Title: Spatiotemporal gait characteristic changes with gait training using the Hybrid Assistive Limb for chronic stroke patients

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Abstract

Background: Robotic rehabilitation has been attracting attention as a means to carry out "intensive", "repetitive", "task-specific", gait training. The newly developed robotic device, the Hybrid Assistive Limb (HAL), is thought to have the possibility of having an excellent effect on gait speed improvement over the conventional automatic programed assist robot. The purpose of this study was to investigate the spatiotemporal characteristics related to gait speed improvement using the HAL in chronic stroke patients.

Research question: To investigate the effects of robotic gait training on gait speed and gait parameters.

Methods: An observational study with an intervention for single group was used. Intervention was conducted in University Hospital. Eleven chronic stroke patients were enrolled in this study. The patients performed 8 gait training sessions using the HAL, 2 - 5 sessions/week for 3 weeks. Gait speed, stride length, cadence, time of gait cycle (double-limb stance phases and single-limb stance phases) and time asymmetry index were measured before and after intervention.

Results: After intervention, gait speed, stride length, and cadence were significantly improved (Effect size = 0.39, 0.29, and 0.29), the affected initial double-limb stance phase was significantly shortened (from 15.8±3.46% to 13.3±4.20%, $p = .01$), and the affected single-limb stance phase was significantly lengthened (from 21.8±7.02% to 24.5±7.95%, $p < .01$). The time asymmetry index showed a tendency to improve after intervention (from 22.9±11.8 to 17.6±9.62, $p = .06$). There was a significant correlation between gait speed and the stride length increase rate ($r = .72$, $p = .01$).

Significance: This study showed that increasing stride length with lengthening of the affected single-stance phase by gait training using the HAL improved gait speed in chronic stroke patients. However, the actual contributions on HAL cannot be separated from gait training because this study is an observational research without a control group.

Keywords

Robotics rehabilitation, Chronic stroke, Gait speed, Gait cycle, the Hybrid Assistive Limb

List of abbreviations

HAL – Hybrid Assistive Limb

10MWT – 10-m Walking Test

DLS – Double-limb stance

SLS – Single-limb stance

CVC – Cybernic Voluntary Control

CIC – Cybernic Impedance Control

CAC – Cybernic Autonomous Control

Introduction

Stroke is a medical condition caused by cerebrovascular ischemia or hemorrhage. Damage to the motor system in the brain causes physical disability and gait dysfunction [1]. Although gait function in most stroke patients improves to some extent during the acute to subacute phase after stroke, most patients have to use an assistive device (e.g., a cane or a quad cane) that compensates for impairments of the lower-extremities, and they remain limited in community ambulation and social participation [2, 3]. The improvement of their gait ability after stroke is, therefore, a social challenge.

The greatest recovery in impairments of the upper and lower extremities and gait ability after stroke is observed within 2-3 months, followed by more gradual improvements occurring for up to 6 months [2, 4]. The remaining deficit after this recovery period is permanent. Nonetheless, some studies have reported that the physical deficits involving muscle weakness and atrophy and gait dysfunction persist even for 1 year after stroke [5, 6]. Therefore, rehabilitation in the chronic phase of stroke is needed to improve the remaining motor dysfunctions. Rehabilitation programs including intensive, repetitive, and task-specific training may accelerate functional restitution and improve motor outcomes even in chronic stroke patients [7-9]. Recently, robot-assisted gait training has been developed to make patients carry out intensive and repetitive gait training. Moreover, the effects of gait training using a robot may be superior to therapist-assisted gait training, because patients can train in accurate and reproducible gait with robotic mechanical training. However, in a recent randomized controlled study that compared robot-assisted gait training with therapist-assisted gait training in chronic stroke patients, the results indicated that improvements in speed and single-limb stance (SLS) time of the affected leg were greater in subjects who received therapist-assisted gait training [10]. Moreover, in a recent systematic review, there was no clear evidence that robot-assisted gait training is superior to conventional physical therapy in patients with chronic stroke [11]. Especially for gait speed, robot-assisted gait training in combination with physiotherapy did not increase gait speed significantly, although some gait parameters were improved significantly [12]. The use of robot such as Lokomat could not enhance the effect of gait training without the robot [10, 13]. A possible reason of insufficient effect of existing robot is that these devices assist joint motion autonomously according to a computer program without taking into account patient’s intention to move and voluntary motion.

