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Analysis of the Gait Characteristics and Usability after Wearable Exoskeleton Robot Gait Training in Incomplete Spinal Cord Injury Patients with Industrial Accidents: A Preliminary Study

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Objective: The aim of this study was to investigate of the foot plantar pressure and usability after gait training using the ExoAtlet wearable exoskeleton robot in an incomplete spinal cord injury (SCI) patient.

Design: A case study

Methods: Six participants with an asymmetry in motor and sensory function completed the gait training using ExoAtlet wearable exoskeleton robot for 15 sessions, five per weeks, 3weeks. They were divided into two groups (low and high strength group) and group differences were evaluated about session at stating of gait, gait distance at final session and foot plantar pressures and useability after training.

Results: Low strength group was faster than high strength group on adaptation of robot gait. And high strength group increased faster than low strength group on the gait distance during training. In standing and gait, weaker leg was higher than stronger leg on mean foot plantar pressure in low strength group. And stronger leg was higher than weaker leg on foot plantar pressure in high strength group. The length of the anterior-posterior trajectory of the center of pressure during gait was similar in low strength group, but different in high strength group. useability was positive about ExoAtlet wearable exoskeleton gait after training.

Conclusions: ExoAtlet wearable exoskeleton robot gait training was positive about improving gait in all participants regardless of differences in severity of symptoms and gait abnormalities.

Key Words: Foot plantar pressure, Useability, Incomplete spinal cord injury, Wearable exoskeleton robot

Introduction

Spinal cord injury patients have difficulty in gait asymmetry due to asymmetry of lower extremity muscle strength [1-4]. Robot-assisted treadmill gait training (RAGT) using an exoskeleton device provides continuous symmetrical gait and opportunity for intensive, repeated, task-oriented training that facilitates learning, without placing undue demands on clinicians [5]. Moreover, robot-assistance extends gait training to patients for whom conventional gait training would not normally be possible, such as patients with paraplegia due to a spinal cord injury (SCI) [6]. Numerous treadmill-based gait rehabilitation robots have been developed and commercialized, including the Lokomat, Walkbot, E-GO, and ReoAmbulator[7]. Despite their commercial availability, these products still have several limitations (e.g., fixed trajectory control strategy and limited degree of freedom) [8], the most important being the inability to support over-ground gait [9].

Wearable exoskeletal robots have been developed to address this limitation and, thus, to directly enhance

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mobility for daily living[10-12]. The use of a wearable exoskeletal robot with crutches, can provide sufficient support to patients with paraplegia who have gait limitation when performing activities of daily mobility, such as standing, over-ground gait and stair ascent and descent[10-12]. Wearable exoskeletal robots provide a distinct benefit over previous commercial RAGT, including the use of a miniaturized battery as a power source, better ergonomic design, using robust and flexible materials, and improvements in the robotic controls[10-12].

The clinical efficacy and safety of these wearable exoskeletal robots have been evaluated in a number of systematic literature reviews, with 8 published on the ReWalk, 3 on the Ekso, 2 on the Indego, and 1 on another wearable gait robot. In these studies, the gait training protocols with wearable exoskeletal robot usually consist of 60–120 min sessions, performed three per week, for 1–24 weeks [10]. Ten studies were laboratory-based, while the other four evaluated performance on outdoor activities[10]. Overall, results indicated that 76% of patients were able to gait using the wearable exoskeletal robotwith a mean distance of 98 m in 6 MWT(Minute Walk Test), a mean decrease in stiffness of 38%, and improvement in toileting of 61%[10]. There were no severe adverse events, but the incidence of falls during training was 4.4% and the incidence of fractures was 3.4%[10]. It is expected that the risk of adverse events will gradually decrease as the next generation of wearable exoskeletal robots is developed and patient qualification criteria are improved[12-15]. However, for now, these devices remain better suited to the rehabilitation than home environment. Moreover, the weight of the devices, the need for upper limb support and supervision, as well as legal restrictions, underline the need for continued improvement of these devices in order for them to be usable in actual daily living[12, 16-20].

Gait training using the ReWalk wearable exoskeletal robot with paraplegic patients has been reported to yield a gait pattern similar to normal gait[21], albeit with smaller magnitudes of plantar pressure[21]. Patients also reported being satisfied with the ReWalk wearable exoskeletal robot, feeling safer and more comfortable, although some patients did report some difficulty operating or controlling the system[20, 22].

