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Original Article

Efficacy of a novel walking assist device with auxiliary laser illuminator in stroke Patients~ a randomized control trial

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Stroke;
Visual cueing

Background/Purpose: Task-oriented functional walking is important in stroke patients. We aimed to investigate effects of a quad-cane with auxiliary laser illuminator (laser-cane) among stroke patients.
Methods: This was a randomized-prospective study. Patients in the experimental group (EG) received 15-min of walking training with laser-cane and 15-min of traditional physical therapy. Patients in the control group (CG) received the same rehabilitation without laser-cane. The rehabilitation lasted for 4 weeks, twice per week. Primary outcome were gait parameters. Secondary outcomes were Berg Balance Scale (BBS), Timed Up and Go Test (TUG), and Barthel index (BI). Outcomes were measured at baseline, at the end of the rehabilitation (visit-1), and 4 weeks later (visit-2).
Results: Both the groups (both n = 15) showed improvement of cadence, relative stance and swing phase duration of non-paretic side, BBS, and TUG at both visits. In the intragroup comparison, the EG additionally improved at stride length, relative stance and swing phase duration of paretic side, and gait speed at both visits; temporal swing symmetry, and toe-off angle of non-paretic side at the visit-2. Intergroup comparing for changing of outcomes with the CG, stride length and gait speed increased, relative stance phase duration of the non-paretic site decreased, and the temporal swing symmetry improved at the visit-1; relative stance phase

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duration of the paretic side decreased and the temporal stance symmetry improved at the visit-2 in the EG.
Conclusion: Rehabilitation with laser-cane improved the balance, activity of daily living, gait symmetry and gait parameters of stroke patients.

Introduction

Stroke is considered one of the major causes of disability and loss of independence in humans. Hemi-paralysis, which is a common condition after stroke, might lead to severe limitation in the activities of daily living (ADL).[1] Spatio-temporal characteristics of hemiparetic gait include a decrease in (1) propulsion on the paretic side, (2) duration of stance phase on the paretic side, (3) step length on the non-paretic side, and (4) walking speed.[2] These series of ambulatory disturbances produce asymmetry in gait and might be associated with weakness, spasticity, and abnormal central neural patterning of muscle activation in many stroke patients months or years after the acute event.[3] Hemi-paretic gait could markedly reduce the gross motor efficiency of ambulation, reduce cardiovascular fitness along with increased energy demands,[4] and even increase possible incidence of fall and other injuries.[5] It may contribute to low ambulatory activity levels and poor rehabilitation outcomes.[6] Therefore, much of the impetus for stroke rehabilitation rests on the desire to regain task-oriented functional walking.

Locomotion and ambulation trainings are the most common and important programs in order to achieve independence of ADL in community-dwelling stroke patients.[4] It has been suggested that the initial use of walking aids improves the quality and stability of mobility during rehabilitation and also prevents falls in stroke patients.[2] It has been reported that as many as 76% of patients use at least one walking aid 3 months post-stroke.[7] Quad-canes are one of the most common walking aids in gait training among patients after stroke because most of these patients presented with hemi-paretic gait. It had been shown that quad-canes could improve symmetry[8] and help to achieve normal muscle activation patterns[9] in patients with stroke presenting with asymmetric gait. Evidence from studies of motor learning show that learning motor skills may be improved when practice is carried out in response to external cues.[10] The use of external cues typically provides a participant with simple visual or acoustic information about the actual physiological function or the current course of physical activity. Auditory cueing, particularly, has many evidences supports their use to elicit normalized walking coordination patterns within gait rehabilitation paradigms.[11,12] However, when it comes gait adjustment in response to the environment, vision cues is more important than auditory ones in the control of walking.[13,14] Studies using additional external visual information about proper gait pattern (such as speed, step length, and gait symmetry) in gait training had shown that visual cues allowed stoke patients to not only improve symmetry of gait but also balance, coordination, turning and maintenance of dynamic stability.[13,15,16] However, when it comes to combining assistive device with visual cues, only few studies were done in patients with Parkinson's disease with the conclusion that it could improve posture and muscle control.[17,18] We designed a quad-cane with auxiliary laser illuminator (laser-cane) as a visual cueing tool for community-dwelling stroke patients and observed that it had an immediate effect in increasing the heel-strike angle of the paretic side.[19] This study aims to evaluate the clinical effects of a novel laser quad-cane on the gait pattern, balance, and function of daily living among community-dwelling stroke patients.

Material and methods

Study design and participants

This randomized, controlled, prospective study was carried out at a tertiary medical center in southern Taiwan from December 2017 to July 2018. After explanation of the study and before the initiation of rehabilitation programs, all patients provided their informed consent. This study was approved by the Institutional Review Board of Kaohsiung Veterans General Hospital (VGHKS17-CT8-11).

We recruited community-dwelling stroke patients who received rehabilitation treatment from the outpatient clinic of one medical center in southern Taiwan. The inclusion criteria were as follows: stroke patients (1) who were diagnosed for more than 3 months, (2) with hemiplegia, (3) with sufficient cognition to follow at least 3-step directions and who could follow instructions and perform the procedures, and (4) who used to use a traditional quad-cane and could walk independently for more than 20 m. Stroke patients associated with (1) other neurological diseases such as Parkinsonism, myopathy, multiple sclerosis, and spinal cord injury that might interfere with walking ability, (2) orthopedic problems that might decrease and interfere with measurement of range of motions, such as fractures of extremities and plantar-flexor or dorsi-flexor contracture, were excluded. All the screening test was done via medical chart reviewing and physical examination by one experienced physiatrist who practiced in rehabilitation for more than 15 years (P. T. Hsu) in his outpatient clinic.

The study consisted of a screen visit, a baseline visit, and follow-up visits at 4 and 8 weeks after the initiation of the study. Before randomization, patients' demographic data and baseline assessments were collected. The study was registered at ClinicalTrials.gov (NCT03786341).