Recently, a wearable exoskeleton device with a hybrid system that allows a voluntary mode of action to support gait training, the Hybrid Assistive Limb (HAL) system (Cyberdyne Inc., 2-2-1, Gakuen Minami, Tsukuba, Ibaraki, Japan 305-0818), has been developed [14, 15]. Comparing with the robot without assisting the voluntary motion or muscle activity in patients, the HAL has the possibility to better promote motor learning than other robots because it can detect the patient’s voluntary muscle activity and assist the patient according to his or her intention to walk. Actually, there are some reports of the beneficial effects if using the HAL for gait training [16, 17]. In stroke patients, extension of the double-limb stance (DLS) time [18] or shortening of the SLS time on the affected side are associated with decrement of their gait speed [19, 20]. These abnormal gait characteristics have significant negative correlations with gait speed. It is therefore important to evaluate the changes in spatiotemporal gait parameters including the gait cycle, such as SLS on the affected side, after gait training with the HAL. However, changes in the gait cycle after intervention using the HAL have rarely been reported. Moreover, although the changes in the gait cycle would improve gait parameters such as stride length and cadence, it is still unclear which factor is related to improvement of gait speed after intervention using the HAL.

The purposes of the present study were to assess the changes of spatiotemporal parameters including the gait cycle and to determine the factors associated with the change in gait speed after gait training using the HAL in chronic stroke patients.

Methods

Study design and Participants

An observational study with an intervention for single group was used. Outcomes were measured before and after the intervention that was gait training with using the HAL for chronic stroke patients. Patients were hospitalized in Kyoto University Hospital between January 2017 and August 2017.

Eleven stroke patients with hemiplegia were enrolled in this study. Their clinical characteristics are shown in Table 1. All patients were in the chronic phase (> 6 months). Walking ability was assessed by the Functional Ambulation Category (FAC; score range 0–5) [21]. Two patients were able to walk independently, six patients used a T-cane to walk, and three patients used a quad-cane. Nine patients wore ankle foot orthoses.

The inclusion criteria were: ability to understand an explanation of the study and to express consent or refusal; body size that can fit in the robotic suit HAL (height range, 145-180 cm; maximal body weight 80 kg); and ability to walk at least 10 m.

The exclusion criteria were: intellectual impairments that limit the ability to understand instructions; contracture restricting gait movements at any lower limb joint (hip, knee, ankle); or cardiovascular or other somatic conditions incompatible with intensive gait training

All subjects were fully informed of the procedures and purpose of the study, which conformed to the Declaration of Helsinki. Written informed consent was obtained from all subjects. This study was approved by the ethics committee of Kyoto University Graduate School and the Faculty of Medicine (C0775).

Training program

All patients performed gait training using the HAL for 8 sessions with 2-5 sessions/week for 3 weeks. Each session lasted approximately 60 min, including change of clothes, setup of the HAL, and gait training. The double-leg type HAL was used for gait training. The gait training was performed with 3-4 physical therapists for operation of the HAL commands, supporting patients' stability, and handling a mobile suspension system (ALL-In-One Walking Trainer, Ropox A/S, 221 Ringstedgade, Naestved, Denmark 4700) if needed. Gait training was conducted with the aim of enhancing patients' gait ability maximally. Each patient received therapy on the treadmill or on the ground so as the patient could train intensively and repetitively as much as possible. For the safety issue, treadmill use was restricted to a patient who could walk at a constant speed. Gait training on the ground with mobile suspension system was selected if a patient needed adjustment of walking speed by therapists. The physical therapists using the HAL had taken the learning program and had a license to use the HAL. Distance and gait speed depended on the patients' tolerance.

HAL

The HAL is a wearable exoskeleton robot that assists the limb motion of the human body. The surface electromyography electrodes were placed on the rectus femoris, gluteus maximus, biceps femoris, and vastus lateralis. The HAL supports hip flexion/extension and knee flexion/extension by detecting the electric signals generated by these muscles.