Recently, the ExoAtlet wearable exoskeletal robot was developed in Russia to address these issues. Like the ReWalk, the ExoAtlet wearable exoskeletal robot was developed to train normal gait in patients with paraplegia, but with various levels of severity, ranging from mild to severe symptoms. Evaluation of the clinical efficacy of the ExoAtlet wearable exoskeletal robot, however, remains to be determined. Moreover, the effects of differences in muscle strength and sensory function and of the extent of impairment, such as left-right asymmetry in lower limb function, on RAGT among patients with an incomplete SCI have not been investigated. Therefore, the aim of our preliminary study was to examine these issues through an evaluation of the usability of ExoAtlet wearable exoskeletal robot in patients with paraplegia due to an incomplete SCI. Specifically, we evaluated the between-leg distribution of plantar pressure during standing and gait as a function of asymmetry in lower limb muscle strength, as well as evaluation of usability after ExoAtlet wearable exoskeletal robot gait training.

Methods

Participants

Participants were selected among patients at a general hospital for victims of industrial accidents who had sustained a work-related incomplete SCI with resulting paraplegia. The inclusion criteria were as follows: duration of injury ≥6 months; American Spinal Injury Association Impairment scale(AIS) = C level; capability for independent gait present prior to the injury but not since the injury; understanding and ability to use the wearable exoskeletal robot; absence of other neurological impairments or orthopedic problems of the lower limbs; and age from 19 to 59 years. Patients weighing > 120 kg, with a history of lower limb fracture and/or hip instability or dislocation, pressure sores on the buttocks or lower limb, or an existing condition making them unable to comply with the gait robot were not considered.

Six incomplete SCI patients who met our inclusion and exclusion criteria were enrolled into our study. All participants were males, presenting with an asymmetry in muscle strength between the lower limbs, with one of the left or rightside having a manual muscle test

(MMT) grade ≤2/5 (poor muscle strength) at knee and ankle joint.

Examinations were performed before the gait analysis by experienced physicians. For age, weight, height, Duration of Injury (DoI), Level of Injury (LoI), Lower Extremity Muscle Score (LEMS), in accordance with the standard neurologic assessment developed by ASIA, the voluntary muscle strength of 5 key muscles (hip flexors, knee extensors, ankle dorsiflexors, long toe extensors & ankle plantar flexors) of both lower extremities was tested using manual muscle testing (MMT) [23]. Each muscle was given a value between 0 and 5 according to the strength of voluntary muscle contraction. Maximum and minimum LEMS were 50 and 0, respectively(five muscles per each side, max 5 points, min 0 points) [24]. Participants were further classified into two groups, based on the MMT grade at the hip, namely the low strength group with a MMT grade ≤2/5 (zero to poor) and a high strength group with a MMT grade >3/5 (fair). Therefore, the level of injury was thoracic 12 in three patients in high strength group and lumbar 1 in three patients in low strength group. Within each group, the MMT of the knee and ankle muscles of the lower extremity was measured, and the stronger leg and the weaker leg were divided. The study was approved by our Institutional Review Board and all participants provided written informed consent.

Study procedure

Participants received instruction on how to fit and adjust the ExoAtlet wearable exoskeletal robot for gait training[25]. Gait training with ExoAtlet wearable exoskeletal robot was gradually increased the gait distance. Gait distance was evaluated by 6 MWT after when can independent gait with ExoAtlet wearable exoskeletal robot at each session[22].

Initially, participants focused on standing and gait in place, gait in circle, independent gait. Once able to perform these preliminary activities and gait training was initiated. Each session started with a 5-10 min of warm-up training (standing and stepping in place) to achieve a stable heart rate of 60-100 beats/min, followed by gait training performed under continual heart rate monitoring and supervision. The ExoAtlet wearable exoskeletal robot is equipped with an error correction system that automatically stops the device if an incorrect movement is produced during gait, returning the participant to a stable standing position.

