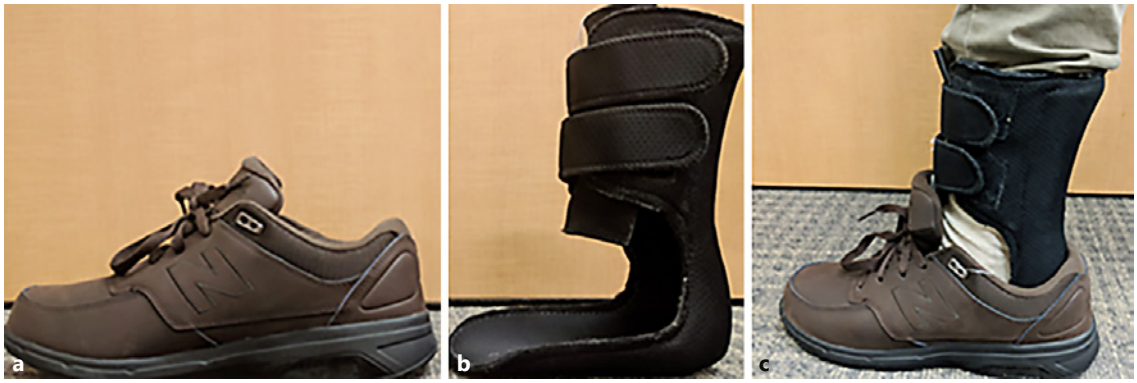

Fig. 1. Illustrations of the footwear provided to the participants. **a** New Balance shoe. **b** AFO. **c** AFO and New Balance shoe worn by a typical participant in the IG.

Study Design

An RCT with two arms, i.e., an intervention group (IG) and a control group (CG), was conducted to evaluate the effectiveness of daily use of bilateral custom-made AFO on postural stability of older adults. Eligible participants were randomized using a computer-generated list for which we used MATLAB (version 2016a; Mathworks, Natick, MA, USA) before the start of participant recruitment.

During the first visit, the eligibility of each potential participant was assessed using the inclusion and exclusion criteria mentioned above. If the patient was eligible, their shoe sizes were measured using a foot-measuring device (RALYN Shoe Care, Chicago, IL, USA) to order fitted walking shoes for each participant (MW813; New Balance, Boston, MA, USA). The feet of each participant in the IG were cast using a contoured footboard provided by the company which made the bilateral custom-made AFO (Moore Balance Brace™; Arizona AFO, Mesa, AZ, USA). Figure 1 shows images of the prescribed footwear. More details about the casting process can be found on the company's website [19]. Participants from both of the groups reported their demographics (age, sex, height, and weight), health information (fall occurrence in the past 12 months, use of walking-assistive devices, medications, and comorbidities), and completed the following questionnaires: Fall Efficacy Scale-International (FES-I, where FES-I ≥23 represents a high concern of falls) [20], Center for Epidemiological Studies-Depression (CES-D, where CES-D ≥16 represent depression) [21], Fried Frailty Phenotype [22], and Visual Analog Scale of foot pain [23].

Additionally, the plantar sensation of all of the participants was assessed via a vibration perception threshold test conducted using a biothesiometer (Xilas Medical, San Antonio, TX, USA) [24]. The TUG test [17] and the Alternate-Step test (AST) [25] were conducted to assess mobility performance and lateral stability, respectively. During the TUG and AST tests, the participants were asked to perform tasks as fast and safely as they could. These baseline characteristics were obtained so that we could use them as potential confounders if there were significant differences between the two groups for any of these characteristics. Balance and gait performance were also assessed at the first visit as part of baseline measurements using validated wearable sensor platforms (BalanSens™ and LEGSys™; BioSensics, Watertown, MA, USA) as described in our previous studies [26, 27], while participants wore their own shoes. After the first visit, all of the participants were provided with a wearable pendant sensor (PAMSys™; BioSensics), which they had to wear for two consecutive days in their unsupervised home environment to collect data for their physical activity [28–30]. Specific details about the balance and physical activity assessments that were carried out are provided in the next subsection.

