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CASE STUDY

Gait training with the newly developed 'LokoHelp'-system is feasible for non-ambulatory patients after stroke, spinal cord and brain injury. A feasibility study

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Abstract

Primary objective: To evaluate the feasibility of using a newly developed electromechanical gait device (LokoHelp) for locomotion training in neurological patients with impaired walking ability with respect to training effects and patients' and therapists' efforts and discomfort.

Methods and procedures: Design: Case series. Setting: A neurological rehabilitation centre for children, adolescents and young adults. Subjects: Six patients with impaired walking function: two after stroke, two after spinal cord injury and two after brain injury. Intervention: Twenty additional training sessions on a treadmill fitted with a newly developed electromechanical gait device and body weight support (BWS), performed over a study-period of 6 weeks.

Main outcomes and results: Patients' progress was assessed with the following instruments: the Functional Ambulation Category FAC (walking ability), the 10-metre walk test (gait velocity), the Motricity Index (lower limb strength), the Berg Balance Scale (postural capacity), the modified Ashworth Scale (spasticity) and the Rivermead Mobility Index (activity). After each therapy session, therapists completed a form, thereby indicating whether manual assistance was necessary and, if so, how much physical effort was expended and how much discomfort was experienced during the therapy session. The therapists also indicated on the form information about the patient's effort and discomfort. No severe adverse events were observed during the locomotion training with the LokoHelp device. Patients improved with regard to Functional Ambulation Category (FAC) (from mean 0.7, SD = 1.6, to mean 2.5, SD = 2.1, $p = 0.048$), Motricity Index (from mean 94 points, SD = 50, to mean 111, SD = 52, $p = 0.086$), Berg Balance Scale (BBS) (from mean 20 points, SD = 23 to mean 25, SD = 23, $p = 0.168$) and Rivermead Mobility Index (RMI) (from mean 5 points, SD = 4, to mean 7, SD = 5, $p = 0.033$). Therapists required a low level of effort to carry out the training and seldom experienced discomfort. Patients described their effort during training as being low-to-exhausting. They rarely experienced discomfort, which was mostly related to difficulties with the BWS-System. Training intensity had to be adjusted in one patient who complained of knee pain.

Conclusions: Locomotion training with the newly developed 'LokoHelp'-system is feasible in severely affected patients after brain injury, stroke and spinal cord injury. In addition,theour results indicate that the described alternative method of gait training may decrease the exertion needed by therapists to carry out the training.

Keywords: *Gait rehabilitation, brain injury, spinal cord injury, stroke, exercise, physiotherapy*

Introduction

Restoration of walking ability is a major goal in the rehabilitation of patients with acquired brain and spinal cord injury [1, 2]. Accordingly, therapeutic efforts should be primarily aimed at restoring independent walking ability, with or without walking aids. Modern therapeutic approaches are goal-directed (i.e. training is the task itself) and largely rely on the principles of repetition and massed practice [3]. These task-oriented training regimes

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are based on fundamental principles of motor learning [4, 5] and are thought to involve mechanisms of central neuroplasticity [6].

There is emerging evidence that neurological deficits can be reduced by intensive, repetitive and task-oriented training [7, 8] and that this approach leads to short- [9] and long-term cortical reorganization [10, 11]. In this context, treadmill training with or without partial body weight support is a promising treatment concept, because it allows repetitive practice of complex gait cycles. Thus, it embodies the two crucial aspects of task-specificity and repetition [12, 13].

Compared to traditional physiotherapy according to the Bobath-Concept, treadmill training is a superior therapeutic approach to help patients improve walking ability [14, 15]. However, sufficient evidence that treadmill training is superior to physiotherapy, emphasizing walking practice on the floor is still lacking [16]. Nevertheless, treadmill training offers severely affected patients the possibility to practice the stance and swing phases of locomotion, even in sub-acute stages of recovery.

Laufer et al.'s [17] findings suggest that treadmill training may be more effective than gait training on the floor for improving stride length, percentage of paretic single stance period and gastrocnemius muscular activity. Finally, treadmill training provides an opportunity to train cardiovascular fitness [18].