Randomization procedures

Patients who fulfilled the inclusion and exclusion criteria were randomized (1:1) into two groups, using sequentially numbered, opaque, sealed envelopes (SNOSE) method containing a group assignment number by a person who was not clinically involved in and, therefore, was blinded to this study.

Intervention

Outpatient rehabilitation for stroke was given to patients in the experimental group (EG), which included ambulation training with laser-cane for 15 min and typical physical therapy with strengthening and balance training for 15 min. The laser-cane consisted of a quad-cane and a laser pointer, which was placed on the shaft of the quad-cane with two laser beams orthogonal to each other (Fig. 2a). Participants were requested to walk by the three-point gait with the laser-cane on the non-paretic side and the both feet parallel to one laser beam first. Then, participants moved forward their paretic lower extremity and placed the mid-foot right over the crossing point made by the two laser beams. Finally, participants were asked to move their non-paretic lower extremity over the other laser beam and put the heel of the non-paretic side forward above the toes of the paretic side (Fig. 2b–d).

Patients in the control group (CG) received conventional ambulation training with traditional quad-cane for 15 min and conventional physical therapy with strengthening and balance training for 15 min.

Both groups received a rehabilitation program twice per week for 4 weeks. The laser quad-cane or traditional quad-cane was hold by the non-paretic hand of the participants. Ambulation training in both groups was conducted on an even-surfaced corridor, 30 m long and 4 m wide. The participants in both groups were trained by the same physical therapist who had 10 years of experience in neuromuscular

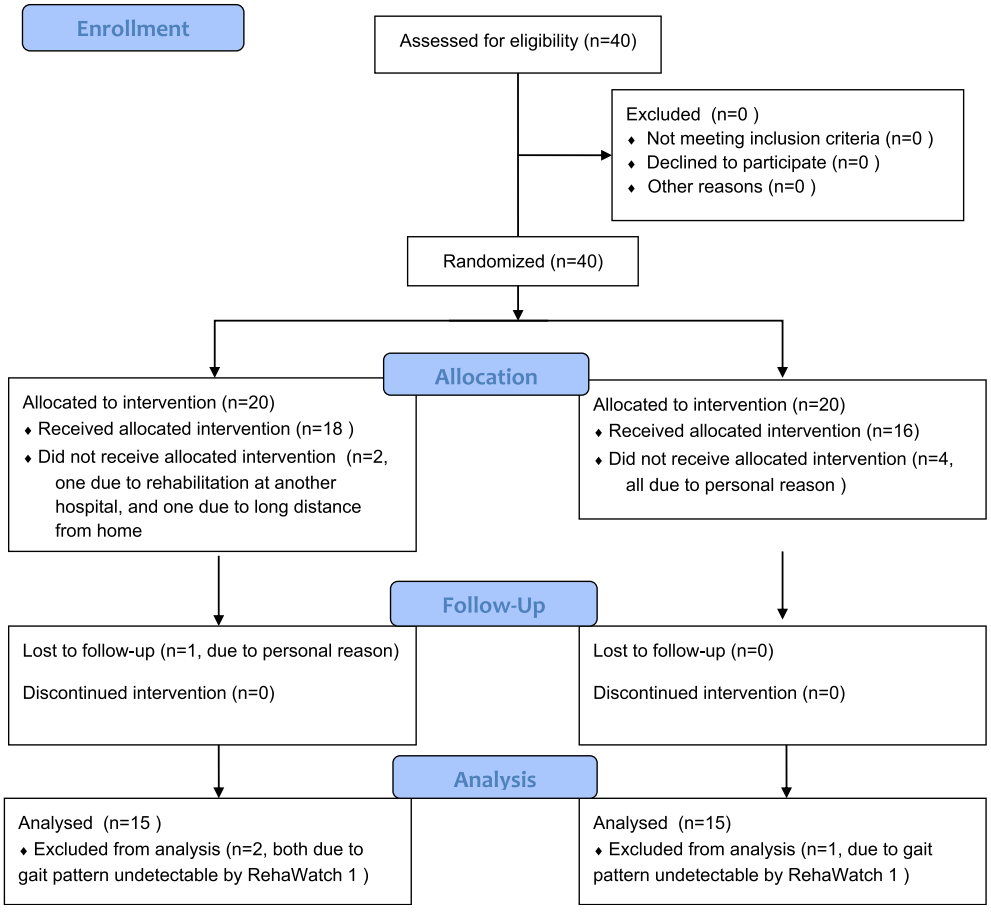
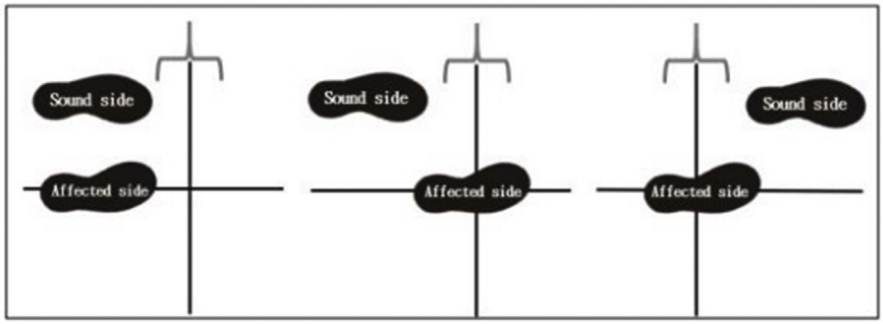
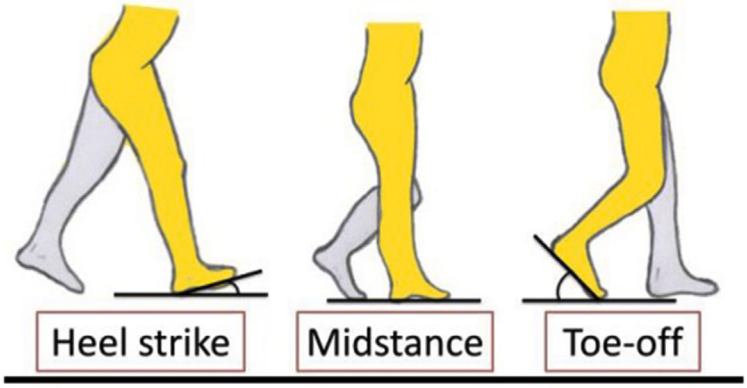


