Spinal Cord (2018) 56:790–795
https://doi.org/10.1038/s41393-018-0088-9

ARTICLE

Impact of orthotic therapy for improving activities of daily living in individuals with spinal cord injury: a retrospective cohort study

Takuya Hada[1] · Ryo Momosaki[2] · Masahiro Abo[1]

Received: 12 October 2017 / Revised: 10 February 2018 / Accepted: 19 February 2018 / Published online: 7 March 2018

Abstract

Study design Retrospective cohort study.

Objective To determine the impact of leg orthotic therapy for improving activities of daily living after spinal cord injury.

Setting Participating acute care and rehabilitation hospitals across Japan.

Methods We retrospectively identified individuals with spinal cord injury admitted to eight participating hospitals in 2015–2016 from the Japan Rehabilitation Database. Data for 293 individuals were analyzed. Propensity score analysis by inverse probability weighting (IPW) was applied to adjust for potential bias and create two comparable groups. Outcomes were compared between the leg orthotic group and the non-leg orthotic group, using IPW. The primary outcome was motor Functional Independence Measure® (FIM) effectiveness score and the secondary outcome was motor FIM score at discharge. FIM was measured on hospital admission and discharge.

Results Leg orthoses were prescribed for 26% of the 293 individuals. Those prescribed leg orthoses had significantly higher motor FIM effectiveness scores than those who were not, before and after IPW (motor FIM effectiveness: 0.54 vs. 0.35, $p < 0.01$ and 0.45 vs. 0.36, $p = 0.02$). Discharge motor FIM was significantly higher in individuals who were prescribed leg orthoses than in those who were not, before and after IPW (discharge motor FIM: 64.5 vs. 52.2, $p < 0.01$ and 58.9 vs. 53.5, $p = 0.02$).

Conclusions Leg orthoses may improve activities of daily living in individuals with spinal cord injury after the acute phase.

Introduction

Spinal cord injury (SCI) is a major health problem worldwide, with a global incidence of approximately 236–1009/100,000 [1]. SCI is a sudden event that causes paraplegia or tetraplegia, and has lifelong consequences in terms of activities of daily living (ADL), especially walking. Along with motor and sensory deficits, instability of the cardiovascular, thermoregulatory and bronchopulmonary systems are common after SCI [2].

Quality of life (QOL) in patients with SCI is a particularly important goal of treatment [3]. Therefore, rehabilitation has an important role in care for individuals with SCI [4]. Various kinds of orthoses are used for rehabilitation of SCI. Positive effects on the kinematics and temporal-spatial parameters of gait have been demonstrated in those with SCI following a period of gait training with orthoses [5, 6]. Leg orthoses are regarded as an important rehabilitation tool, but their contribution to improving ADL after SCI remains unclear [7, 8].

The aim of this retrospective observational cohort study was to determine the impact of leg orthotic therapy for improving ADL after SCI, using propensity score analysis of data in the Japan Rehabilitation Database.

Methods

The study was approved by the Institutional Review Board of the Japanese Association of Rehabilitation Medicine. The requirement for informed patient consent was waived, as retracing is not possible because of the anonymous nature of the data.

✉ Ryo Momosaki
momosakiryo@gmail.com

1 Department of Rehabilitation Medicine, The Jikei University School of Medicine, Tokyo, Japan

2 Department of Rehabilitation Medicine, Teikyo University School of Medicine University Hospital, Mizonokuchi, Kanagawa, Japan

Data source and patient selection

The study included data obtained from the Japan Rehabilitation Database on individuals with a diagnosis of SCI who were discharged between April 2015 and December 2016 to a ward in any of eight participating hospitals for assistance with ADL after the acute treatment phase. The SCI patients included were those were in the rehabilitation phase and had transferred to a hospital after acute treatment and for whom complete data were available for cervical injury, American Spinal Injury Association (ASIA) impairment scale score [9], and manual muscle testing (MMT) scores [10].

The Japan Rehabilitation Database was developed with financial support from the Ministry of Health, Labour and Welfare of Japan [11]. Detailed clinical data were collected for inpatients undergoing rehabilitation at participating hospitals. The database comprises continuous samples from only voluntary hospitals, not random hospitals, and includes unique identifiers for the following data. Individual data were collected on admission by rehabilitation staff. Data for variables not collected on admission were collected at discharge. All data submitted to the Japan Association of Rehabilitation Database were extracted and sent to the study researchers. All personal data entered into the database are coded and any personally identifiable information is deleted.