Researchers supervised all training sessions, ensuring there were no safety issues. In the event of an increase in heart rate, subjective report of fatigue or request to stop during training, participants were first made to rest in a standing position, with follow-up monitoring of heart rate and subjective fatigue. A decision was then made to either stop or continue the gait training. Gait training aimed at increasing the gait velocity, stride length and improving foot clearance to achieve independent gait with ExoAtlet wearable exoskeleton robot for 15 sessions, five per week, 3weeks.

There were evaluated at session of starting of gait (SSG) and gait distance at final session (GDFS) in training. The distribution of the plantar pressure betweenboth legs and self-reported usability were evaluated after gait training.The distribution of plantar pressure was quantified in standing and gait using a pressure measurement device (Dynafoot 2 system, Techno Concept, France). Usability with ExoAtlet wearable exoskeletal robot was measured using a self-reported questionnaire of 10-item after finishing the experimental of gait training.

Robot gait training was performed by two physical therapists, and evaluation during and after training was performed by two researchers.

ExoAtlet exoskeletalwearable robot gait training

The ExoAtlet wearable exoskeletal robot (ExoAtelt-I, ExoAtlet ASIA, Republic of Korea) was approved for use at home under supervision[26]. The robot consists of a metal brace that partially supports the legs and upper body, a motor that provides coordinated movement of the hips, knees and ankles, and a backpack containing a tilt sensor, a computer and an electric power supply. Crutches are used to provide extra stability in gait, standing upright, and sitting and standing from a chair. Robot assistance for gait is controlled via a wireless interface worn on the wrist (Figure 1). The robot provides assistance to the following movements with transition from sitting to standing, from standing to

Figure 1. ExoAtlet exoskeletal robot

gait in place, over-ground gait, and transition from standing to sitting. All training sessions were initiated with the patient in sitting position. A suspension system was used to prevent falls. In addition, researcher stood behind the participant throughout the training session, holding onto the safety handle attached to the robot to control any loss of stability. Research controlled the stages of robot assist through a linked tablet interface. In the event that a participant is unable to match the robot's movement, the robot automatically enters into a safety mode, returning the participant to a standing position. The level of support was gradually decreased as participants gained experience with the robot, progressing to independent gait without additional support (except for the safety harness to prevent falls). The wearable exoskeletal robots have been approved by the US Food and Drug Administration (FDA): the ReWalk, approved in 2014 for personal and hospital use by patients with paraplegia; the Indego, approved in March 2016 for use by patients with a T7 to L5 spinal cord injury (SCI); and the Ekso GT, approved in 2016 for use in stroke patients and those with a C7 SCI [12].

Figure 2. Foot pressure analysis system (Dynafoot2)

Measurement

The 6-MWT was performed by a trained technician. Briefly, patients gaited on level ground using standardized instructions, including to gait "briskly" and as far as possible for 6 min.

A portable plantar pressure measurement system (Dynafoot2, Techno Concept, France) was used to measure the peak plantar pressure during standing and the stance phase of gait, as well as to measure the length of the anterior-posterior path of the center of pressure (CoP)[25]. The mean of plantar pressure was recorded for 30 s during standing. The peakof plantar pressure was averaged over 3 steps for each foot during stable continuous gait.

Usability with the use of the ExoAtlet wearable gait robot was measured using a custom, self-report questionnaire, consisting of 10 questions[21].

Data analysis

Between-group differences in general and functional characteristics mean and peak of plantar pressure and A-P trajectory lengths of the CoP were evaluated using a meanand Mann-Whitney U test. And, Between-leg differences in foot plantar pressure difference of between stronger and weaker leg was evaluated using Wilcoxon's signed-rank test in each group. All analyzes were performed using SPSS (version 24.0), and the significance level was set at lower than 0.05.

Results

General and functional characteristics

The general characteristics were not significantly difference on age, height, weight, duration of injury (DoI) in both groups. The functional characteristics were significantly difference on Lower Extremity Motor Scale (LEMS), Session of Starting of Gait (SSG) and Gait Distance at Final Session (GDFS). A description of the general and functional characteristics of our study group is presented in Table 1.

Foot plantar pressure during standing and gait after training

During standing and gait, the mean and peak plantar pressure was higher on the weaker leg than stronger leg in the low strength group. While the mean and peak plantar pressure was higher on the stronger leg than weaker leg in the high strength group. These between-leg differences were not statistically significant (Table 2).

