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Efficacy of an insole shoe wedge and augmented pressure sensor for gait training in individuals with stroke: a randomized controlled trial

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Objective: To determine whether external feedback to promote symmetrical weight distribution during standing and walking would improve gait performance and balance in people with stroke.
Design: Randomized, controlled, assessor-blinded trial.
Setting: Rehabilitation unit and physical therapy department.
Subjects: Thirty-five individuals with stroke (mean (SD) age = 53.0 (9.3) years) were randomly assigned to an experimental ($n = 17$) or control group ($n = 18$). Time post stroke was less than six months for most subjects ($n = 27$, 77%).
Interventions: Subjects participated in 15 rehabilitation sessions including 30 minutes of gait retraining per session. During gait retraining, the experimental group used an insole shoe wedge and sensors set-up (I-ShoWS) while the control group received a conventional programme. The I-ShoWS set-up consisted of a wedge insole and a footswitch for the non-paretic leg and a pressure sensor on the paretic leg.
Outcome measures: Gait speed, step length and single support time asymmetry ratio, balance and amount of load on paretic leg during stance were evaluated twice: one day before and after training.
Results: The experimental group demonstrated significant increase in standing and gait symmetry compared with the control group ($P < 0.05$). They demonstrated 3 times greater improvement in gait speed than the control group ($P = 0.02$). Balance improvement was significantly greater for the experimental than for the control group ($P < 0.05$).
Conclusion: Gait retraining using the I-ShoWS set-up was more effective in restoration of gait speed, standing and walking symmetry and balance than a conventional treatment programme. These results indicate the benefit of implementing feedback during gait retraining.

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Introduction

Impaired walking ability represents a significant functional limitation after stroke, and recovery

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of walking ability is considered one of the most important outcomes of stroke rehabilitation.[1] Two-thirds of stroke survivors experience some difficulty with walking immediately after stroke and over 30% are unable to walk without assistance at six months post stroke.[2]

Two critical consequences of impaired walking ability after stroke are decreased gait speed and increased fall risk.[3–5] Gait speed has been established as a key predictor of having access to the community, such as negotiating a road crossing in adequate time.[6,7] In addition, individuals with stroke demonstrate 4 times the risk of falls with consequent increased risk of hip fracture compared with healthy individuals.[8] Both decreased gait speed and increased fall incidence have been linked to disuse of the paretic lower extremity, including decreased weight support and asymmetrical weight bearing between the two limbs.[5,9,10] Thus, a rehabilitation programme that emphasizes enhanced loading on the paretic limb and inter-limb symmetry could lead to improved gait performance and decreased fall risk.

Extrinsic feedback in the form of somatosensory, visual and auditory guidance has been used to improve symmetrical weight distribution during standing and walking in individuals with stroke.[11–15] Aruin *et al.*[13] examined the effect of different heights of lifts to the shoe of the non-paretic leg on symmetrical weight bearing. The results showed that a 10-mm shoe lift resulted in promoting symmetrical weight bearing during standing to nearly equal weight distribution between the two legs. A single subject from the above study then participated in a six-week physical therapy programme in conjunction with use of the shoe lift (10 mm maximum). A significant improvement in walking velocity and stride length was demonstrated. Later, Rodriguez and Aruin[12] examined the effect of shoe wedges and lifts applied to the non-paretic leg on symmetrical weight bearing. The results showed that compelled weight shift to the paretic side induced by the shoe wedges and/or lifts promoted improved symmetry of weight bearing during bipedal standing.

The use of auditory feedback during training of a sit-to-stand task was studied in 12 subjects with stroke.[15] The benefit of auditory feedback was demonstrated as improved vertical force production of the paretic lower extremity and symmetrical weight distribution during sit-to-stand.

The present study was conducted to determine whether improved symmetrical weight bearing during standing and walking using auditory and somatosensory feedback would result in improved gait performance and balance in people with stroke. For this purpose, an insole shoe wedge and a pressure and timing sensor were developed (I-ShoWS: Insole Shoe Wedge and Sensors). The I-ShoWS set-up represented combined forms of extrinsic feedback including proprioception, pressure and auditory feedback. This combined extrinsic feedback may augment the potential stroke-related impairment in intrinsic feedback processing as well as overcome the implicit 'disuse' of the paretic lower limb. Therefore, we hypothesized superior performance in standing and walking limb symmetry, balance and gait in participants training with the I-ShoWS set-up compared with those following a conventional gait training programme.