Rehabilitation programs

Rehabilitation programs for SCI focused on gait and exercise related to ADL [12, 13]. The gym exercise program typically comprised 40–80 min of physical therapy daily for 5–7 days per week. The program included range of motion, muscle strengthening, and basic motion exercises (e.g., rolling over, standing up, and walking), typically with use of orthoses.

Leg orthoses

In Japan, leg orthoses can be prescribed by a rehabilitation physician to facilitate physical rehabilitation in individuals with SCI and are covered by health insurance. It was assumed that leg orthoses were prescribed according to the preference of the attending physicians and hospital policy. Ankle-foot orthoses are generally used in SCI rehabilitation, while knee-ankle-foot orthoses tend to be used in patients with more severe SCI. In Japan, orthotics are generally prescribed as training devices during hospitalization but as assistive devices for daily mobility after discharge.

Study variables and outcomes

Admission data were evaluated on admission. Time-dependent variables (total amount of rehabilitation, presence of orthotics prescription, etc.) and outcome data were evaluated on discharge. The extracted data were age and sex; injury type; surgery; comorbidities (cerebrovascular disease, hypertension, diabetes, chronic kidney disease); performing the surgery; ASIA impairment scale score; MMT scores (range 0 [no palpable muscle contraction] to 5 [normal]); days from SCI to admission for rehabilitation; days from admission to starting rehabilitation; duration of hospital stay; total amount of rehabilitation provided by physical therapists (PTs) or occupational therapists (OTs) per day; Functional Independence Measure® (FIM) score (range 18 [totally dependent] to 126 [totally independent]) [14]; type of hospital; and whether leg orthoses were prescribed during hospitalization. FIM was measured on hospital admission and on discharge. MMT scores were acquired according to standardized ASIA/ISNCSCI testing procedures, and were summarized as upper extremity motor scores (UEMS) [15] and lower extremity motor scores (LEMS) [15, 16]. UEMS and LEMS range from 0 to 50 (maximum score of 5 for each of 5 key muscles of each leg).

The primary outcome was motor FIM effectiveness, calculated as (discharge motor FIM score— admission motor FIM score)/(total motor FIM score [maximum 91]—admission motor FIM score) [14]. Motor FIM effectiveness corrects the ceiling effect that is present in motor FIM gain (change in FIM during hospitalization). The secondary outcome was discharge motor FIM.

Statistical analysis

Outcomes were compared between the leg orthotic group (those prescribed leg orthoses during hospitalization) and the non-leg orthotic group, using inverse inverse probability weighting (IPW) to construct a marginal structural model. The IPW method uses weights based on propensity scores to create a synthetic sample in which measured covariates follow a distribution that is independent of treatment assignment [17]. The propensity score is the probability of treatment assignment and is conditional on observed characteristics. When this score is applied, the distribution of observed covariates should be similar between treated and untreated individuals. IPW attempts to simulate a randomized experimental situation in which both groups are comparable with regard to observed prognostic factors.

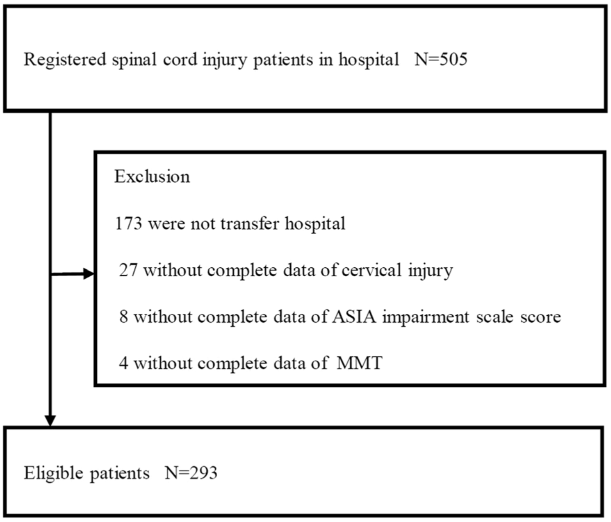

Fig. 1 Flow chart of patient's selection

Quasi-experimental design using a marginal structural model

In a quasi-experimental design, the probability (propensity score) that an individual would have been treated is used to adjust the estimated treatment effect [18]. Using the propensity score to construct a marginal structural model by IPW requires (1) propensity score estimation, (2) weighting, (3) balance checking, and (4) impact estimation.