Figure 1 Algorithm of the study. Forty participants met the study criteria initially and received the randomization. After the randomization, six of them dropped out (four patients had personal issues, one patient dropped out due to rehabilitation at another hospital, and one patient could not make the long commute from home) before intervention. Therefore, 34 patients were recruited for the further study. Patients in each group received rehabilitation for 4 weeks. There were 18 patients and 16 patients in the experimental and the control group 4 weeks after the rehabilitation, respectively. Due to personal factor and the technical problem, there were 15 patients in each group at the 8th week for the final analysis.

(a)



(b) (c) (d)



(e)

Figure 2 (a) Walking assist device with auxiliary laser illuminator (laser quad-cane). The laser quad-cane was consisted of a quad-cane and a laser pointer, which was placed on the shaft of the quad-cane with two laser beams orthogonal to each other. (b)~(d) Procedure of gait training with laser quad-cane. (b) Participants were requested to walk by the three-point gait with the walking assist device on the non-paretic site and the non-paretic lower extremity parallel to one laser beam first. (c) Then, participants moved their paretic lower extremity to the cross made by the two laser beams by the illuminator with the mid-foot right over the crossing point. (d) Last, participants were asked to move their non-paretic lower extremity over the other laser beam and make the heel of the non-paretic site forward the toes of the paretic side. (e) Measurement of heel-strike angle and toe-off angle. During the stance phase of a gait cycle, we defined the angle between calcaneus and ground at the time of heel-strike as heel-strike angle, and the angle between toes and ground at the time of toe-off as toe-off angle.

rehabilitation (W.Y. Huang). All the participants received training in the study only without other rehabilitation training or occupational therapy.

Outcome measures

The primary outcome measures in this study were parameters of gait cycle per se and the changes of these variables after intervention. The parameters of gait cycle included stride length, cadence, walking speed, relative stance and swing phase durations (measured as percentage in a gait cycle), temporal swing and stance symmetry, angle between toes and ground at the time of toe-off (toe-off angle), angle between calcaneus and ground at the time of heel-strike (heel-strike angle) (Fig. 2e). Among these gait parameters, relative stance and swing phase durations, the toe-off angle, and the heel-strike angle, were measured for each leg while the others were measured for the overall performance.

The gait cycle parameters were measured using a gait analyzer (RehaWatch 1 system; HASOMED1 GmbH, Magdeburg, Germany). The system is an inertial, sensor-based gait analysis system with measurement sensors attached to the lateral ankle using a special device. Each sensor contains three accelerometers and three gyroscopes measuring foot motion in 6 degrees of freedom. The measurement range of the accelerometers is $\pm$5 g and gyroscopes $\pm$600°/s. The associated software analyzes the sensor signals and calculates temporal (e.g., stride duration and relative stance and swing phase durations) and spatial (e.g., stride length and foot angle) parameters on this basis.[20] The ideal walking distance for RehaWatch 1 system to measure is more than 10 m.[20] Based on the mechanism of measurement of RehaWatch 1 system and the directions of its product package insert, it could be applied in the analysis of hemiplegic, Parkinson, diplegic, ataxic, myopathic, and neuropathic gait. It has been used in several studies in the gait analysis of different populations,[21–23] including stroke patients with hemiplegic gait.[24] The gait measurement was done twice at each visit, and the data of final analysis was the average of the two. During each measurement, the participants walked with a traditional quad-cane as they used to do (without using the laser-cane) on a 16 m-long corridor without a barrier back and forth for a total 32 m at their comfortable walking speed. The participants could rest for 15 min between each measurement. After the measurement completion, raw data were exported from the manufacturer's software for further analysis and the assessor (M.H. Li) was blind to the participants' group allocation. Gait symmetry, a measure of the parallels of spatiotemporal gait variables between the lower limbs, can be considered an indicator of the degree of gait control. Temporal gait variables we used in this study were the following:

(1) Temporal swing symmetry: defined as paretic swing time divided by non-paretic swing time[25]
(2) Temporal stance symmetry: defined as paretic stance time divided by non-paretic stance time[25]

A ratio value of 1.0 of the both denotes perfect symmetry and they have been shown to represent a meaningful classification of ambulation post-stroke.[2,25] The minimal detectable change (MDC) of the ration was 0.26 for temporal swing symmetry and 0.19 for temporal stance symmetry.[26]

Limiting the degree of asymmetry in post-stroke gait is a common aim of rehabilitation.[27] However, some investigators think that gait asymmetry is a positive adaptation to neurologic deficits associated with stroke and suggest that gait asymmetry should not be changed, particularly in the chronic stage. According to their point of view, it is better to aim for an optimal performance rather than just biomechanical symmetry in chronic stroke patients.[28] Therefore, we used the Berg Balance Scale (BBS), the Barthel index (BI), and the Timed Up and Go Test (TUG) as secondary outcomes to evaluate the functional performance of our participants. The BBS is a 14-item list in which each item consists of a 5-point ordinal scale ranging from 0 to 4, with 0 indicating the lowest level of function and 4 indicating the highest level of function. The higher the score means the better the ability to maintain balance. A score of $<$45 indicates a greater risk of falling.[29] Studies of various populations and stroke patients have shown high intra-rater and inter-rater reliability (intra-class correlation coefficient [ICC] = 0.98 and 0.97, respectively).[30]