All of the participants were scheduled for the footwear fitting and balance and gait assessment with the prescribed footwear at the second visit (1 month after the first visit). Participants in the CG received the fitted walking shoes, which are anticipated to have a potential benefit on gait and balance (active comparator), and participants in the IG received the same brand walking shoes and bilateral custom-made AFO. Participants in both groups were encouraged to wear the prescribed footwear at all times, in particular when walking or standing. Then, balance and gait were reassessed 3, 6, and 12 months after the participants were provided with the footwear, and all of the participants completed these assessments while wearing the prescribed footwear. FES-I and physical activity were only reassessed at 6 and 12 months. In this paper, we focused on the changes in balance, FES-I, and physical activity between baseline and the 6-month follow-up. Figure S1 (online suppl. Fig. 1; see www.karger.com/doi/10.1159/000494114 for all online suppl. material) shows the consort diagram of this study until the 6-month follow-up.

Balance and Physical Activity Assessment

Balance performance was objectively assessed using wearable sensors (BalanSens™, Biosensics, Watertown, MA, USA) attached to the right shin and lower back in double stance (DS; stand as still as possible for 30 s with the feet together) and semi-tandem (ST; stand as still as possible for 20 s with the feet together and with the toe of the dominant foot in line with the heel of the opposite foot) stance, in eyes open (EO) and eyes closed (EC) conditions. The order of the different conditions was randomized across participants. The outcome measures of balance performance were postural sway parameters, including center-of-mass (COM) sway, ankle sway, and hip sway. The COM sway was quantified in mediolateral (ML) and anteroposterior (AP) directions (in cm) as well as in terms of total sway area (AP × ML, in cm^2), whereas ankle sway and hip sway were quantified only in terms of the total sway area (in $degrees^2$), using a validated algorithm [26].

Table 1. Baseline characteristics of the participants

	CG (n = 22)	IG (n = 22)	p value
Demographic characteristics			
Age, years	75.6±6.5	73.7±6.3	0.328
Females	17 (77.3)	14 (63.6)	0.322
BMI	29.3±6.4	27.8±4.8	0.453
Health information			
Fall incidence during the past 12 months	12 (54.5)	16 (72.7)	0.210
Falls during the past 12 months, n	1.8±4.2	2.3±4.2	0.273
Fear of falling	33.3±11.5	32.8±10.7	0.882
High concern for a fall (FES-I ≥23)	20 (90.9)	17 (77.3)	0.216
Frailty phenotypes			0.627
Frail	2 (9.5)	3 (14.3)	
Prefrail	15 (71.4)	12 (57.1)	
Nonfrail	4 (19.0)	6 (28.6)	
Depression	8.0±6.7	8.8±7.2	0.655
Depressed (CES-D ≥16)	3 (13.6)	4 (18.2)	0.680
Use of assistive device	9 (40.9)	12 (54.5)	0.365
Medications per day			
Prescription	4.7±4.0	7.5±5.6	0.144
Over the counter	2.9±2.5	5.0±7.2	0.673
Foot pain (VAS, 0–10 points)	1.2±2.8	1.5±2.2	0.260
Plantar sensation (VPT), V	25.2±13.4	18.5±12.7	0.214
Comorbidities, n	4.2±1.6	4.6±1.7	0.474
Performance-based test			
TUG, s	11.7±4.4	12.1±3.8	0.449
AST, s	12.32±4.18	10.66±2.80	0.155

Values are presented as means ± SD or numbers (%). p values are given for differences between the IG and the CG. VPT, vibration perception threshold.

Physical activity was objectively assessed using a validated wearable sensor (PAMSys™, Biosensics, Watertown, MA, USA) attached to a neck lanyard [28]. Several parameters were extracted from triaxial acceleration signals recorded over 2 consecutive days (including both daytime and nighttime) in a free-living environment, including the time spent walking and standing, the number of walking bouts, and the total steps taken.