Control mode

The HAL has three control systems comprising the Cybernic Voluntary Control (CVC), Cybernic Impedance Control (CIC), and Cybernic Autonomous Control (CAC). The CVC mode assists patients' motion triggered by the electric signals of their muscles. The level and timing of assisting torque can be controlled by using the HAL commands of tuner and/or balance of flexion/extension. The CIC mode can make smooth joint motion by assisting in removing the weight of the HAL suit. The CAC mode assists patients' motion autonomously, based on determining the standing or swing phase from force-pressure sensors in the shoes. In this study, the CVC mode was mainly used, and the CIC mode was used as needed. During gait training with the assistance of the HAL, physical therapists continuously adjust magnitude and timing of HAL setting (i.e. threshold of detecting the muscle activity, torque tuner and limitation, and balance of extensor/flexor muscle activation), so that a patient can walk as smooth as possible with his or her own movement during stance phase in affected side (Figure 1). As a patient's stage of training advanced, the magnitude of assistance was decreased to induce his or her voluntary torque.

Outcome

Gait function

Before and after the intervention, a maximum 10-m walk test (10MWT) was performed without the HAL. Walking time and number of steps were assessed to calculate gait speed (m/s), stride length (m), and cadence (steps/min). The faster time of two trials was selected for analysis. Patients were required to use the same device and/or orthosis before and after the intervention. A therapist supported the subjects as necessary. In the 10MWT, the motion video (30 Hz) was taken from the sagittal plane by a video camera (HC-V550M, Panasonic, 1006, Oaza Kadoma, Kadoma-shi, Osaka, Japan 571-8501). According to the method of previous study [22], the Dartfish Program (9.0 TeamProData, Dartfish Japan, 1-9-8 Iwamoto-cho, Chiyoda-ku, Tokyo, Japan 101-0032) was used to identify the times of the DLS and SLS phases in a gait cycle (Figure 2). Four periods between the markings were defined as the affected initial DLS phases, the affected SLS phase, the unaffected initial DLS phases, and the unaffected SLS phase[18]. These periods were divided by the gait cycle time and calculated as the percent gait cycle (%). In the present study, the intraclass correlation coefficient (ICC 1.1) of dividing into gait cycle using the Dartfish Program was 0.98 and it showed almost perfect reliability [23].

Time asymmetry index

SLS times on the affected and unaffected sides were measured. The difference in the SLS times between the affected and the unaffected sides divided by the sum of both sides was defined as the time symmetry index.

Statistical Analysis

Statistical analysis was conducted using SPSS (version 22.0, IBM Japan Inc., 19-21, Nihonbashi-Hakozaki-cho, Chuo-ku, Tokyo, Japan 103-8510). The normality of the data was evaluated using the Shapiro-Wilk test. The paired *t*-test or Wilcoxon signed-rank test was used to determine the differences in gait speed, stride length, cadence, each gait cycle, and time asymmetry index before and after the intervention. The effect size (Cohen's d) and 95% confidence interval of gait function changes in pre- and post-training were calculated using the methods described previously [24, 25]. Spearman's rank correlation coefficients were calculated between the rates of increase of gait speed and of stride length or cadence.

Results

All patients completed the gait training sessions without any adverse events. Compliance with the interventions in this study was 100%. Therefore, the statistical analysis included all patients' data. Changes in gait function, gait cycle, and the time asymmetry index are shown in Table 2.

Gait function

Gait speed, stride length, and cadence were significantly increased after the intervention. The individual changes are shown in Figure 3. The gait speed was improved in 10 of 11 patients; Pt. 11 showed no improvement.

Correlations between the changes of gait speed and of stride length and cadence

The rate of increase of gait speed was significantly correlated with the rate of increase of stride length ($r = .72$, $p = .01$), but not of cadence ($r = .46$, $p = .15$).

Gait cycle

The total time of a gait cycle was not significantly changed from pre- to post-intervention. The affected initial DLS phase was significantly shortened (from 15.8%±3.46% to 13.3%±4.20%, $p = .01$), and the affected SLS phase was significantly lengthened after the intervention (from 21.8%±7.02% to 24.5%±7.95%, $p < .01$). There were no significant differences in the unaffected initial DLS and unaffected SLS between pre- and post-intervention (unaffected initial DLS from 28.0%±15.5% to 27.4%±17.4%, $p = .63$; unaffected SLS from 34.3%±10.1% to 34.7%±10.6%, $p = .66$).