The BI measures the degree of assistance required by an individual on ten items of mobility and self-care ADL. The total scores range from 0 to 100. The higher the score means the better the function. BI has been shown to have portability and has been used in many major diagnostic conditions. Studies have demonstrated high inter-rater reliability (0.95) and test-retest reliability (0.89) as well as high correlations (0.74—0.8) with different physical disabilities.[31]

The TUG test is designed for determining fall risk and measuring the progress of balance, sit to stand, and walking. To perform the test, the participant starts in a seated position, stands up upon the therapist's command to walk 3 m, then turn around, walk back to the chair, and sit down. All the participants in both groups walked with a traditional quad-cane as they used to do during the TUG test. The time stops when the patient is seated. If a community-dwelling older adult takes 14 s or longer, the risk for falling is high.[32] The TUG showed excellent reliability (ICC$>$0.95) in patients with chronic stroke.[33] All the secondary outcomes were measured by one rater (S.H. Tuan) who was blinded to group allocation of the participants. The BBS and BI were evaluated once at each visit while the TUG was done twice with 15 min break between measurements at each visit.

Statistical analysis

Based on the Statistical G*Power software (version 3.1.9.2, for Windows), at least 14 observations in each group should be observed by detecting a difference, 16.67%, in percentage of change of stride length between the groups with 80% power and 5% alpha, and the effect size was determined to be 0.99.[34]

SPSS for Windows version 19.0 (Released 2010; IBM Corp., Armonk, NY, USA) was used for all of the analyses. The continuous data were expressed as mean $\pm$ standard

deviation, and the categorical variables were presented as absolute numbers or percentages. Normality and homoscedasticity were checked before each analysis. However, there was only 15 participants in each of two groups, and normality assumptions of all variables in study were not satisfied. The non-parametric statistics procedures were used in the study. Fisher's exact test and Mann–Whitney U-test were used to test for differences in the distribution between categorized variables and continuous variables between two groups in the respect of basic characteristics and outcomes at each visit. Changes in primary and secondary outcome measures among the baseline and week 4 or week 8 were analyzed using Wilcoxon signed-rank test for intra-group comparisons and Mann–Whitney U test for intergroup comparisons. Intergroup analysis was performed by comparing the percentage of change in outcomes to avoid the baseline imbalance. A $P < 0.05$ was regarded as statistically significant.

Results

Forty participants met the study criteria initially and received the SNOSE randomization but six dropped out (four patients had personal issues, one patient dropped out due to rehabilitation at another hospital, and one patient could not make the long commute from home) before intervention. Therefore, 34 patients were recruited for the further study. There were 18 and 16 participants in the experimental group (EG) and control group (CG), respectively. During period of the study, three patients in the EG (two patients due to gait pattern undetectable by RehaWatch 1 and one patient due to personal factor) and one patient in the CG (due to gait pattern undetectable by RehaWatch 1) dropped out of this study after 4 weeks. Therefore, 15 patients remained in each group at week 8 of the study (Fig. 1). The final recruited participants included 12 males and 3 females in the EG and 11 males and 4 females in the CG. The basic characteristics in the two groups showed no significant difference. The Brunnstrom stage of paretic limbs were all more (or equal to) than stage III in both the groups. The descriptive characteristics of the participants are presented in Table 1.

Comparisons of primary and secondary outcomes between experimental and control groups at baseline, week 4 and week 8 were presented in Table 2. All of the testing of baseline group differences on the primary and secondary outcome measures were not significant difference in statistic. The intergroup and intra-group comparisons in each group and between the EG and CG are presented in Table 2. With regard to the EG, there were significant increases in (1) stride length ($p = 0.008$ and 0.004, respectively), (2) cadence ($p = 0.016$ and 0.023, respectively), (3) percentage of swing phase on bilateral sides (all $p \leqq 0.05$), (4) gait speed ($p = 0.006$ and 0.049, respectively), (5) scores of BBS (both $p = 0.001$), and (6) scores of BI ($p = 0.007$ and 0.002, respectively), between week 4 or week 8 and the baseline. There were also significant decreases in (1) percentage of relative stance phase duration on bilateral sides (all $p \leqq 0.05$), and (2) time of TUG ($p = 0.001$ and 0.002, respectively), between week 4 or week 8 and the baseline. We also observed significant increases in heel-strike angle of non-paretic side ($p = 0.001$) between week 4 and the baseline, significant increases in toe-off angle of non-paretic side ($p = 0.015$) and temporal swing symmetry ($p = 0.028$), between week 8 and the baseline.

With regard to the CG, there were significant increases in (1) cadence ($p = 0.009$ and 0.001, respectively), (2) percentage of swing phase on the non-paretic side ($p = 0.015$ and 0.008, respectively), and (3) scores of BBS

Table 1 Descriptive characteristics of the stroke patients.

	Experimental group (n = 15)	Control group (n = 15)	P value[a]
Age (years)	57.0 ± 9.5	66.1 ± 9.0	0.14
Height (cm)	168.5 ± 10.3	165.0 ± 6.6	0.37
Weight (kg)	68.5 ± 12.7	66.4 ± 10.5	1.00
Stroke duration (months)	55.5 ± 64.2	88.4 ± 83.9	0.71
Gender (Male/Female) (n/%)	12(80%)/3(20%)	11(73%)/4(27%)	1.00
Hemiparetic side (right/left) (n/%)	10(67%)/5(33%)	10(67%)/5(33%)	1.00
Muscle power			
Brunnstrom stage			
Upper proximal extremity	4.07 ± 0.80 (III = 4, IV = 6, V = 5)	4.27 ± 0.80 (III = 3, IV = 5, V = 7)	0.499
Upper distal extremity	3.87 ± 0.74 (III = 5, IV = 7, V = 3)	4.00 ± 0.76 (III = 4, IV = 7 V = 4)	0.630
Lower extremity	4.00 ± 0.65 (III = 3, IV = 9, V = 3)	4.13 ± 0.74 (III = 3, IV = 7, V = 5)	0.606
Stroke type			
Cerebral infarction (n/%)	7 (47%)	7 (47%)	
Cerebral hemorrhage (n/%)	8 (53%)	8 (53%)	1.00
AFO usage			
With AFO	12 (80%)	10 (67%)	
Without AFO	3 (20%)	5 (33%)	0.68

Experimental group, stroke patient trained by quad-cane with auxiliary laser illuminator; control group, stroke patients trained by conventional rehabilitation; AFO, ankle-foot orthosis.