Adherence and Acceptability to the AFO plus Walking Shoes

The adherence of participants to the prescribed AFO plus walking shoes was quantified using the response to a self-reported question ("How many hours per day did you wear the prescribed footwear?").

A technology acceptance model (TAM) was used to examine the acceptability of the footwear intervention [31]. The TAM includes two major components: perceived usefulness and perceived ease of use. Perceived usefulness was assessed using two questions (i.e., "I feel more stable when standing," and "I feel more stable when walking"). Perceived ease of use was assessed using two questions (i.e., "Was easy to take on and off," and "Was comfortable to wear"). The Likert scale (6-point scale from 0–5) was used to quantify how much they disagreed with each statement, including "strongly disagree," "disagree," "somewhat disagree," "somewhat agree," "agree," and "strongly agree," respectively. In this paper, responses were only categorized as positive (3–5 points) or negative (0–2 points) attitudes towards the use of AFO plus walking shoes.

Statistical Analysis

Baseline group differences were compared using a one-way analysis of variance (ANOVA) for continuous variables that were normally distributed or the Mann-Whitney U test if they were not normally distributed. For categorical variables, the χ^2 test was used to compare baseline group differences. Normality was assessed using Shapiro-Wilk tests ($p > 0.05$). To assess the effect of our intervention, multiple linear mixed models (LMMs) were used to first examine group (2 levels: IG and CG) × time (2 levels: baseline and 6-month follow-up) interaction effects. The LMM was selected because it can account for missing data (to prevent entire subject data from being removed due to lack of a measurement at a specific time point) [32]. The LMMs were also used to assess the main effect of time within each group. Further, effect sizes (in terms of Cohen's d) are provided for within-group changes, where Cohen's d values <0.20 indicate no noticeable effect, values between 0.20 and 0.49 indicate a small effect, values between 0.50 and 0.79 indicate a medium effect, and values above 0.80 indicate a large effect [33]. For the IG, a bivariate correlation between change in COM sway at the 6-month follow-up and COM sway at baseline or adherence to the

Table 2. Outcome measures of balance, fear of falling, and physical activity at baseline and 6-month assessments for both groups