During gait, the length of the A-P trajectory of the CoP was higher on the stronger leg than weaker leg in

Table 1. General and functional characteristics of the all subjects

	Low strength group (n=3)	High strength group (n=3)	z	*p*
Age(years)	40.0 ± 2.6	41.3 ± 13.2	−0.655	0.513
Height(cm)	177.3 ± 2.1	171.3 ± 5.86	−1.348	0.178
Weight(kg)	65.3 ± 3.2	66.6 ± 14.8	−0.655	0.513
DoI(day)	399.7 ± 80.6	513.7 ± 287.2	−0.655	0.513
LEMS	7.3 ± 0.58	10.3 ± 0.58	−2.023	0.043
SSG(days)	5.7 ± 0.58	7.3 ± 0.58	−2.023	0.043
GDFS(m)	104.9 ± 3.6	138.0 ± 6.4	−1.964	0.050

DoI=Duration of Injury; LoI=Level of Injury; LEMS=Lower Extremity Motor Scale; AIS=American Spinal Injury Association Impairment Scale; SSG=Session of Starting of Gait; GDFS=Gait Distance at Final Session

$p<0.05$

Table 2. Between-leg difference in the foot plantar pressure

			Stronger leg	Weaker leg	z	*p*
Standing	Mean pressure (kg)	Low strength group (n=3)	14.7±1.1	25.6±1.5	−1.604	0.109
		High strength group (n=3)	27.0±1.5	17.4±1.0	−1.604	0.109
Gait	Peak pressure (kg)	Low strength group (n=3)	30.0±4.1	49.7±9.6	−1.604	0.109
		High strength group (n=3)	49.3±0.9	24.4±2.5	−1.604	0.109
	A-P trajectory of CoP length (cm)	Low strength group (n=3)	16.5±.1.9	15.9±1.8	−1.604	0.109
		High strength group (n=3)	10.1±1.6	18.6±0.5	−1.604	0.109

CoP=Center of Pressure

$p<0.05$

Table 3. Between-group difference in foot plantar pressure

		Low strength group (n=3)	High strength group (n=3)	z	*p*
Standing Mean pressure (kg)	Stronger leg − weaker leg	−10.9±2.2	9.5±1.3	−1.964	0.050
GaitPeak pressure (kg)	Stronger leg − weaker leg	−19.7±13.3	30.0±2.2	−1.964	0.050
Gait A-P trajectory of CoP lengths (cm)	Stronger leg − weaker leg	0.6±0.4	−8.5±2.1	−1.964	0.050

CoP=Center of Pressure

$p<0.05$

the low strength group. While the mean and peak plantar pressure was higher on the weaker leg than stronger leg in the high strength group. These between-leg differences were not statistically significant (Table 2).

The between-group difference in foot plantar pressure difference of between stronger and weaker leg was reported in table 2. During standing, the mean plantar pressure was higher on the low strength group than high strength group. While, during gait, the peak plantar pressure and lengths of the A-P trajectory of the CoP were higher on the high strength group than low strength group. These between-group differences were not statistically significant (Table 3).

In the low-strength group, the standing posture and gait were adapted faster than in the high-strength

Table 4. Outcome of walking distance at each training session

	Sessions						
	1	**2**	**3**	**4**	**5**	**6**	**7**
Low strength group							
Participant 1	Standing 0 m	Gait in place 0 m	Gait in place 0 m	Gait in circle 0 m	Gait in place 0 m	Gait up to 8.8 m	Gait up to 15.6 m
Participant 2	Standing 0 m	Gait in place 0 m	Gait in place 0 m	Gait in place 0 m	Gait up to 15.6 m	Gait up to 23.3 m	Gait up to 32.8 m
Participant 3	Standing 0 m	Gait in place 0 m	Gait in place 0 m	Gait in place 0 m	Gait in place 0 m	Gait up to 10.7 m	Gait up to 24.5 m
High strength group							
Participant 4	Standing 0 m	Standing 0 m	Gait in place 0 m	Gait in place 0 m	Gait in place 0 m	Gait in place 0 m	Gait in place 0 m
Participant 5	Standing 0 m	Standing 0 m	Gait in place 0 m	Gait in place 0 m	Gait in place 0 m	Gait in place 0 m	Gait up to 17.9 m
Participant 6	Standing 0 m	Gait in place 0 m	Gait in place 0 m	Gait in place 0 m	Gait in place 0 m	Gait in place 0 m	Gait up to 14.7 m