[a] Fisher's exact test and Mann–Whitney U-test were used to test for differences in the distribution between categorized variables and continuous variables between two groups.

Table 2 Comparison of primary and secondary outcomes between experimental and control groups.

Variables	Experimental group (n = 15)					Control group (n = 15)					Intergroup comparison P value[e]		Percentage of change of variables[f]	
	Baseline	Week 4	Week 8	P value[a]	P value[b]	Baseline	Week 4	Week 8	P value[a]	P value[b]	Baseline	Week 4 Week 8	P value[c]	P value[d]
Primary outcomes														
Stride length (meter)	0.6 ± 0.2 (0.5.0.7)	0.7 ± 0.2 (0.6.0.8)	0.7 ± 0.2 (0.6.0.8)	0.008[g]	0.004[g]	0.6 ± 0.2 (0.5.0.7)	0.6 ± 0.1 (0.6.0.7)	0.6 ± 0.1 (0.6.0.7)	0.496	1.000	0.870	0.021[g] 0.041	0.045[g]	0.244
Cadence (step/min)	43.1 ± 9.3 (38.3.47.1)	49.2 ± 12.9 (42.6.55.6)	51.0 ± 15.8 (43.4.59.2)	0.016[g]	0.023[g]	44.6 ± 10.9 (40.1.47.1)	49.8 ± 11.1 (45.3.53.4)	51.7 ± 11.6 (46.3.56.3)	0.009[g]	0.001[g]	0.775	0.653 0.653	0.980	0.555
Stance phase														
Non-paretic side (% of cycle)	84.9 ± 5.2 (82.3.87.6)	78.0 ± 9.7 (62.7.82.7)	79.3 ± 8.6 (75.1.83.8)	0.002[g]	0.004[g]	83.0 ± 6.4 (82.0.86.0)	81.4 ± 5.7 (76.8.82.6)	81.4 ± 5.9 (78.0.83.0)	0.013[g]	0.006[g]	0.512	0.367 0.389	0.048[g]	0.091
Paretic side (% of cycle)	75.8 ± 9.3 (72.0.80.0)	73.2 ± 9.0 (69.2.76.6)	67.0 ± 9.6 (62.6.71.1)	0.050[g]	0.013[g]	70.6 ± 10.4 (66.1.75.5)	70.0 ± 10.4 (65.7.75.1)	68.5 ± 8.5 (64.7.72.5)	0.382	0.506	0.156	0.217 0.567	0.369	0.03[g]
Swing phase														
Non-paretic side (% of cycle)	15.1 ± 5.2 (12.4.17.7)	22.0 ± 9.7 (17.3.27.3)	20.7 ± 8.6 (16.2.25.0)	0.002[g]	0.004[g]	17.0 ± 6.4 (14.0.18.0)	18.6 ± 5.7 (17.4.23.2)	18.6 ± 5.9 (17.0.22.0)	0.015[g]	0.008[g]	0.512	0.367 0.389	0.086	0.106
Paretic side (% of cycle)	24.2 ± 9.3 (20.2.28.0)	26.8 ± 9.0 (23.4.30.8)	33.0 ± 9.6 (29.0.37.4)	0.050[g]	0.013[g]	29.4 ± 10.4 (24.5.33.9)	30.1 ± 10.4 (24.9.34.3)	30.6 ± 7.9 (27.1.34.0)	0.382	0.814	0.156	0.202 0.285	0.339	0.052
Temporal swing symmetry	1.44 ± 0.34 (1.24.1.64)	1.40 ± 0.35 (1.18.1.50)	1.25 ± 0.34 (1.01.1.34)	0.374	0.028[g]	1.72 ± 0.37 (1.56, 1.87)	1.69 ± 0.32 (1.58.1.83)	1.60 ± 0.42 (1.39.1.71)	0.382	0.346	0.128	0.028[g] 0.019[g]	0.773	<0.001[g]
Temporal stance symmetry	0.85 ± 0.12 (0.79.0.95)	0.89 ± 0.09 (0.81, 0.96)	0.95 ± 0.13 (0.84.1.06)	0.156	0.061	0.84 ± 0.08 (0.75,0.091)	0.85 ± 0.08 (0.78.0.92)	0.86 ± 0.10 (0.80.0.94.)	0.820	0.691	0.547	0.120 0.017[g]	<0.001[g]	<0.001%
Overall gait symmetry deviation	0.15 ± 0.12 (0.05.0.25)	0.11 ± 0.09 (0.02.0.20)	0.05 ± 0.13 (0.01.0.11)	0.529	0.038[g]	0.16 ± 0.08 (0.06.0.26)	0.15 ± 0.08 (0.05.0.25)	0.14 ± 0.1 (0.04.0.24)	0.988	0.978	0.547	0.120 0.016[g]	0.653	0.047[g]
Heel-strike angle														
Non-paretic side ()	2.4 ± 2.9 (1.1.3.9)	4.4 ± 4.2 (2.4.6.5)	4.5 ± 3.9 (2.5.6.5)	0.001[g]	0.083	3.8 ± 3.1 (2.1.4.2)	4.3 ± 4.2 (2.9.5.7)	4.2 ± 3.8 (3.0.5.6)	0.589	0.232	0.202	0.870 0.838	0.878	0.939
Paretic side ()	2.7 ± 5.4 (0.1.4.9)	4.0 ± 3.2 (2.7.5.4)	3.7 ± 4.8 (1.6.5.7)	0.441	0.721	0.4 ± 4.9 (−1.6.2.4)	1.8 ± 5.7 (−0.6.4.4)	1.8 ± 5.6 (−0.7.4.4)	0.248	0.064	0.250	0.116 0.217	0.099	0.434

