



Original Article

## Effects of Pedalo<sup>®</sup> training on balance and fall risk in stroke patients

DO-YEON KIM, MPT, PT<sup>1)</sup>, CHAE-GIL LIM, PhD, PT<sup>2)\*</sup>

<sup>1)</sup> Department of Physical Therapy, The Korea Redcross Gyeongin Rehabilitation Hospital, Republic of Korea

<sup>2)</sup> Department of Physical Therapy, College of Health Science, Gachon University: 91 Hambangmoe-ro, Yeonsu-gu, Incheon 21936, Republic of Korea

**Abstract.** [Purpose] This study sought to examine the effects of Pedalo<sup>®</sup> training on balance and fall risk in stroke patients. [Subjects and Methods] Thirty-one subjects with stroke were recruited and randomly allocated into two groups: the Pedalo<sup>®</sup> group (n=15) and the Treadmill group (n=16). The Pedalo<sup>®</sup> group performed conventional physical therapy program with Pedalo<sup>®</sup> training for 30 minutes, five times a week, for 8 weeks, while the Treadmill group conducted conventional physical therapy programs and treadmill gait training for 30 minutes, five times a week, for 8 weeks. [Results] After intervention, both groups showed a significant improvement in balance. A significant greater balance improvement was found in the Pedalo<sup>®</sup> group compared to the Treadmill group. Also, a significant reduction in risk of fall was seen in both group but this reduction was not significantly different between the two groups. [Conclusion] Pedalo<sup>®</sup> training may be used to improve balance and reduce fall risk in stroke patients.

**Key words:** Stroke, Pedalo<sup>®</sup>, Fall risk

*(This article was submitted Mar. 6, 2017, and was accepted Apr. 15, 2017)*

### INTRODUCTION

Survivors of stroke present with approximately twice the risk of falling than do age-matched, healthy subjects<sup>1)</sup>. Up to 76% of survivors of a stroke have experienced at least one fall after being discharged from the hospital, with approximately 55% of those falls resulting in injuries requiring medical attention<sup>2)</sup>. Falls are relatively common among hospitalized patients and are a primary problem during stroke rehabilitation<sup>3, 4)</sup>. Previous reports have indicated that falls occur in approximately 23% to 50% of stroke patients<sup>5)</sup>.

According to previous reports, balance is a chief factor in preventing falls and balance training has been reported to have positive effects in reducing falls in the elderly or stroke patients<sup>6)</sup>. Recently, physical and occupational therapists have used various methods to improve balance function in stroke patients, such as proprioceptive neuromuscular facilitation (PNF), the Bobath concept, robot-assisted device training, under water exercise training<sup>7)</sup>, and virtual reality training<sup>8)</sup>. It has been reported that only resistance training or special exercise can improve gait ability; however, these methods are not effective in improving balance<sup>9, 10)</sup>. Furthermore, specialized and expensive equipment or additional therapists with training must be constantly available for patients who require improvements to their balance ability.

Recently, it has been reported that vestibular exercise, as a new stroke rehabilitation method, can improve balance ability and prevent falls<sup>11)</sup>. Since traditional exercises can be mundane to chronic stroke patients, this exercise can be a good therapeutic motivation. Previous research has shown that specialized vestibular exercise is effective in decreasing neglect symptom as well as improving activity of daily living (ADL) abilities and balance ability in stroke patients experiencing right hemiparesis<sup>12)</sup>. Recently, the Pedalo<sup>®</sup> has been used to improve physical condition, sensory system, and balance ability in

\*Corresponding author. Chae-gil Lim (E-mail: jgyim@gachon.ac.kr)

©2017 The Society of Physical Therapy Science. Published by IPEC Inc.

This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial No Derivatives (by-nc-nd) License. (CC-BY-NC-ND 4.0: <https://creativecommons.org/licenses/by-nc-nd/4.0/>)

elderly people in Europe and it is used as a form of stroke and post-operation rehabilitation in Germany and other countries<sup>13</sup>. The Pedalo<sup>®</sup> company provides several types of equipment that can be used to train balance and gait in younger and elderly people. Among them, the Stabilize-T can be trained to improve balance. The Pedalo<sup>®</sup> exercise provides vestibular training to people who use the Pedalo<sup>®</sup> tools. Furthermore, vestibular sensory integration exercise is effective for improving balance ability in cerebral palsy patients<sup>14</sup>. Currently, there are no studies on the effects of the Pedalo<sup>®</sup> exercise on the balance ability and fall risk of stroke patients.