The propensity score for allocation to the leg orthotic group was estimated using a multivariable logistic regression model [19] including as indicators the admission data listed in the "Study variables and outcomes" section. These variables included confounders and variables related to exposure and outcome. The c-statistic for goodness of fit was 0.76 in the propensity score model. Within-hospital correction was done using generalized estimation equations, which are commonly used to analyze clustered data, while correcting for the effects of confounders by clustering [20].

The leg orthotic group was weighted by 1/(propensity score) and the non-leg orthotic group was weighted by 1/(1 −propensity score). We used descriptive statistics for all individuals, with or without IPW adjustment, to check covariate balance and to estimate effect. The leg orthotic group and non-leg orthotic group were compared using Student's *t*-test and the chi-squared test.

Continuous variables that were normally distributed are expressed as the mean (standard deviation). Ordinal and continuous variables that were not normally distributed are expressed as the median [interquartile range]. We conducted all statistical analyses using IBM SPSS Statistics for Windows version 22.0 software (IBM Corp., Armonk, NY). A *p*-value of less than 0.05 was considered statistically significant.

Results

Of 505 individuals with SCI, 212 were excluded because of incomplete data on leg orthotic prescription, leaving 293 for analysis (Fig. 1). Table 1 shows the demographics for all individuals in the leg orthotic group and in the non-leg orthotic group, before and after IPW adjustment. Seventy-six of the 293 individuals (26%) were prescribed leg orthoses and 217 (74%) were not. Mean age was 53.9 years, and 84% were male. SCI was traumatic in 82% of individuals, and 58% had undergone orthopedic surgery. In terms of comorbidities, 5% had cerebrovascular disease, 19% had hypertension, 11% had diabetes, and 5% had chronic kidney disease. On the ASIA impairment scale, 26% were grade A, 12% were grade B, 23% were grade C, 33% were grade D, 2% were grade E, and the score was unknown in 4% of cases. Admission UEMS was 19.4 and admission LEMS was 18.8. The median interval between SCI and admission for rehabilitation was 58 days, and the median interval between admission for and starting rehabilitation was 1 day. Mean total daily amount of rehabilitation provided by PTs and OTs was 92 min. Mean hospital stay was 146 days. On admission, mean motor FIM score was 32.4. In the unadjusted results, individuals who were prescribed leg orthoses were younger than those who were not. After adjustment by IPW, there was no statistical difference between the two groups in these characteristics.

Table 2 shows the outcomes in the leg orthotic and non-leg orthotic groups. Individuals who were prescribed leg orthoses had significantly higher motor FIM effectiveness scores than those who were not (0.54 vs. 0.35, $p < 0.01$). The same result is obtained before and after adjustment by IPW (0.45 vs. 0.36, $p = 0.02$). Discharge motor FIM was significantly higher in individuals who were prescribed leg orthoses than in those who were not (discharge motor FIM: 64.5 vs. 52.2, $p < 0.01$). The same result is obtained after adjustment by IPW (discharge motor FIM: 58.9 vs. 53.5, $p = 0.02$).

Discussion

In this study, a large database of rehabilitation inpatients was used to examine the impact of leg orthotic therapy for improving motor ability in activities of dialing living and rehabilitation outcomes after SCI. After IPW adjustment, prescription of leg orthoses was significantly associated with increased motor FIM effectiveness and discharge motor FIM.

Many studies have investigated the effectiveness of leg orthoses in individuals with stroke, cerebral palsy, or multiple sclerosis [21–24], although none have evaluated improvement in motor ability. One study involving persons

Table 1 Demographic and clinical characteristics of individuals with spinal cord injury