Toe-off angle															
Non-paretic side ()	−34.6 ± 7.7 (−30.6,-38.2)	−36.2 ± 8.9 (−31.7,-40.3)	−38.0 ± 6.7 (−34.6,-41.3)	0.125	0.015[g]	−35.7 ± 8.9 (−32.1,-38.0.)	−35.6 ± 12.0 (−32.1,-40.0)	−37.9 ± 9.5 (−35.3,-41.0)	0.955	0.280	0.713	0.744	0.624	0.590	0.778
Paretic side	−11.3 ± 11.0 (−7.2,-16.6)	−13.6 ± 13.1 (−8.4,-19.7)	−13.0 ± 10.5 (−8.8,-17.8)	0.374	0.169	−12.4 ± 6.8 (−9.6,-15.9)	−16.0 ± 10.0 (−11.8,-20.7)	−15.8 ± 11.4 (−11.5,-21.0)	0.075	0.136	0.267	0.367	0.595	0.582	0.931
Gait speed (m/s) ()	0.42 ± 0.12 (0.36,048)	0.56 ± 0.19 (0.46.0.65)	0.60 ± 0.27 (0.48.0.74)	0.006[g]	0.049[g]	0.43 ± 0.13 (0.37.0.51)	0.47 ± 0.17 (0.39.0.56)	0.50 ± 0.16 (0.43.0.59)	0.930	0.113	0.775	0.187	0.595	0.015[g]	0.221
Secondary outcomes															
Berg balance scale	32.8 ± 10.3 (26.7.37.7)	41.0 ± 11.1 (34.3.45.7)	42.3 ± 10.2 (36.2.46.8)	0.001[g]	0.001[g]	32.1 ± 9.9 (27.1.37.4)	38.6 ± 10.9 (32.9.43.9)	39.2 ± 11.9 (32.6.44.9)	0.001[g]	0.003[g]	0.512	0.461	0.539	0.45	0.52
Barthel index	79.0 ± 19.3 (68.3.88.2)	89.3 ± 12.1 (82.1.94.7)	91.7 ± 11.9 (84.4.96.9)	0.007[g]	0.002[g]	81.0 ± 18.5 (71.7.90.3)	87.0 ± 12.8 (80.5.93.8)	90.7 ± 10.7 (85.0.95.8)	0.09	0.01[g]	0.775	0.713	0.713	0.68	0.69
Timed up and go test	49.2 ± 16.3 (41.3.51.2)	38.5 ± 15.5 (31.1.47.1)	37.0 ± 13.0 (28.7.42.2)	0.001[g]	0.002[g]	49.1 ± 20.2 (39.2.59.3)	37.4 ± 12.8 (30.7.43.4)	35.7 ± 12.7 (28.6.41.2)	0.007[g]	<0.001[g]	0.967	0.713	0.775	0.70	0.77

Data were presented as mean ± standard deviation.
(95% confidence interval).

[a] P value: Intra-group comparison between data of baseline and week 4 by Wilcoxon signed-rank test.

[b] P value: Intra-group comparison between data of baseline and week 8 by Wilcoxon signed-rank test.

[c] P value: Inter-group comparison between change of data of baseline and week 4 by Mann–Whitney U test.

[d] P value: Inter-group comparison between change of data of baseline and week 8 by Mann–Whitney U test.

[e] Inter-group comparison between data of baseline, week 4, and week 8 by Mann–Whitney U test, respectively.

[f] Percentage of change of variables: change between week 4 or week 8 and baseline divided by data of baseline overall symmetry deviation, overall temporal symmetry minus 1; heel-strike angle, angle between calcaneus and the ground at the time of heel-strike during a gait cycle; toe-off angle, angle between toes and the ground at the time of toe-off during a gait cycle.

[g] $p < 0.05$.

($p = 0.001$ and 0.003, respectively), between week 4 or week 8 and the baseline. There were significant decreases in (1) percentage of relative stance phase duration on the non-paretic side ($p = 0.013$ and 0.006, respectively), and (2) time of TUG ($p = 0.007$ and $p < 0.001$, respectively), between week 4 or week 8 and the baseline. We also observed significant increases in BI scores ($p = 0.01$) between week 8 and the baseline.

Regarding the intergroup comparisons (Table 2), patients in the EG significantly had lower temporal swing symmetry at the week 4 and 8 ($p = 0.028$ and 0.019, respectively), and higher temporal stance symmetry ($p = 0.017$) at the week 8 than those in the CG. Comparing to patients in the CG, patients in the EG also had significant increases in the percentage of change of (1) stride length ($p = 0.045$) and gait speed ($p = 0.015$) at the week 4, (2) temporal stance symmetry (both $p < 0.001$) at both the week 4 and 8; significant decreases in the percentage of change of (1) relative stance phase duration on the non-paretic side at the week 4 ($p = 0.048$), (2) relative stance phase duration on the paretic side ($p = 0.03$), and temporal swing symmetry ($p < 0.001$) at the week 8. Moreover, in the EG, the decreases of temporal swing symmetry at the week 8 was more than 0.19 from the baseline, a number showed to have clinical relevance.[26]

Discussion

To the best of our knowledge, this was the first study carried out to evaluate the training effect of a laser-cane during ambulation training in stroke patients. There were few studies discussed about the laser visual cueing device in the literatures. Most of the studies identified immediate improvements during gait initiation and even improved posture and muscle control when using the laser cueing devices in patients with Parkinson's disease.[17,18] There is even a commercial laser walking cane for patients with Parkinson's disease to break freezing of the initiation of gait.[35] However, the device use in Parkinson's disease is mostly single cane. There was no study about using the laser cueing device on the quad-cane before this study finished. Since the only difference of the laser-cane from the traditional quad-cane is that it consisted of an extra laser pointer, the cost of the laser-cane is affordable and the use is as convenient as the traditional one.