Table 4. Outcome of walking distance at each training session (continued)

	Sessions							
	8	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Low strength group								
Participant 1	Gait up to 34.5 m	Gait up to 52.9 m	Gait up to 65.1 m	Gait up to 72.4 m	Gait up to 80.7 m	Gait up to 84.8 m	Gait up to 93.1 m	Gait up to 101.5 m
Participant 2	Gait up to 50.2 m	Gait up to 59.0 m	Gait up to 65.5 m	Gait up to 72.7 m	Gait up to 82.8 m	Gait up to 88.3 m	Gait up to 95.5 m	Gait up to 104.5 m
Participant 3	Gait up to 37.4 m	Gait up to 53.6 m	Gait up to 68.4 m	Gait up to 78.7 m	Gait up to 86.3 m	Gait up to 92.1 m	Gait up to 100.9 m	Gait up to 108.6 m
High strength group								
Participant 4	Gait up to 19.3 m	Gait up to 41.5 m	Gait up to 55.7 m	Gait up to 78.5 m	Gait up to 94.5 m	Gait up to 110.3 m	Gait up to 126.7 m	Gait up to 140.2 m
Participant 5	Gait up to 44.5 m	Gait up to 60.3 m	Gait up to 79.7 m	Gait up to 90.5 m	Gait up to 105.7 m	Gait up to 119.7 m	Gait up to 133.5 m	Gait up to 142.9 m
Participant 6	Gait up to 27.7m	Gait up to 45.7 m	Gait up to 63.2 m	Gait up to 74.5 m	Gait up to 90.3 m	Gait up to 108.0 m	Gait up to 122.2 m	Gait up to 130.8 m

Table 5. Usability after training (n = 6)

	Statement	Likert scale Mean±SD
1	The wearable exoskeleton robot training process is easy.	3.2±1.1
2	Fitting and adjusting wearable exoskeleton robot is easy.	2.5±1.0
3	I felt comfortable using wearable exoskeleton robot.	3.7±0.6
4	Using wearable exoskeleton robot did not cause me any pain.	3.1±1.0
5	I did not feel especially fatigued when using wearable exoskeleton robot.	3.5±0.8
6	When I finished training, I felt comfortable using wearable exoskeleton robot.	3.2±0.9
7	Use of the device has lessened the spasticity in my lower limbs.	3.0±0.8
8	I did not experience any respiratory problems when using the device.	3.4±0.5
9	During the period when I was using the device, I felt an improvement in my intestinal activity.	3.5±0.6
10	At the end of the training period, I felt confident using the device.	3.8±0.4

SD = Standard Deviation

group. However, the high strength group was slow the adaptation to the standing posture and gait, but after adaptation, they were able to walk much longer distances than the low strength group (Table 4).

Usability after training

Responses to each of the self-reported usability of10 items are reported in Table 5. The Likert scale scores were defined as follows: 1–2, clear disagreement with the statement; 2–3, disagreement; 3–4, agreement; and 4–5, clearly agreement. Overall, participants agreed that the training process was positive (items 1-3) and improved medical outcomes (items 4-5 and 7-9). As well, participants reported feeling safe and comfortable using the robot (items 6 and 10).

Discussion

Among paraplegic individuals, the use of a wearable gait robot has been shown to provide significant positive effects on mobility, 6-walking distance, metabolic activity, subjective improvement in function, lower limb stiffness, and bladder function[10, 14, 17, 19, 20, 22]. However, as previously stated, despite technical advances in the design of wearable gait robots, these devices remain better suited for use in rehabilitation than in a home environment and, therefore, continued evolution of these devices is needed to make them usable in actual daily living, as well as addressing the current legal constraints around their use[12, 16-20, 28]. The recently developed ExoAtlet wearable gait robot, like the ReWalk robot, was developed to facilitate the re-learning of normal gait among individuals with paraplegia of varying degrees of severity. In this study, one of our specific aims was to evaluate the usability of asymmetry in lower limb function and of the strength of the hip musculature on the outcomes of gait training using the ExoAtlet wearable gait robot. We demonstrated that lower strength group adapted to the faster to achieve the SSG than high strength group. However, high strength group achieved the in higher gait distance than low strength group in final session. This indicates that individuals in the high strength group take longer to adapt to the wearable gait robot, but capable of progressing their gait faster than those in the low strength group once they have adapted. A previous study reporting on the 6 MWT of patients with a SCI indicated that those who were able to gait independently with the help of a brace and assistive device needed less assistance from a wearable gait robot and achieved a faster gait speed than those who required dependence for gait[17]. Thus, although higher lower limb strength is associated with a longer adaptation phase, ultimately this greater strength reduces the amount of assistance required from the robot, with greater speed of gait and longer distances achieved, with lower energy expenditure than needed by patients with lower strength and, thus, requiring greater robot assistance. These results are consistent with the initial adaptation process observed in our study.