		Unadjusted data			Data adjusted by IPW		
	Total (*N* = 293)	Leg orthotic group (*n* = 76 (26%))	Non-leg orthotic group (*n* = 217 (74%))	*p*-value	Leg orthotic group (*n* = 76)	Non-leg orthotic group (*n* = 217)	*p*-value
Mean age (SD), years	53.9 (17.8)	48.3 (17.1)	55.9 (17.7)	<0.01	53.1 (15.5)	54.3 (18.0)	0.39
Male, *n* (%)	243 (84)	60 (78)	185 (85)	0.20	(87)	(85)	0.39
Type of injury, *n* (%)				0.85			0.21
Traumatic	241 (82)	62 (82)	179 (83)		(86)	(82)	
Non-traumatic	52 (18)	14 (18)	38 (18)		(14)	(18)	
Operative, *n* (%)	170 (58)	43 (57)	127 (59)	0.76	(59)	(58)	0.84
Comorbidities, *n* (%)							
Cerebrovascular disease	14 (5)	2 (3)	12 (6)	0.30	(4)	(5)	0.67
Hypertension	56 (19)	10 (13)	46 (21)	0.12	(19)	(20)	0.85
Diabetes	32 (11)	8 (11)	24 (11)	0.89	(11)	(12)	0.83
Chronic kidney disease	14 (5)	5 (7)	9 (4)	0.39	(5)	(5)	0.99
ASIA impairment scale score, *n* (%)				0.61			0.19
A	75 (26)	21 (28)	54 (25)		(31)	(26)	
B	36 (12)	9 (12)	27 (12)		(9)	(12)	
C	67 (23)	21 (27)	46 (21)		(21)	(23)	
D	97 (33)	22 (29)	75 (35)		(35)	(33)	
E	5 (2)	0 (0)	5 (2)		(0)	(2)	
Unknown	13 (4)	3 (4)	10 (5)		(4)	(4)	
Cervical injury, *n* (%)	169 (58)	35 (46)	134 (62)	0.17	(57)	(59)	0.74
Admission UEMS (SD)	19.4 (17.8)	16.8 (15.9)	20.3 (18.4)	0.14	18.3 (17.1)	19.4 (18.2)	0.45
Admission LEMS (SD)	18.8 (17.7)	16.8 (15.9)	20.3 (18.4)	<0.01	18.3 (17.1)	19.4 (18.2)	0.08
Days from SCI to admission [IQR]	58 [34–85]	66 [39–113]	56 [33–79]	0.46	63 [39–109]	57 [33–82]	0.52
Days from admission for to starting rehabilitation [IQR]	1[0–1]	1 [0–1]	1 [0–1]	0.78	1 [0–1]	1 [0–1]	0.92
Mean total amount of rehabilitation (SD), min/day	92 (30)	88 (27)	94 (30)	0.14	90 (28)	92 (30)	0.31
Mean hospital stay (SD), days	146.3 (76.9)	139.1 (58.0)	148.8 (82.5)	0.34	143.6 (60.1)	146.1 (82.0)	0.67
Admission FIM (SD)	65.9 (24.2)	71.4 (23.4)	64.0 (24.3)	0.21	67.6 (23.7)	64.9 (23.8)	0.18
Admission motor FIM (SD)	32.4 (5.3)	33.7 (3.7)	31.9 (5.7)	0.11	33.0 (4.5)	32.3 (5.3)	0.10
Type of hospital, *n* (%)							
Acute care hospital	202 (69)	65 (86)	137 (63)	<0.01	(80)	(66)	<0.01
Rehabilitation hospital	91 (31)	11 (14)	80 (37)		(20)	(34)	

FIM Functional Independence Measure, *IPW* inverse probability weighting, *IQR* interquartile range, *MMT* manual muscle test, *UEMS* upper extremity motor score, *LEMS* lower extremity motor score, *SD* standard deviation

with thoracolumbar SCI reported that an individualized reciprocating gait orthosis significantly improved their ability for ADL and locomotion [25]. In the present study, we investigated the impact of conventional leg orthoses (i.e., not specialized orthoses such as those with electrical stimulation) used in daily clinical practice in individuals with SCI.

Previous studies have found leg orthotic therapy to be an important therapeutic intervention that often leads to better improvement of motor ability after SCI [12, 13]. However,

Table 2 Outcomes in the leg orthotic and non-leg orthotic groups

	Leg orthotic group ($n = 76$)	Non-leg orthotic group ($n = 217$)	p-value
Unadjusted data ($n = 293$)			
Motor FIM effectiveness	0.54 (0.42)	0.35 (0.47)	<0.01
Discharge motor FIM	64.5 (24.9)	52.2 (28.5)	<0.01
Data adjusted by IPW ($n = 293$)			
Motor FIM effectiveness	0.45 (0.45)	0.36 (0.47)	0.02
Discharge motor FIM	58.9 (27.2)	53.5 (28.1)	0.02

Data are shown as the mean (standard deviation)

FIM Functional Independence Measure, *IPW* inverse probability weighting

these studies may have been confounded by clustering. We assumed that leg orthoses were prescribed according to the preference of attending physicians. These preferences would cause within-center correlations with the response variables. Such correlation or clustering occurs when outcomes within a center tend to be more similar to each other than to outcomes at other centers. Here, we used generalized estimation equations to adjust for data clustering.