Time asymmetry index

The difference in SLS time between the affected side and the unaffected side was significantly decreased after intervention ($p < .05$), though there was no significant difference in the sum of both sides ($p = .89$). The time asymmetry index tended to improve after the intervention (from 22.9±11.8 to 17.6±9.62, $p = .06$).

Discussion

In this study, the gait speed, stride length, and cadence after the intervention were greater compared with pre-intervention values. These results are consistent with previous reports of gait training using the HAL for chronic stroke patients [16, 17, 26]. Moreover, one of the main results in this study was that the affected SLS phase was significantly lengthened after gait training. Additionally, the time asymmetry index after intervention tended to improve, though the difference was not significant.

In general, cadence and stride length during walking are the key determinants of gait speed. In the present study, the change in gait speed after training was found to correlate with that of stride length, but to have no correlation with that of cadence. These results suggested that gait speed was improved by increasing stride length. In most reports aimed at improvement of gait speed, both stride length and cadence were improved together with improvement of gait speed [27-30]. However, the relationship between gait speed and stride length or cadence was rarely reported, though the relationship is important to let clinicians know how the intervention affected their patients' gait pattern.

In the present study, the SLS phase on the affected side was greater after intervention. The HAL can promote motor learning by matching the timing of patient's muscle activity and actual movement of lower extremity. Moreover, the HAL tend to facilitate muscle activity at stance phase than swing phase because muscles related to stance phase were detected from gluteus maximus, rectus femoris, and vastus lateralis which are mainly responsible for stability of the SLS phase. On the other hand, in the HAL program, the monitored muscle related to hip swing consists only rectus femoris, without including iliopsoas muscle. These characteristics of the HAL may improve the stability of the affected stance by promoting muscle activity of the lower extremity related to the SLS phase (hip extension and knee extension). Promoting weight-bearing to the affected side by improving its stability may increase the step length of the unaffected side, resulting in improved stride length. There are some reports of a significant increase in unaffected step length with robot-assisted gait training (Gait Trainer and SMA) [29, 30]. However, these reports did not investigate the relationship between gait parameters (step length) and gait speed. In the present study, lengthening of stride length was correlated with improved gait speed. To the best of our knowledge, this is the first report to identify the mechanism of improving the gait speed by gait training using the HAL. These results will provide guidance to clinicians in the development of more effective rehabilitation strategies to improve gait ability in chronic stroke patients.

To improve gait function in chronic stroke patients efficiently, intensive and repetitive training is needed [31]. Traditionally, therapist-assisted gait training and treadmill training with partial body weight support [32] were conducted. However, these approaches have critical limitations for intensive and repetitive training because of the therapist's burden and a lack of manpower. Robot-assisted training would solve these problems. As indicated in previous studies [11, 33], an equivalent effect to therapist-assisted training can be obtained without any burden on a therapist. Moreover, rehabilitation strategies using robotics such as the HAL, including the concept of promoting motor learning, in addition to repetitive, intensive, task-oriented training, may be critical for improving patients' physical functions.

Assessment of participant compliance with the study protocol is important to interpret the key results of a trial. Some studies showed that gait training using the HAL was feasible with regard to adverse events and compliance [17, 26, 34]. Compliance with the interventions in this study was 100%, and the participants safely completed all sessions because all training programs were supervised by experienced physical therapists.

In the present study, 8 sessions of gait training using the HAL were conducted. In other reports of patients with chronic stroke, 8 sessions were given by Yoshimoto et al. [26], with 16 sessions by Kawamoto et al. [16] and Kubota et al. [17]. Differences in the effects on gait function by the number of training sessions have not been reported. The appropriate number of sessions will need to be studied in the future.

Study Limitations

First, there was no control group in this study. Therefore, it is impossible to compare the effect of conventional rehabilitation or other robotic rehabilitation and the effect of the HAL in the present study. Second, whether unaffected step length actually was increased was unknown because kinematic changes were not measured. In the future, detailed studies using a three-dimensional motion analysis device are necessary to capture actual kinematic changes. Third, the frequencies of treatment session of HAL in this study allowed a wide range of 2 to 5 times/week. Whether the frequency of treatment would influence outcomes after intervention remains to be solved. Finally, only a limited number of patients were included in this study. Further study is needed to determine the sample size sufficient to generalize the results.