	CG				IG				*p* value
	baseline	6 months	effect size	*p* value	baseline	6 months	effect size	*p* value	
Balance									
DS-EO									
COM sway, cm^2	0.85±0.65	0.76±0.45	0.16	0.791	0.71±0.50	0.32±0.18	1.04	0.006	0.019
COM ML sway, cm	0.76±0.35	0.75±0.30	0.04	0.834	0.74±0.31	0.39±0.14	1.42	<0.001	0.004
COM AP sway, cm	1.28±0.46	1.25±0.38	0.08	0.789	1.17±0.54	0.93±0.29	0.57	0.080	0.266
Ankle sway, $degrees^2$	3.21±2.43	3.56±2.54	0.14	0.578	3.50±3.74	1.03±0.69	0.92	0.003	0.005
Hip sway, $degrees^2$	3.75±3.63	3.89±2.15	0.05	0.168	3.65±3.22	2.15±1.24	0.61	0.111	0.040
DS-EC									
COM sway, cm^2	1.43±1.12	1.09±0.69	0.37	0.219	1.12±1.07	0.60±0.39	0.65	0.019	0.246
COM ML sway, cm	1.00±0.37	0.87±0.39	0.32	0.274	0.89±0.38	0.58±0.24	0.96	<0.001	0.035
COM AP sway, cm	1.60±0.55	1.65±0.52	0.10	0.735	1.37±0.47	1.36±0.44	0.01	0.930	0.781
Ankle sway, $degrees^2$	4.50±2.90	4.39±2.50	0.04	0.922	4.58±6.11	1.88±0.90	0.62	0.003	0.026
Hip sway, $degrees^2$	6.08±6.53	6.09±5.92	<0.01	0.830	4.76±3.11	3.98±3.15	0.25	0.263	0.448
ST-EO									
COM sway, cm^2	0.88±0.55	0.87±0.53	<0.01	0.959	0.76±0.43	0.48±0.35	0.70	0.001	0.026
COM ML sway, cm	0.95±0.36	0.91±0.31	0.10	0.734	0.83±0.22	0.63±0.29	0.79	0.012	0.056
COM AP sway, cm	1.09±0.31	1.04±0.46	0.13	0.431	1.01±0.47	0.98±0.68	0.05	0.453	0.767
Ankle sway, $degrees^2$	3.80±2.71	4.38±2.93	0.20	0.866	3.33±1.85	1.35±0.83	1.38	<0.001	0.008
Hip sway, $degrees^2$	4.00±2.41	4.54±2.66	0.21	0.239	4.17±4.21	3.32±2.83	0.24	0.113	0.052
ST-EC									
COM sway, cm^2	1.41±0.98	1.48±1.15	0.07	0.860	1.20±0.91	0.90±0.75	0.35	0.319	0.447
COM ML sway, cm	1.09±0.31	1.10±0.40	0.03	0.911	1.07±0.42	0.76±0.38	0.77	0.001	0.030
COM AP sway, cm	1.53±0.83	1.47±0.59	0.08	0.967	1.20±0.59	1.38±0.88	0.24	0.550	0.639
Ankle sway, $degrees^2$	5.86±4.45	6.87±6.77	0.18	0.764	4.59±3.23	2.63±2.11	0.72	0.060	0.081
Hip sway, $degrees^2$	6.63±6.24	8.99±9.23	0.30	0.267	5.31±3.75	6.35±4.81	0.24	0.591	0.716
Fear of falling									
FES-I score	33.3±11.5	30.1±13.9	0.25	0.122	32.8±10.7	27.0±9.0	0.58	0.036	0.650
Daily physical activity									
Time for walking, %	5.4±3.9	5.2±2.7	0.04	0.357	5.0±2.0	6.1±3.1	0.41	0.443	0.647
Walking bouts, *n*	164±94	183±95	0.20	0.886	191±76	249±139	0.52	0.440	0.770
Total steps taken, *n*	3,847±3,645	4,297±2,735	0.20	0.894	4,017±2,008	4,872±2,657	0.36	0.669	0.756
Time spent standing, %	16.9±6.2	17.7±2.5	0.14	0.848	15.1±3.8	17.5±7.1	0.42	0.396	0.686

Results are presented as means ± SD unless otherwise stated. *p* values are given for between and within groups using LMM. Effect sizes are given for within groups using Cohen's *d*.

AFO was reported using Pearson's correlation coefficient [34]. All statistical analyses were performed using IBM SPSS Statistics version 24 (IBM, Armonk, NY, USA). For all statistical analysis, $p < 0.05$ was considered statistically significant.

Results

Baseline Characteristics and Immediate Balance Change after Footwear Fitting

The baseline characteristics of our participants are provided in Table 1. Eleven participants (25%) dropped out prior to the 6-month follow-up (CG: $n = 1$, withdrew due to back pain unrelated to our study; $n = 1$, loss of contact; and $n = 2$, deceased; IG: $n = 2$, withdrew due to relocation; $n = 2$, loss of contact; $n = 2$, loss of ambulatory ability unrelated to our study; and $n = 1$, deceased). No significant differences were observed between the CG and the IG for any of the characteristics that were assessed at baseline.