Our study had a large sample size, which is required to achieve statistically reliable results in propensity score analysis. This was possible because we used the Japan Rehabilitation Database, which contains a large proportion of the individuals with SCI who undergo rehabilitation in Japan. This large-scale observational study using propensity score analysis was a practical alternative to a randomized controlled trial, which ethically cannot be conducted because conventional orthoses are commonly used in SCI rehabilitation. However, we believe that a large representative prospective cohort study is feasible and necessary in the future.

There are several mechanisms by which leg orthoses might be associated with favorable rehabilitation outcomes. Leg orthoses improve the biomechanics of standing and walking [26]. This might have allowed individuals to perform rehabilitation exercises more safely (at least for individuals whose do not use a wheelchair as their primary mode of mobility), confidently, and effectively, contributing to the greater capability improvement seen in our study. Another possibility is that they were motivated to perform rehabilitation exercises by prescription of leg orthoses or that leg orthoses made the exercises easier, allowing them to be done without supervision by therapists. Leg orthoses likely made other types of therapy possible.

This study has several limitations. First, selection bias was the major limitation of this study. Prescription of leg orthoses is affected by prior information on patient characteristics and hospital records, so there was a systematic difference between the characteristics of the leg orthotic group and those of the non-leg orthotic group. The non-orthotic group was older and had more comorbidities. This may have created bias on the part of the prescribing physicians that resulted in fewer orthotic prescriptions for that group. Accordingly, these systematic differences must be considered when estimating the influence of leg orthoses on outcomes. Regression adjustment can be used for this purpose, but selection bias generally makes it difficult to analyze causal effects in an observational study. To adjust for selection bias and ensure comparability, we used IPW to adjust for differences in patient characteristics [27]. Second, the database used in this study does not contain detailed information on the type of leg orthoses used, the timing of the prescription, and MMT scores for the hamstrings. Third, we did not have detailed data on within-center practices, so specific qualities and practices that achieved good recovery outcomes could not be identified. Fourth, the Japan Rehabilitation Database comprises samples from only voluntary hospitals, not random hospitals and therefore generalizability of our findings to all individuals with SCI undergoing rehabilitation may be limited. Fifth, we did not have data regarding the details of the rehabilitation patients received.

In conclusion, our data suggest that leg orthotic therapy is associated with improved motor ability for ADL in individuals with SCI undergoing rehabilitation on an inpatient basis. Leg orthoses might be a useful strategy for improving the quality of rehabilitation in these individuals.

Acknowledgements The authors gratefully acknowledge the Japan Association of Rehabilitation Database for its development of the Japan Rehabilitation Database used in this study. The manuscript reflects the views of the authors and not the official views of the Japan Association for Rehabilitation Database. This study was supported by a medical a research grant from The General Insurance Association of Japan (No. 17-1-57).

