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Immediate Effect of Foot Drop Stimulator in Outpatients with Chronic Stroke: A Mixed Method Study

Background: The foot drop stimulator is designed to improve the walking ability of foot drop in patients after stroke, however, studies on clinical effects are still lacking.
Objective: To investigate the effect of a foot drop stimulator on the walking and balancing abilities of foot drop patients after a stroke.
Design: One-Group (Pretest-Posttest) Design.
Methods: All subjects walked in all three conditions: foot drop stimulator (FDS) ankle foot orthosis (AFO) and barefoot. Primary outcome measures were assessed for walking and balance using a 10-m walking test (10MWT) and a timed up and go test (TUG). Secondary outcome measures consisted of a brief user interview, and the patients recorded the advantages and disadvantages of each condition.
Results: FDS, AFO, and barefoot conditions showed a statistically significant difference in 10MWT and TUG ($P<.001$) as a result of comparing three conditions. FDS and AFO were significantly different from the barefoot condition as post-hoc results; however, there was no significant difference between the two conditions ($P>.05$).
Conclusion: In this study, the foot drop stimulator contributed to improving the balance ability, and the walking ability was similar to the effect of the ankle-foot orthosis.

Keywords: *Balance; Stroke; Foot drop; Foot drop stimulator; Walking*

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INTRODUCTION

Foot drop symptoms frequently occur in stroke patients due to common peroneal nerve injuries or paralysis and have a negative effect on walking.[1] Foot drops cause abnormal gait patterns, such as excessive movement of the hip and knee joints, which contribute to unsafe walking.[2] It is therefore important to prevent foot drops for safer and more efficient walking. However, rehabilitation to reduce foot drop symptoms in chronic stroke remains difficult.

Ankle foot orthosis (AFO) has been used clinically to compensate for foot drop symptoms in hemiplegic patients. The AFO is made in various forms and is an ankle-wearing orthosis that has the effect of preventing foot drop immediately during walking.[3] Previous studies have reported that AFO not only improves the walking ability (e.g., stride length, velocity, and cadence) of stroke patients with foot drops[4-6] but also increases the walking stability, balance, and energy costs.[4,7,8] Thus, it reduces the risk of falls during walking and positively affects more efficient walking. Nonetheless, the AFO assures an immediate orthosis effect but has no therapeutic effect. In other words, when the AFO is removed, foot drop symptoms occur immediately. Therefore, it is important to provide a therapeutic effect while simultaneously preventing foot drop during gait through a combined form of therapeutic methods ensuring an orthosis effect of AFO.

Functional electrical stimulation (FES) is a therapeutic device that causes muscle contractions through repeated stimulation of the neuromuscular regions of the body. FES can effectively prevent muscle atrophy and improve muscle strength by stimulating the skeletal muscles.[9] FES is commonly used in stroke rehabilitation and as a therapeutic method for foot drop recovery.[10] However, since FES is stimulated repeatedly without the patient's voluntary movement, it is performed in the form of a simple contraction and relaxation of muscles.

The foot drop stimulator (FDS) is equipped with a tilt sensor on the functional electrical stimulation, which provides electrical stimulation to the common peroneal nerve when the angle of the affected knee changes from 0° (i.e., when starting the swing phase).[11] As a result, ankle dorsiflexion is generated to stabilize walking. FDS, as a therapeutic device for foot drop, has as advantage for neuromuscular re-education, sensory stimulation, circulation, and muscle strength, as well as immediate prevention of foot drop through electric stimulation during the swing phase during walking.[12] Therefore, it is important to investigate the effect of FDS on foot drop. However, the FDS study is not only insufficient, but also has no effect on foot drop in patients with chronic stroke. Therefore, this study compared FDS with AFO to investigate the effect of FDS on patients with chronic stroke with foot drop. In addition, we conducted interviews with participants to evaluate their usability.

SUBJECTS AND METHODS

Subjects

This study recruited 13 patients with foot drop after stroke. The inclusion criteria of the subjects were as follows: the patient had a stroke with only one right or left hemisphere lesion, duration since onset was >12 months, and ability to walk independently. The Modified Ashworth Scale was <grade 3, Mini-Mental Status Examination-Korean version score was >22, Manual Muscle Testing of the ankle dorsiflexor was < fair grade, and lower limb sensory status was intact. The exclusion criteria were as follows: the patient had visual impairments (visual acuity, field), which may limit their participation; showed visuospatial neglect; experienced pain, inflammation, or swelling in the affected leg; had bilaterally affected limbs; and had an anatomical structural abnormality of the foot or ankle. Ethical approval was obtained from the Inje University Institutional Review Board before conducting the experiment (2019-07-024-002).