After immediately fitting the prescribed footwear, no significant between-group differences were observed for COM sway parameters during DS-EO and DS-EC conditions ($p = 0.058–0.802$). However, descriptive results re-

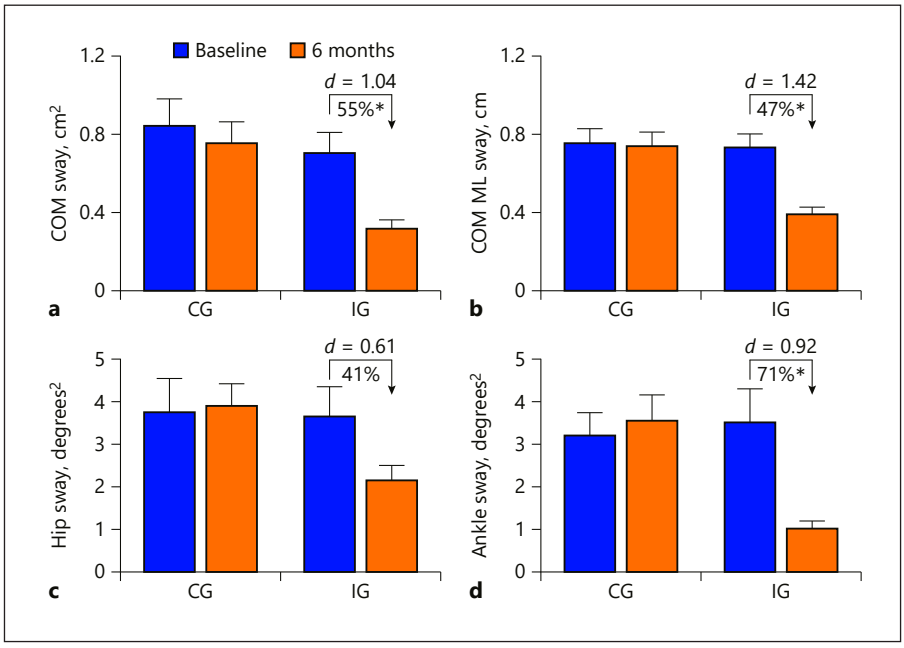

Fig. 2. Outcome measures of balance performance (mean and SE) at baseline and the 6-month follow-up during the DS-EO condition. **a** COM sway. **b** COM sway in the ML direction. **c** Hip sway. **d** Ankle sway. * Significant within-group difference for the IG as obtained from LMM.

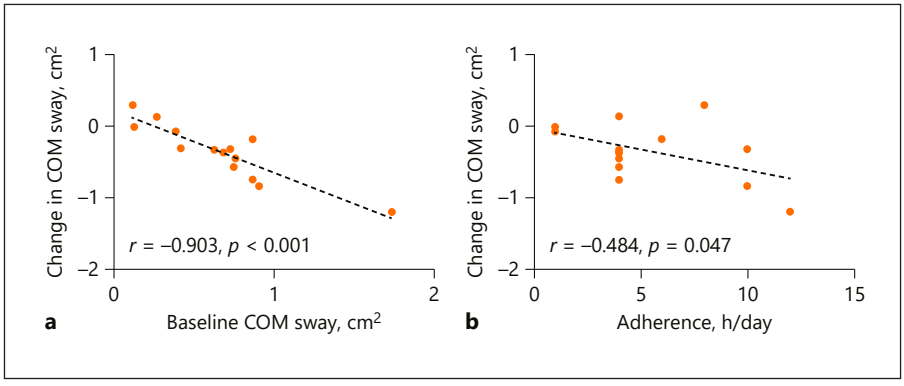

Fig. 3. Correlation between change in COM sway over the 6-month AFO intervention in the IG and baseline COM sway (**a**) and adherence (**b**).

vealed a greater reduction in COM sway during DS-EO and DS-EC conditions in the IG (range 28–34%) after use of the prescribed footwear compared to the CG (range –9 to 26%). The reduction was statistically significant in the IG (p = 0.019–0.024) and not significant in the CG (p = 0.055–0.845).