Therefore, in this study, we investigated the effects of the Pedalo<sup>®</sup> exercise on balance ability and fall risk in stroke patients.

## SUBJECTS AND METHODS

Thirty-one patients with hemiparetic stroke were recruited from a rehabilitation hospital located in the Incheon province of South Korea. We enrolled subjects who were diagnosed with first onset of unilateral hemisphere stroke more than 6 months previously, could walk for more than 30 seconds (regardless of using an assistive device), and had a mini-mental state examination Korean version (MMSE-K) score greater than 24. After the subjects were informed about the study, they agreed to participate and signed consent forms. 31 stroke patients were randomly assigned into the Pedalo<sup>®</sup> group (n=15) and the Treadmill group (n=16) under blinded-condition. All experimental procedures were approved by a Gachon University review board.

The Stabilize T (Pedalo<sup>®</sup>) provides patients with balance problems and forces them to exert effort to return to a stabilized position. Stabilizer T is a piece of equipment that trains an individual to improve sensory control of their posture and movement as well as reaction and stabilization of their loco-motor system. Through the movement limiter, the area of movement and the speed of swaying can be adjusted individually. The Pedalo<sup>®</sup>-Stabilizer is most appropriate in patients with neurological deficiencies and in senior citizens who are undergoing training to improve balance and steadiness as well as fall prevention. The platform can either be mounted on springs (three-dimensional effect) or suspended from ropes (two-dimensional effect)<sup>13</sup>. Exercise methods: 1. Subjects were asked to look straight ahead while standing with knee slightly bent. They were then asked to close their eyes for 15 seconds, subsequently open their eyes for 10 seconds, then maintain their balance for 30 seconds. 2. Subjects were asked to look straight ahead while standing with knee slightly bent. They were then asked to open their arms and slowly rotate neck to the left, center, right for 30 seconds each, and maintain their balance for 30 seconds. 3. Subjects were asked to look straight ahead while standing with knee slightly bent. They were then asked to open their arms and extend their neck for 10 seconds. Subjects were asked to repeat the neck extension 3 times and afterward they maintain their balance for 30 seconds. The number one is the easiest difficulty level and the three is the hardest. We applied one of these methods to the patients considering of their ability. These exercise methods were provided by the Pedalo<sup>®</sup> company.

The Pedalo<sup>®</sup> group underwent a conventional physical therapy program plus Pedalo<sup>®</sup> training while the Treadmill group underwent treadmill gait training and conventional physical therapy programs. The Pedalo<sup>®</sup> tools (stabilizer T) were used in this study. Both groups underwent exercise for 30 minutes, 5 times a week for 8 weeks.

A Biodex Balance system (BBS, Biodex Medical System, Inc., USA) was used to measure balance ability and fall risk. This machine is designed to assess postural balance function on a static or dynamic surface. The BBS consisted of a circular platform that was free to move in the anterior-posterior and medial-lateral axes simultaneously, while being able to control the degree of movement on the platform within 12 levels. The BBS device interfaces with dedicated software (Biodex, Version 1.08, Biodex, Inc.), thereby allowing it to measure the degree of tilt in each axis and provides an average sway score. Eight springs located underneath the outer edge of the platform provided resistance to movement (stability level of the platform). The resistance levels ranged from 8 (most stable) to 1 (least stable)<sup>15, 16</sup>.

The subjects stood on the BBS surface on their both legs and stared at the display all time trials. Test was performed for 20 seconds without brace or shoes, and the changes of center of gravity were measured using coordination in the platform's grid. Three trials were conducted for each trial for 20 seconds, which was followed by a 10 min break. This was repeated three times. From these repetitions, we calculated and averaged the mean value.

And, we measured fall risk in subjects while they stood on an unstable platform as it moved. BBS permits obtain the fall risk index using with standard software configuration. The platform was moved for five seconds over six levels of increasing instability. Once reaching level 2, each level continued for 20 seconds, which was followed by a 10 minute break. This was repeated three times. We calculated the mean value of these repetitions.

To assess the effectiveness of Pedalo<sup>®</sup> training on each variable, pre-treatment and post-treatment scores were statistically compared using paired t-tests. In all analyses,  $p < 0.05$  was considered statistically significant.

## RESULTS

Table 1 shows a list of the general characteristics of subjects. All 31 patients who were enrolled in this study completed the protocol with no medical complications.