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

References

1. Cripps RA, Lee BB, Wing P, Weerts E, Mackay J, Brown D. A global map for traumatic spinal cord injury epidemiology: towards a living data repository for injury prevention. Spinal Cord. 2011;49:493–501.
2. Hagen EM. Acute complications of spinal cord injuries. World J Orthop. 2015;6:17–23.
3. Moghimian M, Kashani F, Cheraghi MA, Mohammednejad E. Quality of life and related factors among people with spinal cord in- juries in Tehran, Iran. Arch Trauma Res. 2015;4:e19280.
4. Wyndaele M, Wyndaele JJ. Incidence, prevalence and epidemiology of spinal cord injury: what learns a worldwide literature survey? Spinal Cord. 2006;44:523–9.
5. Arazpour M, Bani MA, Hutchins SW, Curran S, Javanshir MA, Mousavi ME. Influence of orthotic gait training with powered hip orthosis on walking in paraplegic patients. Disabil Rehabil Assist Technol. 2014;9:226–30.
6. Arazpour M, Hutchins SW, Ahmadi Bani M. The influence of a rocker sole adaptation on gait parameters in spinal cord injury patients ambulating with the advanced reciprocating gait orthosis - a pilot study. Disabil Rehabil Assist Technol. 2015;10:89–92.
7. Tator CH. Review of treatment trials in human spinal cord injury: issues, difficulties, and recommendations. Neurosurgery. 2006;59:957–87.
8. Kirshblum SC, Priebe MM, Ho CH. Spinal cord injury medicine. 3. Rehabilitation phase after acute spinal cord injury. Arch Phys Med Rehabil. 2007;88:62–70.
9. Maynard FM Jr, Bracken MB, Creasey G, Ditunno JF Jr, Donovan WH, Ducker TB, et al. International standards for neurological and functional classification of spinal cord injury. Spinal Cord. 1997;35:266–74.
10. Hislop HJ, Montgomery J. Daniels and Worthingham's muscle testing: Techniques of manual examination. 9th edn. St Louis, MO: Saunders/Elsevier; 2013.
11. Inoue Y, Jeong S, Kondo K. Changes in hospital performance after implementation of pay-for-performance in Japan. Clin Audit. 2011;3:17–23.
12. McCagg C. Postoperative management and acute rehabilitation of patients with spinal cord injuries. Orthop Clin North Am. 1986;17:171–82.
13. Keppler JP. Rehabilitation in spinal cord injury. Crit Care Clin. 1987;3:637–54.
14. Koh GC, Chen CH, Petrella R, Thind A. Rehabilitation impact indices and their independent predictors: a systematic review. BMJ Open. 2013;3:e003483.
15. Hasegawa T, Uchiyama Y, Uemura K, Harada Y, Sugiyama M, Tanaka H. Physical impairment and walking function required for community ambulation in patients with cervical incomplete spinal cord injury. Spinal Cord. 2014;52:396–69.
16. Shin JC, Yoo JH, Jung TH, Goo HR. Comparison of lower extremity motor score parameters for patients with motor incomplete spinal cord injury using gait parameters. Spinal Cord. 2011;49:529–33.
17. Linden A, Adams JL. Using propensity score-based weighting in the evaluation of health management programme effectiveness. J Eval Clin Pract. 2010;16:175–9.
18. Indurkhya A, Mitra N, Schrag D. Using propensity scores to estimate the cost-effectiveness of medical therapies. Stat Med. 2006;25:1561–76.
19. Yoo JS, Kim JB, Jung SH, Choo SJ, Chung CH, Lee JW. Echocardiographic assessment of mitral durability in the late period following mitral valve repair: minithoracotomy versus conventional sternotomy. J Thorac Cardiovasc Surg. 2014;147:1547–52.
20. Hanley JA, Negassa A, Edwardes MD, Forrester JE. Statistical analysis of correlated data using generalized estimating equations: an orientation. Am J Epidemiol. 2003;157:364–75.
21. Tyson SF, Sadeghi-Demneh E, Nester CJ. A systematic review and meta-analysis of the effect of an ankle-foot orthosis on gait biomechanics after stroke. Clin Rehabil. 2013;27:879–91.
22. Tyson SF, Kent RM. Effects of an ankle-foot orthosis on balance and walking after stroke: a systematic review and pooled meta-analysis. Arch Phys Med Rehabil. 2013;94:1377–85.
23. Brehm MA1, Harlaar J, Schwartz M. Effect of ankle-foot orthoses on walking efficiency and gait in children with cerebral palsy. J Rehabil Med. 2008;40:529–34.
24. Sheffler LR, Hennessey MT, Knutson JS, Naples GG, Chae J. Functional effect of an ankle foot orthosis on gait in multiple sclerosis: a pilot study. Am J Phys Med Rehabil. 2008;87:26–32.
25. Shuai L, Yu GH, Feng Z, Wang WS, Sun WM, Zhou L, et al. Application of a paraplegic gait orthosis in thoracolumbar spinal cord injury. Neural Regen Res. 2016;11:1997–2003.
26. Yen SC, Schmit BD, Wu M. Using swing resistance and assistance to improve gait symmetry in individuals post-stroke. Hum Mov Sci. 2015;42:212–24.
27. Austin PC. An introduction to propensity score methods for reducing the effects of confounding in observational studies. Multivar Behav Res. 2011;46:399–424.