Experimental Procedures

All participants assessed walking and balance ability in all three conditions (FDS, AFO, and barefoot). The sequence of the three states was performed randomly, and all procedures were performed by an experienced occupational therapist and a physical therapist. The following procedure was performed to evaluate walking and balance ability in three conditions. First, all patients walked with bare feet without wearing any equipment or orthoses. Second, all patients walked with AFO. The AFO is an individual-owned ready-made product that uses the same product and form (partially open type). A therapist attached the AFO to the patient's ankle. Third, all subjects used Walkami® (Walkami, Seoul, Korea), which was made as a ready-made product for FDS application. FDS is a portable device that includes an accelerometer and gyroscope.[8] The patient was sitting on the chair and attached Walkami to the leg. Two surface electrodes are specifically placed near the lateral head of the fibula, directly over the motor nerve and proximal musculature (Figure 1).

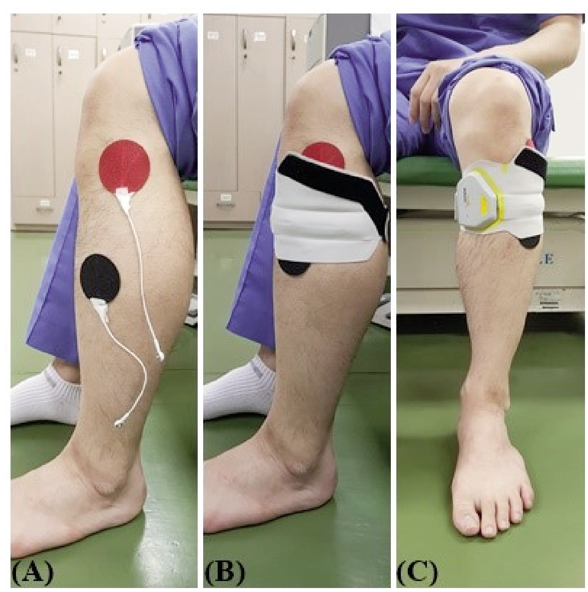

Figure 1. Foot drop stimulator.
(A) Placement of two surface electrodes,
(B) Lateral view,
(C) Anterior view.

The intensity of the electrical stimulation was applied to induce sufficient dorsiflexion of the ankle without pain. The operating principle of Walkami is as follows: The patient wore a Walkami on the paralyzed leg and walked. When entering the swinging phase of the paralyzed limb (angle change due to