Methods

Participants were recruited from the rehabilitation unit, university hospital and the physical therapy clinic, Faculty of Associated Medical Sciences, Chiang Mai University, Thailand. The inclusion criteria were: (1) first episode of unilateral stroke with hemiparesis; (2) Orpington prognostic score at initial assessment between 3.2 and 5.2 (moderately severe);[16] (3) able to walk at least 10 m with or without assistance; (4) stable medical condition; and (5) able to comprehend instructions and willing to participate. They were excluded from the study if they had: (1) any comorbidity or complication that would preclude gait training; (2) impaired cognition and/or communication; (3) severe leg spasticity (Modified Ashworth Scale $\geq$3); (4) neglect; and (5) missed more than three training sessions. The study protocol was approved by the Human Ethical Review Board of the Faculty of Medicine, Chiang Mai University, Thailand. All participants gave written informed consent prior to participation.

Design

An assessor-blinded, randomized controlled design was used. Stratified randomization was performed to equalize enrollment of subjects both early (≤6 months) and late (≥6 months) post stroke. Blocked randomization procedure was performed for each stratified subgroup to ensure an equal number of subjects in the experimental and control groups. Randomization was performed by using sequentially numbered, opaque sealed envelopes to preserve allocation concealment. The flow diagram of the study is shown in Figure 1. The control group received a conventional stroke rehabilitation programme. The experimental group received conventional stroke rehabilitation programme with the use of the I-ShoWS set-up during stance and gait training.

Insole Shoe Wedge and Sensors (I-ShoWS)

The I-ShoWS set-up was used to provide somatosensory and auditory feedback during standing and gait training. The devices consisted of (1) a 7-degree lateral wedge insole inserted in the shoe of the non-paretic foot; (2) a pressure sensor embedded in the shoe insole of the paretic foot during stance training; and (3) a timed footswitch attached to the non-paretic shoe during gait training (Figure 2). The wedge functioned to compel a weight shift onto the paretic limb. A 7-degree wedge was selected based on the effectiveness of this size wedge determined by Rodriguez *et al.*[12] as well as the fact that it would not induce subtalar joint eversion that exceeds the normal range observed during gait.[17] The pressure sensor functioned as augmented audio feedback pertaining to the amount of weight bearing on the paretic limb during standing. The footswitch functioned as augmented audio feedback pertaining to the amount of time the non-paretic limb was in the swing phase. During stance training, if the weight-bearing load on the paretic leg exceeded a set threshold, an audio signal was emitted. During gait training, if the duration of non-paretic limb swing phase exceeded a set threshold (i.e. the paretic limb was in the stance phase for a sufficient duration), an audio signal was emitted.

Intervention

Participants in both groups participated in 15 physical therapy sessions (60 minutes/session, 5 days/week). For each 60-minute session, 30 minutes focused on gait retraining and 30 minutes involved other conventional stroke rehabilitation programmes. The conventional stroke rehabilitation programme included neuromuscular facilitation techniques, therapeutic exercises, balance and functional training. Gait training included pre-gait activities such as weight-bearing and weight-shifting activities, stepping, strengthening of the lower extremities and practise of walking overground with and without manual and verbal guidance. The training programme was similar between the two groups with the exception that participants in the experimental group used the I-ShoWS set-up throughout the 30-minute stance and gait training sessions. Both the pressure and the timed sensors of the I-ShoWS were adjusted to progressively challenge the participant's capability. For example, during stance training with the feet parallel, the pressure sensor would be gradually increased as the participant practised to achieve 50% weight-bearing in each lower extremity (symmetrical weight distribution). During anterior–posterior weight shifting, the pressure sensor would be gradually increased as the participant practised to achieve 100% weight bearing on the paretic limb regardless of whether the paretic limb was positioned forward or back.

Progression of the time sensor involved increasing the stance time on the paretic leg and swing time on the non-paretic leg during gait. For both stance (pressure sensor) and gait (time sensor) training, the audio feedback would be emitted for each successful practice trial.