Balance Change at the 6-Month Follow-Up between Groups

The outcome measures of balance change are shown in Table 2. When comparing the changes in postural sway parameters at the 6-month follow-up between groups, significant differences were found in COM sway, COM sway in the ML direction, ankle sway, and hip sway (p = 0.004–0.040) during the DS-EO condition (Fig. 2); COM sway in the ML direction (p = 0.035) and ankle sway (p = 0.026) during the DS-EC condition; COM sway (p = 0.026) and ankle sway (p = 0.008) during the ST-EO condition; and COM sway in the ML direction (p = 0.030) during the ST-EC condition. Within the IG, significant reductions were found in almost all of those postural sway parameters which showed significant between-group differences, except hip sway (p = 0.111) during the DS-EO condition. Additionally, two more postural sway parameters (COM sway during the DS-EC condition and COM sway in the ML direction during the ST-EO condition) showed a significant reduction (p = 0.019–0.012, respectively) only within the IG. Medium or large effect sizes (d = 0.57–1.42) were observed in all postural sway parameters during the DS-EO condition; in COM sway, COM

sway in the ML direction, and ankle sway during the DS-EC condition; in COM sway, COM sway in the ML direction, and ankle sway during the ST-EO condition; and in COM sway in the ML direction and ankle sway during the ST-EC condition (Fig. 2). In the CG, no significant changes were found compared to baseline, and only small effect sizes ($d < 0.4$) were observed.

Fear of Falling and Physical Activity Changes at the 6-Month Follow-up between Groups

Although no significant difference was found in the change of FES-I score at the 6-month follow-up between groups (Table 2), the reduction of the FES-I score was significant ($p = 0.036$) within the IG (online suppl. Fig. S2), and this reduction had a medium effect size ($d = 0.58$).

No significant differences were found between groups for any of the outcome measures of daily physical activity. In the IG, all four of the outcome measures of daily physical activity had nonsignificant but positive trends. Additionally, a medium effect size ($d = 0.52$) was observed for the number of walking bouts. In the CG, only small effect sizes were observed, where three outcome measures had a positive trend (walking bout number, total steps taken, and time spent standing), and one (time spent walking) had a negative trend.

Adherence and Acceptability in the IG

The average daily time spent wearing the prescribed AFO plus walking shoes was 5.4 h in the IG. According to TAM, 79% of the participants perceived the AFO plus walking shoes to be useful and 93% of the participants perceived it to be easy to use.

Correlations between Balance Improvement and Baseline Balance/Daily Adherence in the IG

There was a strong and significant correlation ($r = -0.903$, $p < 0.001$) between COM sway at baseline and change in COM sway at the 6-month follow-up (Fig. 3a). There was a moderate and significant correlation between daily hours of wearing the AFO plus walking shoes and change in COM sway at the 6-month follow-up ($r = -0.484$, $p = 0.047$; Fig. 3b).

Discussion

To our knowledge, this is the first prospective RCT study assessing the effectiveness of daily use of bilateral custom-made AFO in older adults with concern about or at risk for falling. While a few studies had investigated the effectiveness of AFO in improving balance, they had several limitations. Those studies were limited to specific patient populations (e.g., hemiplegic, post-stroke, and cerebral palsy) and/or did not use RCT and/or prospective study design and/or did not examine acceptability and adherence and/or did not use bilateral custom-made AFO design [35]. The results of this study indicate that daily use of bilateral custom-made AFO plus walking shoes reduced the upright standing postural sway compared to baseline and compared to the CG patients who were provided with walking shoes alone. Within the IG, wearing AFO plus walking shoes resulted in a significant reduction in fear of falling, and a noticeable positive trend in the number of walking bouts, with medium effect size, compared to baseline. These parameters have previously been shown to be associated with less prospective or recurrence of falls in older adults [36–38].