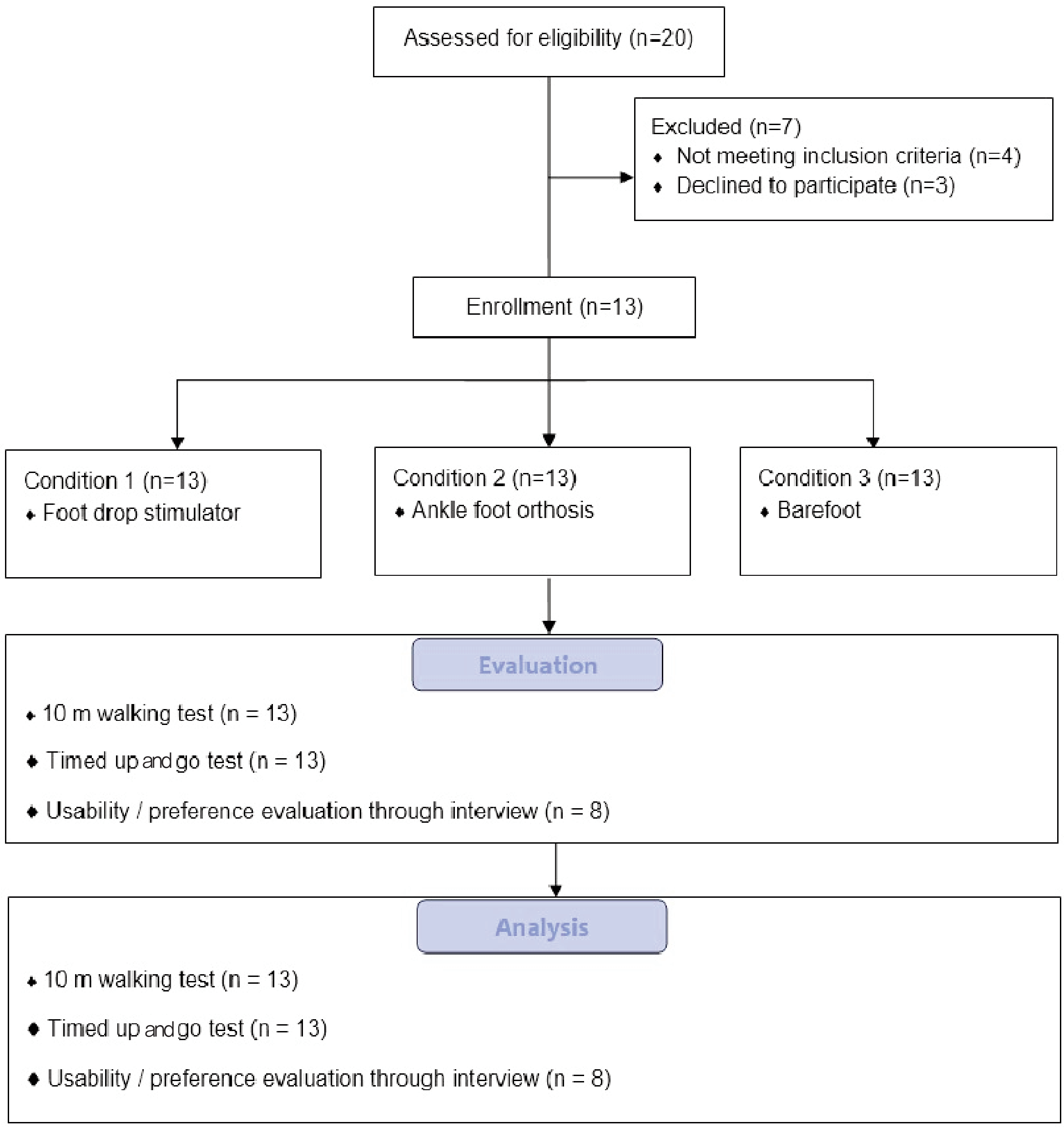

Figure 2. Study flowchart.

flexion of the knee joint), an electrical stimulation is provided by detecting the angle change, resulting in ankle dorsiflexion in the swing phase. The flowchart of the study is shown in Figure 2.

Outcome measures

Walking ability was assessed using a 10–m walking test (10MWT). The 10MWT is a measure of one's walking ability with an intra–rater and inter–rater reliability correlation coefficient of r=.95–.96.[13] Beginning with a start command, the 10MWT measured the time required for the subject to walk 10 m on a course that was a total distance of 14 m. Tape, at 2 m and 12 m, indicated the start and end of the 10–m walking distance. The first and last 2 m of the course were used for acceleration and deceleration and were not timed.

Balance ability was assessed using the timed up and go test (TUG). TUG is a simple test that can quickly measure mobility and balance with an intra–rater and inter–rater reliability correlation coefficient of r=.98–.99.[14] Beginning with a 'start' command, TUG measured the time that the subject took to rise from a 46–cm height armchair, walk 3 m, turn around as fast as possible in the direction of the affected side, walk back to the chair, and sit down.

After the evaluation, the user was evaluated by FDS AFO and barefoot condition through a brief interview with the patients, and the summary of the interview was described in Table 3. The contents of the inter–view were recorded using a tape recorder with the consent of the participants.

Data and Statistical Analysis

The statistical analyses were performed using SPSS version 15.0 (IBM Corporation, Armonk, NY, USA). Descriptive statistics are presented as means with standard deviations. One–sample Kolmogorov–Smirnov Z–tests were conducted to confirm the assumption of normal distribution. Mean values for the FDS condition, AFO condition, and barefoot con–dition were analyzed using a one–way repeated measures analysis of variance. The statistical signifi–cance level, p, for each analysis was set at .05. Bonferroni corrections were conducted as post–hoc tests (0.05/3=.017).

RESULTS

General characteristics of the patient

In this study, 13 patients (60.1±7.4 years) were recruited and their walking and balance ability were evaluated during walking with three conditions. The general characteristics of the subjects are shown in Table 1.

Effect of three conditions on walking ability

As a result of comparing three conditions, FDS, AFO, and barefoot conditions showed statistically significant difference in 10MWT ($P<.001$). As post–hoc results, FDS and AFO were significantly differ–ent from barefoot condition, but there was no sig–nificant difference between the two conditions ($P>.05$) (Table 2) (Figure 3).