Outcome measurements

Spatio-temporal gait parameters, balance and amount of load on the paretic leg during stance were evaluated twice: at baseline (one day before training) and one day after training without the I-ShoWS. Gait parameters examined in the present study were gait speed, step length asymmetry ratio and single support time asymmetry ratio. Balance ability was determined by the Berg

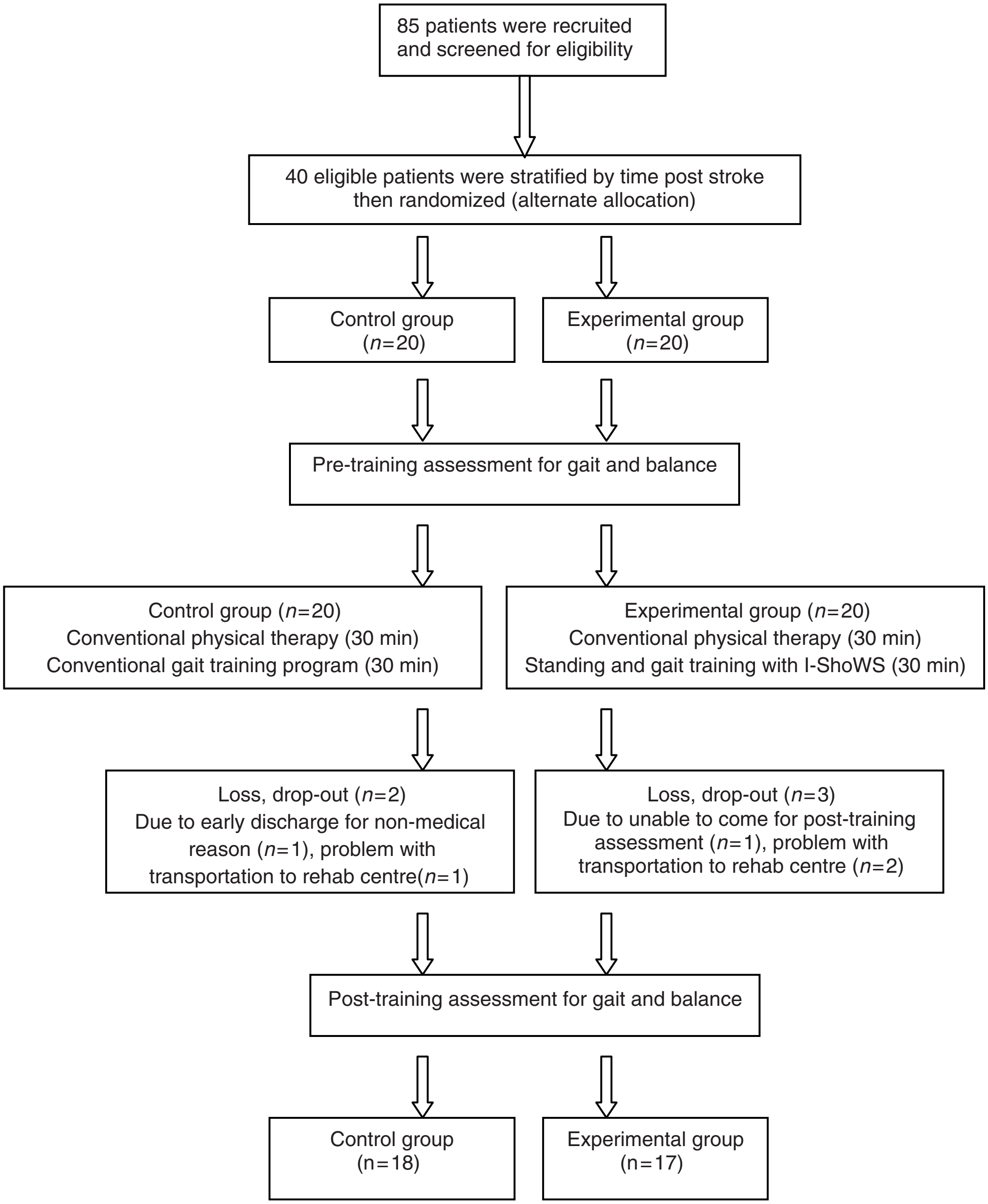

Figure 1 Flowchart of the study.