As shown in Table 2, there was a significant increase in the balance score (overall, A-P, M-L) after training in the Pedalo<sup>®</sup> group and the Treadmill group. After training, the balance score (overall, M-L) of the Pedalo<sup>®</sup> group was greater than that

**Table 1.** Common and clinical characteristics of the subjects (N=31)

Variable	Pedalo <sup>®</sup> group (n=15)	Treadmill group (n=16)
Gender		
Male	9	10
Female	6	6
Lesion side		
Left	9	13
Right	6	3
Lesion type		
Infarction	11	11
Hemorrhage	4	5
Age (years)	49.6 ± 17.3	59.4 ± 12.2
Height (cm)	165.5 ± 5.9	166.8 ± 6.7
Weight (kg)	62.5 ± 9.4	65.1 ± 10.1

**Table 2.** Comparison of balance and fall risk (N=31)

		Pedalo <sup>®</sup> group (n=15)	Treadmill group (n=16)
Overall (Score)	Pre	3.5 ± 2.23	2.9 ± 1.18
	Post	1.8 ± 1.00*	2.1 ± 1.10*
	Post - Pre	1.7 ± 1.44 <sup>†</sup>	0.8 ± 0.73
A-P (Score)	Pre	2.0 ± 0.85	2.0 ± 0.87
	Post	1.3 ± 0.77*	1.5 ± 0.77*
	Post - Pre	0.8 ± 0.58	0.5 ± 0.58
M-L (Score)	Pre	2.5 ± 2.08	1.6 ± 0.78
	Post	1.0 ± 0.63*	1.1 ± 0.71*
	Post - Pre	1.4 ± 1.59 <sup>†</sup>	0.5 ± 0.70
Fall risk (Score)	Pre	4.5 ± 3.10	3.8 ± 1.98
	Post	1.6 ± 0.79*	2.0 ± 0.95*
	Post - Pre	2.9 ± 3.18	1.8 ± 1.65

A-P: anterior-posterior; M-L: medial-lateral. Significant difference, paired t-test: \*p<0.05, independent t-test: <sup>†</sup>p<0.05

of the Treadmill group. Both groups experienced significant changes in fall risk after intervention. However, there were no significant differences between both groups at post-test.

## DISCUSSION

This investigation assessed the effects of Pedalo<sup>®</sup> training in stroke patients. In doing so, we found that balance ability and fall risk significantly improved compared with those in the Treadmill group. According to a previous study, Lee et al. reported that, after applying Pedalo<sup>®</sup> training to patients who experienced stroke greater than six months previously, static balance and dynamic balance, which were measured using BBS and Time Up to Go (TUG), significantly improved. They showed that Pedalo<sup>®</sup> training was effective in improving balance ability; however, they did not compare the outcomes in stroke patients to those in the Treadmill group. This study used an objective measuring machine to compare BBS and Time Up to Go (TUG) test.

Jung et al. separated 20 stroke patients into an experimental group and control group and provided treadmill training to the control group and vestibular stimulation training to the experimental group<sup>17</sup>). In doing so, they showed that the BBS, which was determined using the biodex balance evaluation system, and the TUG test were significantly improved in the experimental group compared with the control group, with the exception of the static gait index.

An Bogaerts reported that the 1 year whole-body vibration exercise was effective in improving balance control ability in elderly people between 60 to 80 years of age<sup>18</sup>). Meanwhile, Hiroshige K et al. found that the whole-body vibration exercise was more effective in balance control ability in older people<sup>17</sup>).

The stabilizer T that was used in this study allowed subjects to participate in postural maintenance training. Furthermore, eye open-close, neck rotation forward, and backward bending motion are the methods of training used by Pedalo<sup>®</sup> to stimulate the vestibular system so that training using Stabilize T improved balance ability and decreased fall risk.

The current study assessed the effectiveness of training using Pedalo<sup>®</sup> on balance and fall risk in stroke patients. However, there are also some limitations to this study. The subjects were of a different gender, age, height, and weight, and each subject did not have the same level of balance ability; however, the same Stabilize T and method were used for all subjects. For this reason, some subjects had trouble in training using this method, which should be addressed in future studies.

## Conflict of interest

The authors in this study declare that there is no conflict of interest.