With regard to peak plantar pressure in standing, we identified an asymmetry among participant in both groups, with greater plantar pressure on the stronger than on the weaker leg among participants in the high strength group and, in contrast in the low strength group, greater plantar pressure on the weaker than on the stronger leg. Therefore, even though the robot provides equal assistance to both lower limbs, the actual mean plantar pressure during standing remained asymmetrical in all patients, with the direction of this asymmetry being influenced by the individual's residual muscle strength in each leg. The difference in the direction of asymmetry in peak plantar pressure between the high and low strength groups was also identified during gait. Of note was our finding of a comparable length of the A-P trajectory of the CoP for both legs in the low strength group, while the length was shorter for the stronger than weaker leg in the high strength group. This identified difference in the direction of asymmetry in plantar pressure between the low and high strength groups might explain the longer period of adaptation of the high strength group. Specifically, it is possible that patients with greater strength will try to balance themselves and control their own movements. As such, these patients would show adaptive responses to gait that differ from those pre-programmed in the robot and this resistance to the symmetrical robot assistance and requiring greater demands on time and effort to adapt to the robot's movement[21].

Previous studies have reported on the significant improvements in physical and functional function for daily living provided by gait assist wearable robots. However, concerns have been raised regarding the safety of these devices specifically due to the weight of the equipment and the need for additional upper limb support and supervision required in case of falls[28]. The greatest obstacle to the use of these devices for daily activities remains the unnatural movements produced due to limitations in the robot-human interaction[12]. Our results were consistent with these findings, with self-reported difficulty in adapting to the robot being identified as a barrier, with the risk to safety being highest during the period of adaptation. Other studies have also reported that although patients feel safe and comfortable overall using a wearable robot, they do experience some difficulty operating and controlling the device[20, 22]. In our study, although participant-reported usability was good overall, participants did report that sitting and standing movements felt unnatural, as well as complaining of instability during the single stance support phase of gait. They also reported some difficulty in controlling and operating the device.

Although our results identified some limitations in the ability of individuals with a paraplegia, due to an incomplete SCI, in adapting to a wearable gait robot, these devices could be an important means to improve quality of life during daily living by enabling these individuals to gait. Nevertheless, the current ExoAtlet wearable gait robot requires adaptation to the robot's movements, leading to differences in adaptation depending on the baseline lower limb strength. We also identified safety risks, which were highest during the period of adaptation. Meanwhile, a combination of problems in the flexibility of the hardware, such as the unnatural restraint to ankle movements and instability during gait, caused limitations in performing normal activities of daily living.

In summary, future development of wearable gait robots is required for therapeutic use; specifically, there is a need to divide control of single support from the rest of the gait cycle, as well as to implement a control mode that will enable the different phases of gait to be individually controlled and repeated, as necessary. As well, in order to further develop these devices for use in daily living, further improvements and integration are required in terms of hardware flexibility, artificial intelligence, and the use of biological signals to detect intention. Such developments will need to be embedded in a cycle of research to evaluate efficacy and safety.

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Abbreviations

RAGT: robot-assisted treadmill gait training
SCI: spinal cord injury
FDA: food and drug administration
CoP: center of pressure
MWT: minute walk test
AIS: american spinal Injury association impairment scale
MMT: manual muscle test
DoI: Duration of Injury
LoI: Level of Injury
LEMS: Lower Extremity Muscle Score
SSG: starting of gait
GDFS: gait distance at final session

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