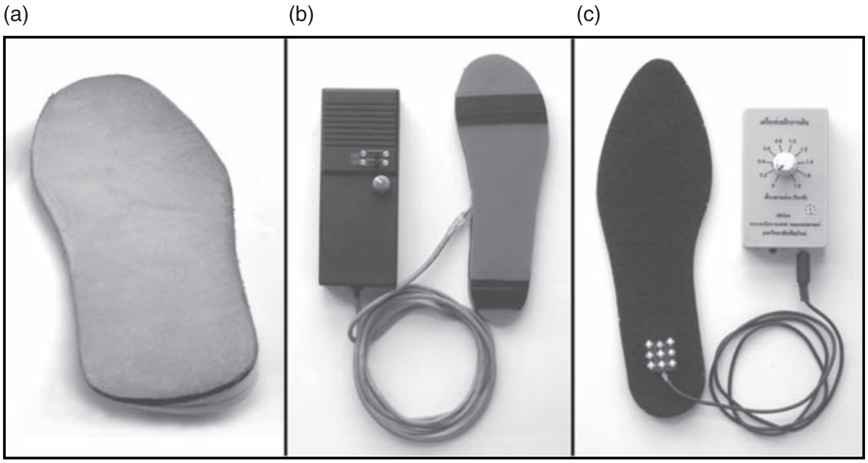

Figure 2 Devices used in the insole shoe wedge and sensors (I-ShoWS) set-up. (a) Shoe-wedge; (b) pressure sensor; and (c) foot switch.

Balance Scale and the Timed Up and Go. The examiners were blinded to group assignment.

Spatial and temporal parameters of gait including gait speed, step length, single-limb support time for both limbs were measured using the GAITRite electronic walkway system (CIR systems Inc. Clifton, NJ, USA). All participants were instructed to walk on the GAITRite mat at their self-selected gait speed for three trials with rest between each trial. Gait aid and ankle-foot orthosis were allowed if needed. Step length asymmetry ratio and single-support time asymmetry ratio were used to quantify the extent of spatial and temporal asymmetry between the two limbs, respectively. They were calculated as follows:

$$\text{Single-Support-TimeAsymmetry Ratio} = \left|1 - \frac{\text{single support time (affected)}}{\text{single support time (unaffected)}}\right|$$

$$\text{Step-Length Asymmetry Ratio} = \left|1 - \frac{\text{step length (affected)}}{\text{step length (unaffected)}}\right|^{18}$$

Greater ratios were indicative of greater asymmetry. A value of zero indicates perfect symmetry.

Berg Balance Scale[19] and Timed Up and Go[20] were used to assess balance. The Berg Balance Scale has been shown to be responsive to change with intervention for frail elders as well as individuals with neuromuscular impairment.[21] While individuals with scores less than 45 points on Berg Balance Scale are considered to be at risk for falls,[22] individuals who take more than 14 seconds to complete the Timed Up and Go are considered to be at risk for falls.[23] Structured instructions and demonstration of the Berg Balance Scale and Timed Up and Go were given to all participants prior to testing. Participants were allowed to wear their regular shoes and use an ankle-foot orthosis and/or gait aid if necessary.

To measure weight bearing during quiet stance, two digital bathroom scales were embedded in the floor such that they did not move and the participants did not have to step up onto the scales. The scales were tested for accuracy and consistency of measurement. Participants were instructed to stand still with one foot on each scale and look straight ahead. The measurement was taken with bare feet and repeated three times. For each participant, the weight distribution on the affected limb was averaged across the three trials then calculated as a percentage of the individual's body weight.

Data analysis

Independent samples *t*-tests were used to compare the demographic characteristics, the pre-training and post-training outcome measures between the control and the experimental groups. To identify the effect of training, the differences between pre- and post-training within each group (i.e. change scores) of all outcome measures were calculated. Among the dependent variables, gait speed did not conform to the normal distribution, therefore data transformation (taking square root) was used prior to statistical analysis.[24] The change scores of the experimental group were then compared with those of the control group using independent sample *t*-tests. A significant level of 0.05 was set for all analyses.

Results

Figure 1 shows the flow diagram of the randomization. Of 40 participants, 35 participants completed the trial. All participants in the experimental group were able to use the I-ShoWS set-up throughout the training programme without any accident or injury. Demographic and clinical characteristics of participants in the two groups are presented in Table 1. The two groups were similar in terms of age, gender, time post onset, paretic side, degree of severity as measured by the Orpington score and type of injury.

Table 2 summarizes the group means for all outcome measures before and after training and the mean difference of the pre-training and post-training scores (i.e. change score) of both groups. Independent samples *t*-test revealed no significant differences between the two groups for all outcome measures at baseline ($P > 0.05$). After training, the experimental group demonstrated significant

Table 1 Demographic information of the two groups

Variables	Experimental group ($n = 17$)	Control group ($n = 18$)	*P*-value
Age (years)	52.12 ± 7.17	53.83 ± 11.18	0.93
Gender (male:female)	12:5	12:6	–
Time post stroke (months)	3.94 ± 4.79	4.7 ± 5.8	0.46
Post acute:chronic	13:4	14:4	–
Paretic side (right:left)	10:7	11:7	0.91
Orpington score	3.55 ± 0.55	3.44 ± 0.39	0.64

Values are mean ± standard deviation.