## REFERENCES

- 1) Jørgensen L, Engstad T, Jacobsen BK: Higher incidence of falls in long-term stroke survivors than in population controls: depressive symptoms predict falls after stroke. *Stroke*, 2002, 33: 542–547. [[Medline](#)] [[CrossRef](#)]
- 2) Harris JE, Eng JJ, Marigold DS, et al.: Relationship of balance and mobility to fall incidence in people with chronic stroke. *Phys Ther*, 2005, 85: 150–158. [[Medline](#)]
- 3) Forster A, Young J: Incidence and consequences of falls due to stroke: a systematic inquiry. *BMJ*, 1995, 311: 83–86. [[Medline](#)] [[CrossRef](#)]
- 4) Mayo NE, Korner-Bitensky N, Becker R, et al.: Predicting falls among patients in a rehabilitation hospital. *Am J Phys Med Rehabil*, 1989, 68: 139–146. [[Medline](#)] [[CrossRef](#)]
- 5) Stapleton T, Ashburn A, Stack E: A pilot study of attention deficits, balance control and falls in the subacute stage following stroke. *Clin Rehabil*, 2001, 15: 437–444. [[Medline](#)] [[CrossRef](#)]
- 6) Smee DJ, Berry HL, Waddington GS, et al.: A balance-specific exercise intervention improves falls risk but not total physical functionality in community-dwelling older adults. *Phys Occup Ther Geriatr*, 2014, 32: 310–320. [[CrossRef](#)]
- 7) Chu KS, Eng JJ, Dawson AS, et al.: Water-based exercise for cardiovascular fitness in people with chronic stroke: a randomized controlled trial. *Arch Phys Med Rehabil*, 2004, 85: 870–874. [[Medline](#)] [[CrossRef](#)]
- 8) Lee DY, Shin WS: The effects of reality-based exercise on energy expenditure during gait in chronic stroke patients. *The Korea Academia-industrial Cooperation Society*, 2010, 11: 3826–3832. [[CrossRef](#)]
- 9) Orr R, Raymond J, Fiatarone Singh M: Efficacy of progressive resistance training on balance performance in older adults: a systematic review of randomized controlled trials. *Sports Med*, 2008, 38: 317–343. [[Medline](#)] [[CrossRef](#)]
- 10) van de Port IG, Wood-Dauphinee S, Lindeman E, et al.: Effects of exercise training programs on walking competency after stroke: a systematic review. *Am J Phys Med Rehabil*, 2007, 86: 935–951. [[Medline](#)] [[CrossRef](#)]
- 11) Cakar E, Dincer U, Kiralp MZ, et al.: Jumping combined exercise programs reduce fall risk and improve balance and life quality of elderly people who live in a long-term care facility. *Eur J Phys Rehabil Med*, 2010, 46: 59–67. [[Medline](#)]
- 12) Dai CY, Huang YH, Chou LW, et al.: Effects of primary caregiver participation in vestibular rehabilitation for unilateral neglect patients with right hemispheric stroke: a randomized controlled trial. *Neuropsychiatr Dis Treat*, 2013, 9: 477–484. [[Medline](#)] [[CrossRef](#)]
- 13) [www.pedalo.de](http://www.pedalo.de).
- 14) Lee D, Kim Y, Yun J, et al.: A comparative study of the electromyographic activities of lower extremity muscles during level walking and Pedalo riding. *J Phys Ther Sci*, 2016, 28: 1478–1481. [[Medline](#)] [[CrossRef](#)]
- 15) Gunnarsson U, Johansson M, Strigård K: Assessment of abdominal muscle function using the Biodex System-4. Validity and reliability in healthy volunteers and patients with giant ventral hernia. *Hernia*, 2011, 15: 417–421. [[Medline](#)] [[CrossRef](#)]
- 16) Sherafat S, Salavati M, Ebrahimi Takamjani I, et al.: Intrasession and intersession reliability of postural control in participants with and without nonspecific low back pain using the Biodex Balance System. *J Manipulative Physiol Ther*, 2013, 36: 111–118. [[Medline](#)] [[CrossRef](#)]
- 17) Jung K, Kim Y, Chung Y, et al.: Weight-shift training improves trunk control, proprioception, and balance in patients with chronic hemiparetic stroke. *Tohoku J Exp Med*, 2014, 232: 195–199. [[Medline](#)] [[CrossRef](#)]
- 18) Bogaerts A, Verschueren S, Delecluse C: Effects of whole-body vibration on postural balance and proprioception in healthy young and elderly subjects: a randomized crossover study. *Sports Med Phys Fitness*, 2014, 54: 216–224.