Improvements in balance can be explained by both additional mechanical support at the ankle and auxiliary sensory cues to the intact tissues of the lower limbs provided by AFO [39]. With custom-made footplates and an open gauntlet style, the prescribed AFO in this study would have further enhanced proprioception due to an increased contact area of the foot and shin in contrast to the prefabricated AFO. The observed immediate effect of AFO on reducing the COM sway during DS-EO (34.4%) was in agreement with the reduction observed in the study by Yalla et al. [15] (i.e., 40.7%). However, our study suggests that this immediate effect is not significant compared to that of walking shoes alone. Also, our results suggest that 6-month daily use of AFO plus walking shoes posed a larger reduction in body sway (54.9% at 6-month vs. 34.4% for immediate effect), which is also significant compared to walking shoes alone. The further improvement in postural control over time may be linked to user habituation to AFO and/or lower-extremity muscle restoration due to an increase in physical activity. This hypothesis is supported by this study, as we have observed a positive effect on both the fear of falling and physical activity. The reduced fear of falling in the IG may be in response to stabilization of the ankle joint by the AFO. The positive trends in physical activity may be explained by an increase in self-efficacy at avoiding falls (reduction of the fear of falling) during activities of daily living.

While the daily self-report adherence to the AFO plus walking shoes (5.4 h/day) may be perceived to be low, this duration is comparable with the 5.7 h of combined walking (1.5 h) and standing (4.2 h) estimated in our sample.

This may suggest that our participants wore the AFO plus walking shoes for almost 95% of the walking and standing period. Also, more than 90% of the participants favorably perceived the ease of use of the AFO plus walking shoes according to the TAM that we used. The high adherence and perceived ease of use could be explained by the custom-made footplate and open gauntlet-style design, which made the AFO easy to fit with walking shoes and potentially helped in reducing the foot pain over time [14]. This is aligned with prior reports suggesting that pain induced by AFO without custom-made footplates or lack of proper shoes to accommodate AFO are key reasons for low compliance towards the daily use of AFO [12].

In this study, we also explored the parameters that could affect the benefit observed from the bilateral custom-made AFO plus walking shoes. Our results suggest that those who had a higher baseline COM sway (poorer balance) and those who had a longer daily wear time for the AFO plus walking shoes (better adherence) received a significantly higher benefit of daily use of AFO. Our regression model suggests that every additional usage hour of AFO plus walking shoes per day will lead to an additional 0.058-cm^2 reduction in COM sway (8.2% improvement compared to baseline balance) during the DS-EO condition.

Limitations and Future Directions

This study was underpowered to observe significant benefits in fear of falling and physical activity between the IG and the CG. Based on the effect sizes observed in this study, we did a power analysis and found that at least 242 and 32 subjects per group will be needed to clinically validate significant between-group effects for fear of falling and physical activity, respectively, assuming 80% power and an α level of 5%, and using independent two-sided *t* test. Additionally, this study examined the effectiveness of a custom-made AFO on improving parameters that are surrogates of prospective falls (balance, fear of falling, and physical activity). In the future, we will examine whether the observed benefits could lead to a lower rate of falls in older adults based on the data from the entire 12-month follow-up.

Kluding et al. [40] reported significant improvements in balance and gait for post-stroke patients without wearing AFO during the assessment, after a 30-week AFO intervention. This result may suggest therapeutic effects of AFO to correct abnormal gait and balance. Therefore, it will be interesting to investigate whether general older adults will be able to sustain benefits of daily use of bilateral custom-made AFO on upright postural stability even if they do not wear AFO plus walking shoes during the balance assessment. We will consider performing such an assessment in our future studies.

Conclusions

This study suggests that daily use of bilateral custom-made AFO plus walking shoes is perceived to be beneficial and is highly acceptable in older adults with concerns about or at risk of falling. Also, it suggests that daily use of a bilateral custom-made AFO plus walking shoes is effective in improving balance in older adults with concern about or at risk for falling. Furthermore, the observed within-group significant reduction in fear of falling and the noticeable positive trend in physical activity could be explained by this improved postural stability. The results also indicate that those with poorer balance and higher daily adherence to the AFO will gain the most benefit from AFO intervention.

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