Table 2 Comparisons of outcome measures before and after training and change scores after training between the control and the experimental groups

Outcome measures	Pre-training		*P*-value	Post-training		*P*-value	Post-training–Pre-training		*P*-value
	Control group ($n = 18$)	Experimental group ($n = 17$)		Control group ($n = 18$)	Experimental group ($n = 17$)		Control group ($n = 18$)	Experimental group ($n = 17$)	
Gait speed (cm/s)	22.24 ± 9.1	23.52 ± 10.8	0.70	26.30 ± 8.5	35.09 ± 13.6	0.03	4.06 ± 6.0	12.24 ± 11.7	0.02
Step length asymmetry ratio	1.0 ± 0.89	1.4 ± 0.39	0.43	0.78 ± 0.31	0.37 ± 0.09	0.19	0.22 ± 0.02	1.03 ± 0.37	0.03
Single support time asymmetry ratio	0.52 ± 0.02	0.53 ± 0.05	0.92	0.51 ± 0.04	0.39 ± 0.03	0.01	0.01 ± 0.03	0.14 ± 0.05	0.03
Berg Balance Scale (points)	38.35 ± 8.0	36.18 ± 4.7	0.34	41.76 ± 7.3	45.64 ± 4.3	0.06	3.41 ± 2.4	9.47 ± 4.0	0.001
Timed Up and Go (s)	31.57 ± 11.3	32.14 ± 14.2	0.89	27.17 ± 10.9	22.26 ± 10.4	0.18	4.41 ± 6.4	9.88 ± 9.2	0.04
Loading on paretic leg during stance (% body weight)	39.1 ± 6.7	36.4 ± 7.7	0.28	39.8 ± 9.7	45.5 ± 4.8	0.04	0.7 ± 9.4	9.2 ± 6.7	0.004

Values are shown in mean ±standard deviation.

greater improvement in gait speed, single support time asymmetry ratio and the amount of loading on paretic leg during stance than the control group ($P < 0.05$). While the Berg Balance Scale approached significance ($P = 0.06$), time to complete the Timed Up and Go was not different between the two groups ($P = 0.18$). For the change score, independent samples *t*-test revealed significant differences between the two groups for all variables ($P < 0.05$), indicating greater improvement after training for the experimental group. The results were similar for the subgroup of participants with time post stroke onset less than six months (data not shown). Because of the small numbers of participants in the chronic subgroup ($n = 4$ for each group), their data were not analysed separately.

Discussion

This study investigated whether improved symmetrical weight distribution during standing and walking by using the I-ShoWS set-up, consisting of three components providing somatosensory (wedge) and auditory feedback (pressure and time sensors), would result in improved gait performance and balance in people with stroke. The results demonstrated that training with the I-ShoWS set-up was more effective in restoration of symmetrical weight distribution in standing, bipedal limb symmetry in walking, balance and walking speed than the conventional rehabilitation programme. After training, the experimental group demonstrated greater improvement in gait speed and balance (as demonstrated by the Berg Balance Scale and Timed Up and Go) than the control group. While both groups showed improvement, the experimental group demonstrated approximately 3 times greater improvement in gait speed and Berg Balance Scale score than the control group.

Consistent with our results, several studies have demonstrated that augmented feedback is beneficial for motor learning in people with stroke.[11,25,26] In contrast to our findings, a systematic review by Van Peppen *et al.*[27] showed no significant effects of visual feedback training on symmetry of weight distribution in bilateral standing, postural sway, balance control measured with Berg Balance Scale and Timed Up and Go. Importantly, visual feedback training in standing failed to generalize to improved performance during gait and gait-related activities. The authors concluded that training of postural control should be applied while performing the gait-related tasks itself. Our intention to improve symmetry during standing and walking necessitated that practice occur within both of these contexts using forms of feedback that do not interfere with dynamic upright performance.

In accordance with previous studies, participants in the present study demonstrated reduced loading on the paretic limb during standing[12–14,28] and asymmetrical step length during walking.[18,29] Eighty per cent ($n = 28$) of participants in the present study walked with longer paretic step length. Improvement in loading onto the paretic leg during standing and decrease in asymmetrical step length and asymmetrical single limb support time during walking was demonstrated after training with the I-ShoWS set-up. Although we attribute these results to the augmented feedback that the experimental group received during task-specific training, we cannot discount the possibility of improved lower extremity strength as a potential contributor to improved standing and walking symmetry.