Effects of the three conditions on balance ability

As a result of comparing the three conditions, the FDS, AFO, and barefoot conditions showed a statisti–cally significant difference in TUG ($P<.001$). As post–hoc results, FDS and AFO were significantly different

Table 1. Demographic characteristics of the subjects.

Subject	Gender	Age (years)	Stroke type	Affected limb	MMSE–K	Height (cm)/ Weight (kg)	Post stroke (months)
1	Man	65	Infarction	Right	23	161/56	14
2	Man	53	Infarction	Right	24	175/69	13
3	Woman	66	Hemorrhage	Left	24	15549	15
4	Woman	48	Infarction	Left	23	163/52	12
5	Woman	50	Hemorrhage	Left	25	151/53	13
6	Man	57	Hemorrhage	Left	26	172/65	15
7	Man	49	Hemorrhage	Left	26	177/73	14
8	Woman	65	Infarction	Right	28	146/51	18
9	Woman	69	Infarction	Right	23	150/52	13
10	Woman	61	Infarction	Left	23	157/54	20
11	Man	70	Hemorrhage	Right	26	163/62	17
12	Woman	63	Infarction	Left	26	160/55	12
13	Man	64	Infarction	Right	24	165/63	23

MMSE–K: Mini–Mental Status Examination–Korean version

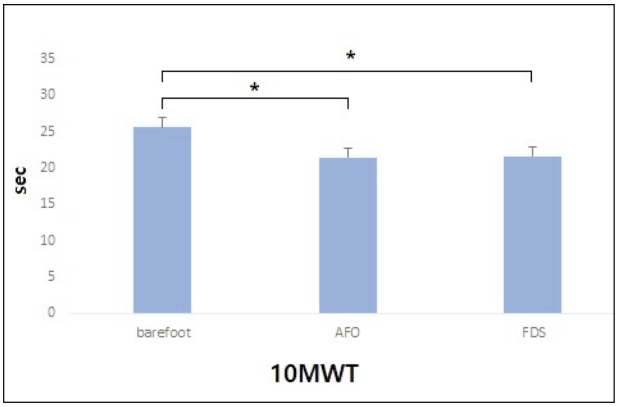

Figure 3. 10MWT: 10–m walking test, AFO: Ankle foot orthosis, FDS: Foot drop stimulator.

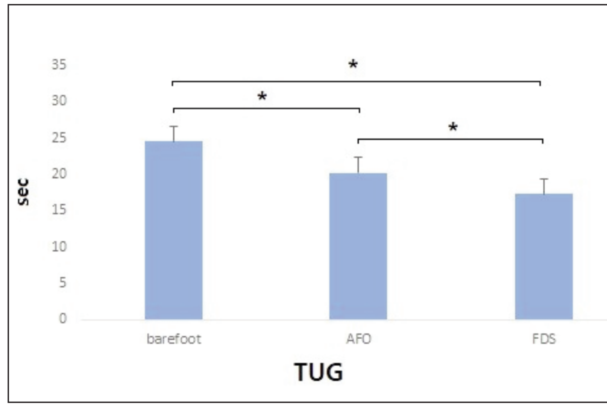

Figure 4. TUG: Timed up and go test, AFO: Ankle foot orthosis, FDS: Foot drop stimulator.

Table 2. Gait and balance evaluation of two condition.

	Barefoot	AFO	FDS	*P*	post–hoc
10MWT	25.6 ± 2.0	21.5 ± 2.3	21.6 ± 2.2	〈.001*	〈.05
TUG	24.5 ± 2.6	20.2 ± 2.8	17.3 ± 2.1	〈.001*	〈.05

AFO: Ankle Foot Orthosis, FDS: Foot Drop Stimulator, TUG: Timed Up and Go test, 10MWT: 10–m walking test

Table 3. Subject interview.