Various temporal (time-dependent) and spatial (distance-dependent) asymmetry have been observed in a hemiplegic gait.[27] Patterson et al. found that 55.5% post-stroke hemiplegic patients had temporal gait asymmetry, whereas only 33.3% of the same group had spatial asymmetry.[25] Given that reports on the amount of time hemiplegic patients spend in single-limb support on each leg are inconsistent,[27] we used temporal swing symmetry and temporal stance symmetry to evaluate the symmetry of gait after training. We did observe that patients in both the EG and the CG had improvement in temporal swing and stance symmetry after training but the statistical significant change (p value < 0.05) and clinical relevance change from baseline (more than 0.19[26]) only presented in the EG. Moreover, the percentage of the change of both the temporal swing and stance symmetry from baseline was significant higher in the EG. We observed that the relative stance phase duration of both the paretic and the non-paretic sides decreased significantly and that the relative swing phase duration of both the paretic and the non-paretic sides increased significantly at weeks 4 and 8 after ambulation training in the EG. The relative stance and swing phase durations of the paretic side in the EG at week 8 accounted for approximately 67% and 33% of the entire gait cycle, a ratio approaching the symmetry pattern.[35] For a normal adult walking at a comfortable gait speed, the relative stance and swing phase duration accounted for approximately 62% and 38% of the entire gait cycle, respectively.[35] However, hemiplegic stroke patients presented asymmetrical postures and movements, and they also shifted their center of gravity to the non-paretic side during walking, causing the ratio of the stance phase in the gait cycle to increase.[15,19] By combining the findings of symmetry variables, we could confirm that ambulation training with laser-cane improve the gait symmetry in chronic stroke patients.

One of the characteristic temporal features of hemiplegic gait is reduced walking velocity.[27] Chronic stroke patients were reported to walk at a preferred paced from 0.10 m/s to 0.76 m/s.[36] Gait velocity might serve as an indirect marker of the severity of neurological impairment, outcome predictors, and overall gait performance.[37] Ambulation velocity of greater than 0.34 m/s was found to be a better identifier of independent community living.[37] We observed that the walking speed in the EG increased significantly at both the week 4 (0.56 ± 0.19 m/s) and week 8 (0.60 ± 0.27 m/s) as compared to the baseline. Combining the findings of gait symmetry index and gait velocity, it can be speculated that by using laser-cane during ambulation training, stroke patients in chronic stage would present a more symmetrical gait cycle and better functional status among community dwelling stroke patients.

Decreases in the relative stance phase duration and increases in the relative swing phase duration of the non-paretic side in the CG also occurred at both weeks 4 and 8. Similar results did not occur in the paretic side in the CG. The participants in this study were stroke patients in the chronic stage with a mean duration more than 4 years from the onset to the date of experiment, which means that all the participants might be used to the gait they used with different degrees of compensation strategy.[37] It is reasonable to observe the differences between the paretic and non-paretic sides of the CG since the traditional ambulation training in a long term stroke survivors with compensation strategy might focus more the non-paretic side if there was no verbal or visual reminder during the training.[37]

Participants in the EG also had significantly longer stride length and a significantly smaller percentage of relative stance phase duration on the non-paretic side than those in the CG 4 weeks after the training. The decrease in the percentage of relative stance phase duration on the paretic side was also more in the EG than in the CG at week 8.

Impairments in visually guided motor control are common in patients with stroke.[18] Evidence suggested that manipulating visual cueing can enhance motor function by decreasing motor error and motor variability after stroke[15] and, therefore, can improve motor output.[17] In addition, hemiplegic stroke patients presented asymmetrical postures and movements, and they also shifted their center of gravity to the non-paretic side during walking, causing the ratio of the relative stance phase duration in the gait cycle to increase.[15,38] With the use of the auxiliary illuminator to provide visual cueing, stroke patients in this study used their vision to correct the steps of the paretic limbs. By following the guidance of the therapist to move their paretic lower extremity to step on the cross made by two laser beams, the participants might not only reduce the external rotation in the tibia of the paretic leg but also reduce the use of circumduction gait. Unfortunately, we could only make speculation since the RehaWatch system could only measure the range of motions of the ankle. Meanwhile, using the visual cue of the illuminator, the participants understood the commands of therapist better and would move their non-paretic leg over the laser beam and even parallel to the heel of their paretic leg. Therefore, we could observe that the percentages of improvement in all of the parameters of the gait cycle were higher in the EG than in the CG.

In normal gait pattern, there is rapid plantar flexion to approximately 10 degrees of plantar flexion that occurs during the heel strike. Then the angle gradually dorsi-flexed to a peak of 10° just before pre-swing.[39] However, in hemiplegic gait, lack of dorsiflexion at heel strike[40] and insufficient plantar flexors power at the pushing-off phase[41] are commonly reported kinematic deviations and stroke patients might use energy-consuming gait pattern, such as abducting the swing hip, laterally flexing the trunk towards the non-paretic side, and decreasing peak knee flexion to compensate them.[41] The increase of heel-strike angle at initial contact and toe-off angle before swing phase might improve gait stability and lessen the energy consumption of walking in stroke patients. Our study found that participants in both the EG and CG had insignificant increase of heel-strike and toe-off angle at the paretic side after training, which might result from the ability to contract the paretic plantar flexors concentrically at toe-off and to generate sufficient paretic dorsi-flexor muscle moment at heel-strike[27] improved after ambulation training with laser-cane.