Conclusion

The results of the present study suggest that improvement of gait speed caused by gait training using the HAL was due to the increase in stride length with extension of affected SLS time. The present study showed that gait training using the HAL could lengthen the single-stance phase on the affected side. The result may contribute to the mechanism of the HAL for gait improvement and support the importance of robotic rehabilitation in order to achieve good clinical outcomes.

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Table 1. Characteristics of individual patient

Pt	S	Age (yr)	Height (cm)	Weight (kg)	Diagnosis	Side of paresis	Period	BRS	FAC	Gait assistance aid	Gait orthosis
1	M	71	166.0	66.0	CI	Left	72	V	4	A cane	AFO
2	F	53	153.5	49.4	ICH	Right	53	III	4	A cane	AFO
3	M	68	163.4	69.6	CI	Left	144	VI	4	None	None
4	F	72	153.7	57.6	CI	Left	84	VI	5	None	None
5	M	21	170.2	51.5	ICH	Right	13	V	4	A cane	AFO
6	F	33	166.7	63.4	ICH	Right	43	V	4	A cane	AFO
7	M	81	158.0	59.4	CI	Right	24	IV	4	A cane	AFO
8	M	69	166.2	57.1	CI	Right	104	III	4	A cane	AFO
9	M	68	156.3	56.4	ICH	Left	10	III	4	A quad-cane	AFO
10	M	53	165.3	72.6	ICH	Left	52	II	3	A quad-cane	AFO
11	F	60	156.8	59.5	ICH	Right	43	III	3	A quad-cane	AFO

Pt: Patient number, S: Sex

M: Male, F: Female, CI: Cerebral infarction, ICH: Intracerebral hemorrhage

Period: Period from onset (months)

BRS: Brunnstrom recovery stage

FAC: Functional Ambulation Category (0–5 score range)

AFO: Ankle-foot orthosis

Table 2. The changes of gait function, gait cycle, and time asymmetry index

	Pre			Post			*p* value	SW test	Effect size (95%CI)
Gait speed (m/s) *	0.52	±	0.32	0.66	±	0.42	< .01	> .05	0.39 (-0.45 – 1.23)
Stride length (m) *	0.72	±	0.31	0.82	±	0.34	< .01	> .05	0.29 (-0.55 – 1.13)
Cadence (step/min) *	82.6	±	28.4	91.3	±	33.5	.01	> .05	0.29 (-0.55 – 1.13)
Gait cycle									
Total time (sec)	1.60	±	0.49	1.55	±	0.55	.35	> .05	-0.10 (-0.94 – 0.74)
DLS (AI) (%) *	15.8	±	3.46	13.3	±	4.20	.01	< .05	- 0.63 (-1.49 – 0.23)
SLS (A) (%) *	21.8	±	7.02	24.5	±	7.95	< .01	< .05	0.35 (-0.49 – 1.19)
DLS (UI) (%)	28.0	±	15.5	27.4	±	17.4	.63	< .05	- 0.04 (-0.87 – 0.80)
SLS (U) (%)	34.3	±	10.1	34.7	±	10.6	.66	< .05	0.04 (-0.80 – 0.88)
Time asymmetry index	22.9	±	11.8	17.6	±	9.62	.06	< .05	- 0.49 (-1.34 – 0.35)

* significant difference between pre- and post-training ($p < 0.05$)