Subject	Interview content	Preference
1	FDS stimulation during walking was quite uncomfortable. So, I was more comfortable with AFO than FDS during walk.	AFO 〉 FDS 〉 Barefoot
2	–	
3	The AFO interrupted the walking because of the toe bending during walking. FDS, on the other hand, helped to spread the toe during walking.	FDS 〉 AFO 〉 Barefoot
4	–	
5	Both AFO and FDS were pretty good. But I was more comfortable to wear AFO than FDS. Because the electrical stimulation of FDS is terrible.	AFO 〉 FDS 〉 Barefoot
6	AFO is familiar and comfortable because I usually wear AFO every day. The FDS was initially het–erogeneous in electrical stimulation, but it quickly got used to it. It seems to have helped quite a lot of walking than expected.	FDS 〉 AFO 〉 Barefoot
7	–	
8	Both were comfortable during the walk and stable walking was possible. The electrical stimulation of FDS was similar to that of FES and was not so heterogeneous. The AFO, on the other hand, was a great equipment for everyday wear.	FDS = AFO 〉 Barefoot
9	–	
10	AFO was familiar with it because it was not inconvenient to walk because it was worn normally. FDS was quite uncomfortable with electrical stimulation during walking. But a few times I wore it and got used to it.	FDS = AFO 〉 Barefoot
11	–	
12	AFOs tend to irritate the skin while walking because the material is hard. FDS, on the other hand, was a little uncomfortable with electrical stimulation, but was more comfortable with walking than AFO.	FDS 〉 AFO 〉 Barefoot
13	Both FDS and AFO were comfortable and I do not know the big difference. However, both were more comfortable walking than barefoot.	FDS = AFO 〉 Barefoot

AFO: Ankle foot orthosis, FDS: Foot drop stimulator from barefoot condition, and there was a significant difference between the two conditions ($P<.05$) (Table 2) (Figure 4).

Usability / preference evaluation through interview

Among 15 participants of this study, eight users who were interviewed for usability and preference evaluation were interviewed by evaluating the usability of the advantages, disadvantages, and usability of FDS, AFO and barefoot condition. Table 3 summarizes the recorded contents in the recorder.

DISCUSSION

This study investigated the effects of FDS on walking and balance ability in chronic stroke patients with foot drop. As a result, FDS and AFO condition showed a significant decrease at 10MWT and TUG compared to barefoot condition. Furthermore, the FDS condition was more effective than the AFO condition in the balance ability. Therefore, this study demonstrated that FDS not only had similar effects on AFO condition in walking ability but also had better balance ability.

In this study, FDS has an orthosis effect in walking similar to AFO but its principle is obviously different. The AFO limits the movement of the ankle during the entire gait cycle to prevent foot drop. However, FDS allows electrical stimulation during the swing phase, allowing movement of the ankle during walking, thus inducing dorsiflexion of the ankle to enable safer and more efficient walking. Therefore, FDS seems to have similar results of walking ability of foot drop patients after stroke, like AFO.

However, we have found through the TUG assessment that FDS is more effective in balancing abilities than AFO. This may be explained by the base of support (BOS) difference between FDS and AFO condition. The disadvantage of walking in the AFO condition is that it does not prevent claw toe. Patients with stroke generally have increased muscle tone during walking, resulting in claw toe.[15] During walking, claw toe does not evenly distribute the pressure from the sole and reduces BOS, negatively affecting balance and activity level.[16,17] However, FDS induces toe extension as well as ankle dorsiflexion through electrical stimulation during walking. Toe extension reduces claw toe production and results in an increase in BOS, which can contribute positively to balance.

Another reason may be explained by sensory stimulation provided from the ground. For safe walking, it is important to provide enough sensation from the ground, and FDS is able to receive more sensory input from the ground because the soles are fully open unlike the AFO. FDS is clearly a potential positive contributor to walking ability and fall prevention because it provides more sensory input from the ground directly to the sole of the foot than the AFO. It is known that tactile stimulation from sensory inputs improves the postural schema.[18] Therefore, the FDS has the advantage of receiving sufficient sensory information about the motion and position from the ground for the muscles, ligaments, and joints during walking,[19] which directly affects the balance ability. Therefore, this study suggests that FDS is more effective in balancing ability than AFO because it can broaden BOS during walking and provide more sensory input.

In this study, the strength and weaknesses of FDS and AFO condition were investigated through interviews with all participants. The results of this study are as shown in Table 3, and the opinions related to various advantages and disadvantages of AFO and FDS were reported. Interestingly, FDS was more effective in balancing abilities with similar effects on AFO and walking ability, but a greater number of participants were more comfortable walking in AFO conditions than on FDS. This is because patients felt that the intermittent electrical stimulation of FDS during walking was uncomfortable and heterogeneous, as shown in the interview. On the other hand, the AFO is able to walk in a relatively relaxed state with no irritating stimuli during the walk. Also, they are mostly chronic stroke patients who have been walking on the AFO condition for the past few years, so it is possible that they are already quite accustomed and adapted. For this reason, the results of this study suggest that FDS was more effective in balancing abilities than AFO, but patients preferred to walk in AFO condition. If, on the other hand, most participants were familiar with FDS, it would be impossible to rule out the possibility that the AFO made of hard material would be more uncomfortable.