In addition to the improvement of symmetry and gait parameters, functional performance is also important in ambulation training for chronic stroke patients.[28]

We chose BI since it is the most widely used scale to evaluate the basic ADL.[31] We chose TUG to evaluate the ambulation ability[33] and BBS to assess the balance control.[30] Moreover, since the participants in the EG had to use visual cueing in the use of laser-cane, the risk of fall was another outcome we wanted to detect. TUG and BBS are shown to be good indicators of fall.[42] Similar to findings in previous studies, we observed that stroke patients in both groups had significant improvement in parameters of gait cycle, BBS, BI, and TUG after ambulation training.[2,9] Both EG and CG showed significant improvement after the training at weeks 4 and 8 except that the change in BI in the CG did not reach statistical significance at week 4. The intergroup analysis showed no significant difference between the EG and the CG in all three measurements. Sometimes, statistical significance does not equal to clinical significance. The minimal clinically important difference (MCID), defining as the minimal amount of change that is required to distinguish a true performance change from a change due to variability in performance or measurement error, is more important and practical to apply when it comes to scales such as BBS,TUG, and BI.[43,44] The MCID of BBS in the elderly had been tested to be a change of 4 points if a patient scored within 45—56 initially, 5 points if they scored within 35—44, 7 points if they scored within 25—34, and finally 5 points if their initial score was within 0—24.[45] The MCID of BI in stroke patients was estimated to be 1.85 points in the 20-point scale (equals to 9.25 points in the 100-point scale).[46] Although no available studies assessed the MCID of TUG among stroke patients, the studies from different populations had found that the MCID of TUG varied from 3.4 s to 4.09 s.[22,23] The changes from baseline in the BBS scores, BI points, and TUG seconds during each follow-up exceeded the MCID of BBS, BI and TUG in both the EG and CG except for the changes in the BBS and BI at the week 4 in the CG. Accordingly, we presume that chronic stroke patients can regain their balance and basic functional performance more quickly by using a laser-cane during ambulation training without increasing the risk of fall.

By combing the change of primary and secondary outcomes after training with laser-cane together, we could make the following reasoning. First, the stroke patients walked more stable and confident with visual cueing from laser-cane, which increased the stride length and gait velocity, and also improved the gait symmetry. Since the gait pattern approximated to symmetrical pattern gradually, the moment of paretic lower limb improved and the strength of plantar flexors at toe-off and dorsi-flexors at heel-strike of the paretic leg improved. In turn, the balance control and functional performance improved as revealed in BBS, BI, and TUG. Unfortunately, we could only interpret the results by reasoning rather than direct evidence. Given that the key movement of ankle joint complex occurs in the sagittal, transverse, and frontal planes,[47] further biomechanical analysis in these three axis should be performed. Moreover, since walking is a series of complex movement related to multiple joints, muscles, and nerve systems, further kinematic, moment, and muscle activation studies are warranted to evaluate the clinical effectiveness of laser-cane.

Our study had several limitations. First, the number of participants in the study was relatively small. We only met the minimal required sample size if the estimation was done by high effect size. In addition, the subjects were recruited randomly in a single medical center, and all of the patients were in chronic stage. Because of the small number of participants, this study was less representative of the general population, and the results might be generalizable only to similar populations. Second, by using the visual cueing of the laser-cane, patients lowered their head during walking, which might influence their balance. It is also a possibility that asking the participants to look at the ground as they heel strike could reduce their ability to scan the environment for obstacles. Although there were no significant differences in BBS and cadence between both

groups, additional studies to assess the change of the patients' center of gravity might be warranted to eliminate this concern. Third, we used laser-cane only in the ambulation training during rehabilitation in the hospital rather than home. Future studies about whether the effect we observed in this study could still apply when it comes to use the laser-cane in home program without increasing the risk of fall is warranted. Forth, the reliability and validity information about the RehaWatch 1 is lacking. Reha-Watch 1 system has some limitations in the gait measurement, including it could only provide data of stride length rather than step length and it could only measure the range of motions of the ankle. Kinematic measurement based on wearable accelerators and gyroscopes attached to all the hip, knee, and ankle joints of unilateral lower limb is warranted in the future for further spatial analysis in gait pattern.[44] Fifth, we only measured the stride length rather than the step length of both the paretic and non-paretic sides due to the limitation of Reha-Watch 1 system. Step length is an important spatial variable to measure in hemiplegic gait,[27] especially when one of our rationales of inventing this laser cane is to use a visual cue to guide stroke patients to elongate their step length of the non-paretic leg. Although, many literatures suggested that gait symmetry is more important than step length since asymmetrical step length does not necessarily limit the gait which might be compensated by compensatory generation of propulsion.[48] Sixth, although assessors were blind to both the primary and the secondary outcomes, the therapist who gave instructions during the training might be biased by knowing participants' group. Finally, the training duration was only 4 weeks and the follow-up lasted only 2 months in this study. To verify whether long-term use of the laser-cane for stroke patients can effectively improve gait pattern, increasing training frequency, duration, or volume is warranted in the future study.

Conclusions

Using the characteristics to provide visual cueing during ambulation training, we observed that laser-cane use could improve the gait symmetry, parameters of gait cycle, balance, and basic ADL in community dwelling stroke patients after the acute stage. The use of laser-cane is convenient and affordable. We suggest combining the ambulation training with laser-cane rather than traditional quad-cane, especially in chronic stroke patients who are used to use compensatory gait pattern for propulsion. Larger and nationwide prospective, blinded studies with long-term follow-up are warranted to assess the long-term clinical effectiveness of this promising, portable, and easy-to-use assistive device.

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Declaration of competing interest

The authors have no conflicts of interest relevant to this article.

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Appendix A. Supplementary data

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