SW test: Shapiro-Wilk test

DLS (AI): Affected initial double limb stance phases

SLS (A): Affected single limb stance phase

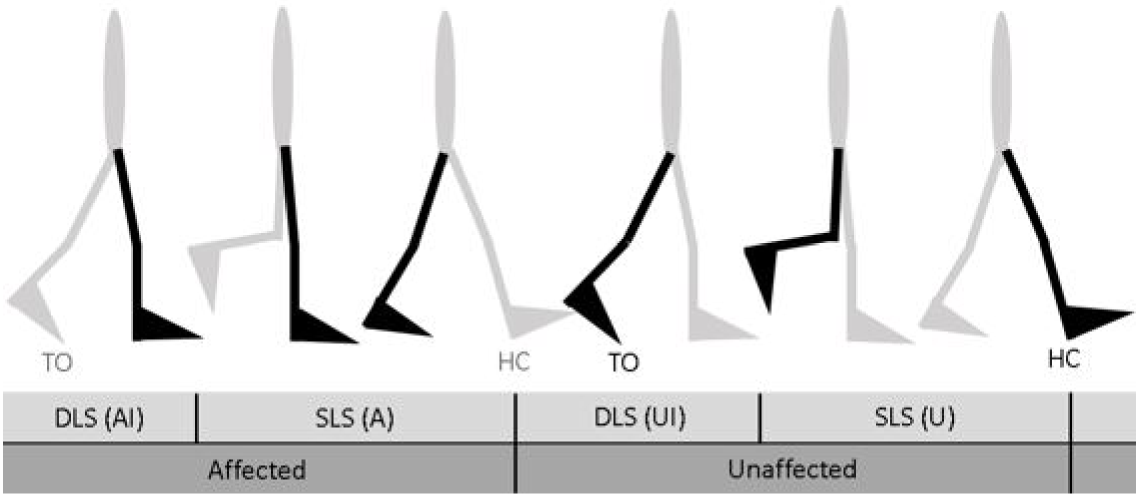
DLS (UI): Unaffected initial double limb stance phases

SLS (U): Unaffected single limb stance phase

Figure legends

Figure 1. The command of the HAL

Figure 2. Gait cycle definition



TO: Toe off

HC: Heel contact

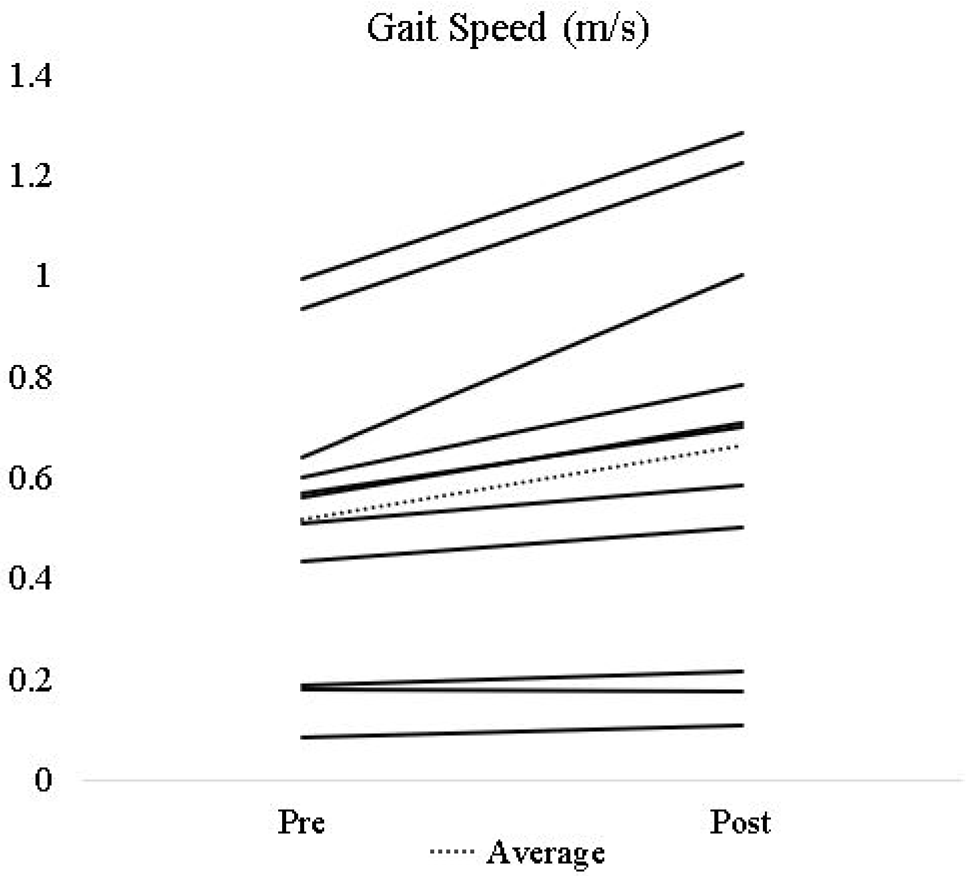
DLS (AI): Affected initial double-limb stance phases

SLS (A): Affected single-limb stance phase

DLS (UI): Unaffected initial double-limb stance phases

SLS (U): Unaffected single limb-stance phase

Figure 3. Individual improvement of gait speed



Pt: Patient

Average: Average of all patients