This study has some limitations. First, the results of this study cannot be generalized because of the small number of subjects. Second, the long-term effect could not be confirmed because only the immediate effect was confirmed. Third, because the foot pressure analysis was not performed, the actual BOS between the three conditions could not be confirmed. These limitations should be supplemented in future studies.

CONCLUSION

This study demonstrated that FDS has a positive effect on walking ability as well as a balance ability by preventing foot drop during walking through the orthosis effect like AFO. However, intermittent electrical stimulation during walking can be perceived as an unpleasant or heterogeneous stimulus depending on the general characteristics of the patients, so it should be applied considering this.

CONFLICT OF INTEREST

The author declares no conflicts of interest.

REFERENCES

1. Dunning K, O'Dell MW, Kluding P, et al. Peroneal stimulation for foot drop after stroke: a systematic review. *Am J Phys Med Rehabil*. 2015;94(8):649–664.
2. Zissimopoulos A, Fatone S, Gard S. Effects of ankle–foot orthoses on mediolateral foot–placement ability during post–stroke gait. *Prosthet Orthot Int*. 2015;39(5):372–379.
3. Hwang YI, An DH, Yoo WG. Effects of the Dual AFO on gait parameters in stroke patients. *NeuroRehabilitation*. 2012;31(4):387–393.
4. Abe H, Michimata A, Sugawara K, et al. Improving gait stability in stroke hemiplegic patients with a plastic ankle–foot orthosis. *Tohoku J Exp Med*. 2009;218(3):193–199.
5. de Wit DC, Buurke JH, Nijlant JM, et al. The effect of an ankle–foot orthosis on walking ability in chronic stroke patients: a randomized controlled trial. *Clin Rehabil*. 2004;18(5):550–557.
6. Tyson SF, Thornton HA. The effect of a hinged ankle foot orthosis on hemiplegic gait: objective measures and users' opinions. *Clin Rehabil*. 2001;15(1):53–58.
7. Bleyenheuft C, Caty G, Lejeune T, et al. Assessment of the Chignon dynamic ankle–foot orthosis using instrumented gait analysis in hemiparetic adults. *Ann Readapt Med Phys*. 2008; 51(3):154–160.
8. Wang RY, Lin PY, Lee CC, et al. Gait and balance performance improvements attributable to ankle–foot orthosis in subjects with hemiparesis. *Am J Phys Med Rehabil*. 2007;86(7):556–562.
9. Howlett OA, Lannin NA, Ada L, et al. Functional electrical stimulation improves activity after stroke: a systematic review with meta–analysis. *Arch Phys Med Rehabil*. 2015;96(5):934–943.
10. Eraifej J, Clark W, France B, et al. Effectiveness of upper limb functional electrical stimulation after stroke for the improvement of activities of daily living and motor function: a systematic review and meta–analysis. *Syst Rev*. 2018;6(1) :40.
11. Nolan KJ, Yarossi M, Mclaughlin P. Changes in center of pressure displacement with the use of a foot drop stimulator in individuals with stroke. *Clin Biomech*. 2015;30(7):755–761.
12. van Loo MA, Moseley AM, Bosman JM, et al. Test–re–test reliability of walking speed, step length and step width measurement after traumatic brain injury: a pilot study. *Brain Inj*. 2004;18(10):1041–1048.
13. Podsiadlo D, Richardson S. The timed "Up & Go": a test of basic functional mobility for frail elderly persons. *J Am Geriatr Soc*. 1991;39(2):142–148.
14. Chiong Y, Tay SS, Lim PA, et al. The effects of toe spreader in people with overactive toe flexors post stroke: a randomized controlled pilot study. *Clin Rehabil*. 2013;27(1):90–95.
15. de Saca LR, Catlin PA, Segal RL. Immediate effects of the toe spreader on the tonic toe flexion reflex. *Phys Ther*. 1994;74(6):561–570.
16. Lim EC, Ong BK, Seet RC. Botulinum toxin–A injections for spastic toe clawing. *Parkinsonism Relat Disord*. 2006;12(1):43–47.
17. Longo MR, Azanon E, Haggard P. More than skin deep: body representation beyond primary somatosensory cortex. *Neuropsychologia*. 2010; 48(3):655–668.
18. Paton J, Hatton AL, Rome K, et al. Effects of foot and ankle devices on balance, gait and falls in adults with sensory perception loss: a systematic review. *JBI Database System Rev Implement Rep*. 2016;14(12):127–162.