While the above discussion establishes that training with the I-ShoWS set-up improved symmetry, the clinically relevant outcomes relate to improvement in gait speed and balance. Gait speed is a preferred outcome measure due to the simplicity and reliability of measurement as well as its predictive ability for functional independence.[30,31] After training, the experimental group demonstrated approximately 3 times greater improvement in gait speed than the control group. However, the post-training gait speed (35.09 ± 13.6 cm/s) of the experimental group was considerably less than that required for community ambulation (80 cm/s).[6] Similarly, although the experimental group showed greater improvement in spatial and temporal symmetry between the paretic and non-paretic limb during walking than controls, both groups continued to demonstrate asymmetry in step length and single limb support time, suggesting residual deficits even after the rehabilitation programme.

The mean Berg Balance Scale improvement of 9.47 points in the experimental group after training was not only statistically significant but also clinically meaningful. A previous study reported that a 6-point change in the Berg Balance Scale score is required to be 90% confident of a genuine change in balance in individuals with stroke.[32] We postulate that a training protocol aimed at increasing loading onto the paretic leg may consequently result in balance improvement as impaired balance in individuals post stroke is often related to uneven weight bearing.[33,34] After training, while the average Berg Balance Scale score of the experimental group was at the cut-off point for fall risk (i.e. 45),[22] their average time taken to complete the Timed Up and Go still indicated high risk of fall.[20]

Two possible explanations for the differential effect of the I-ShoWS set-up on the two balance measures are that while all components of the Timed Up and Go require dynamic transitional movements, several items of the Berg Balance Scale are less challenging on the postural control system, such as sitting still, standing still and turning to look behind. Thus, the Berg Balance Scale may be less difficult than the Timed Up and Go. Second, training with the I-ShoWS may encourage the subject to increase the loading of the paretic limb rather than speed of movement, a critical feature of the Timed Up and Go. The training concurrent with the use of the I-ShoWS set-up involved loading on the paretic leg during standing and walking but did not emphasize speed; a component that should be included in future studies with the I-ShoWS.

While training with the I-ShoWS set-up in conjunction with standing and gait training resulted in better performance in standing and walking limb symmetry, balance and gait than a conventional gait training programme, issues with respect to the degree of improvement, patient considerations and additional measurements need to be considered.

As there were residual deficits in gait speed, asymmetry indices, the Berg Balance Scale and Timed Up and Go after training with the I-ShoWS set-up, the intervention 'dose' with respect to frequency, duration and intensity may have been insufficient. Future studies would consider manipulation of these parameters to determine the optimal dose of gait training in conjunction with the I-ShoWS. Issues of long term follow-up and time since stroke onset must be taken into account when interpreting the results from this study. Given that the post-training assessment was done one day after training, it is not known whether the improvement shown in the experimental group was lost, sustained or whether the subjects even continued to improve. Sullivan *et al.*[35] demonstrated further increases in gait velocity three months after body weight-supported treadmill training suggesting that participants were able to capitalize on their training experience for further improvement.

With respect to patient considerations, the relatively small sample size in the present study may have weakened statistical power in some outcome measures. A larger sample size would enhance the power analysis and external validity of the study. Along these lines, homogeneity with respect to time from stroke onset would ensure that the results were due to the experimental manipulation of gait and standing training with the I-ShoWS set-up and not due to spontaneous recovery from stroke. Although an equal number of post-acute and chronic participants were randomly allocated in both the experimental and control groups in this study, future studies could be conducted using only post-acute or chronic participants to determine the interaction between type of training and time since stroke onset. Finally, by adding more measures of impairment such as lower extremity strength and control, it would be possible to determine the relationship between changes in stroke-related impairment and the efficacy of gait and standing training with the I-ShoWS set-up.

Clinical messages

- An insole shoe wedge and sensors, a combined form of external feedback, utilized during standing and gait retraining in individuals with stroke is more effective in restoration of standing and walking symmetry, balance and gait than conventional gait retraining programme.
- A training protocol aimed at increasing symmetrical weight distribution during standing and walking may consequently result in gait and balance improvement.

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Conflict of interest

No commercial party provides financial support to the study or has financial interest in the results of this study. The authors have no commercial interest in the device.

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