One disadvantage of treadmill training is the effort and the number of physiotherapists needed to set and guide the paretic limbs through different movement phases and to control weight shift [19]. The assistance needed for severely handicapped patients is physically exhausting. Based on experience, therapists often complain about this high level of physical exertion. Therapy sessions are therefore limited in duration. As Kosak and Reding [20] have pointed out, therapists prefer to use task-oriented walking on the floor with ankle-knee bracing instead of treadmill training. In an effort to address this problem, an electromechanical gait trainer [21] and a robot-driven gait orthosis [22] have been recently developed and introduced in the rehabilitation for patients who have suffered stroke or injuries to the head or spinal cord.

The aim of this case series was to determine whether walking training using a newly developed electromechanical gait device (LokoHelp, Medburg Basel) is feasible with respect to training effects and patients' and therapists' efforts and discomfort.

Methods

Subjects

Patients participating in the study were all inpatients for the entire duration of the clinical trial. They demonstrated a hemi-, tetra- or paraparesis as a result of brain injury, stroke or spinal cord injury. All patients met the following inclusion criteria: impaired walking ability, ability to sit without any assistance from another person, capacity to participate in 1 hour of physiotherapy and ability to understand instructions. Except for one patient, all participants had a Functional Ambulation Category (FAC) score of 0 [23, 24] (i.e. they could not walk at all or required help from two or more therapists). Exclusion criteria were: a restricted passive range of motion in flexion/extension of hip or knee joint $>20^{\circ}$ and unstable fractures of the lower extremities. Over the course of 2.5 months (24 October 2006 to 12 January 2007), the first two patients per respective diagnostic group (brain injury, stroke or spinal cord injury) who met the inclusion criteria were recruited.

All participants or their legal representatives gave their written informed consent.

The interval between onset of the impairment and the start of the study treatment protocol was between 1–36 months. The patients' ages ranged from 11–37 years. The characteristics of the six patients are presented in Table I.

Table I. Patient characteristics.

Initials	Diagnosis	Age (years)	Duration of illness (months)	Sex (M/F)	Symptoms
FD	Incomplete spinal cord injury (Th 3)	11	1	F	ASIA C
MB	Incomplete spinal cord injury (Th 12)	37	16	M	ASIA C
AH	TBI	22	36	M	Tetraparesis
KG	TBI	26	12	F	Tetraparesis
SP	Ischemic stroke	31	1	M	Left-sided hemiparesis
JC	Intracerebral haemorrhage	20	1	F	Right-sided hemiparesis

Notes: TBI = traumatic brain injury.
ASIA = American Spinal Injury Association's (ASIA) International Classification of Spinal Cord Injury as a measure of recovery and for describing the neurological level and completeness of injury.

Intervention

All patients were admitted to a comprehensive in-patient rehabilitation programme, which did not change due to the investigation. In addition to their individual rehabilitation programmes, all patients participated in a gait-therapy programme based on walking training with the electromechanical gait device (LokoHelp).

The LokoHelp device is fixed onto the band of a motor-driven treadmill and transmits the treadmill movement to levers positioned on both sides of the device. Simulation of gait is achieved by the track of the levers, which imitate the stance and swing phases in a sequentially accurate manner. Velocity and cadence can be set individually from 0–2.5 km h^{-1}. Step length is fixed at 400 mm. The patients are secured with a harness that supports body weight and is positioned over the LokoHelp. Each lower leg is set into an orthosis which maintains the ankle joint at a 90° angle. The orthoses are then attached to the side levers (Figure 1). The movements of the centre of mass are controlled by ropes attached to the side and front bars, which the patient may grasp.

In this study, physical assistance (e.g. for the control of the knee or hip extension in the stance phase) was administered according to individual needs. Each patient received a total of 20 treatments consisting of 30 minutes of repetitive locomotor training (plus 15 minutes preparation time) with the electromechanical gait device. The training sessions were kept at a demanding level. Treadmill velocity was set to the maximum speed tolerated by the patients and varied from 0.3–1.8 km h^{-1}. Therapists motivated patients to actively move their legs and bear weight. If the patient signalled exhaustion during the treatment, a short break was made and/or the speed reduced. The initial body weight support ranged from 10–30%, which was reduced as soon as possible. Treatment sessions took place three to five times a week and were completed within the 6 weeks of the study.

Figure 1. Patient engaged in treadmill training with the LokoHelp device.

Assessments

Data pertaining to each patient's progress were collected before the study began (baseline) and after the last therapy session using LokoHelp (follow-up). The following assessments were made:

(1) Gait ability was measured using the Functional Ambulation Categories (FAC). The FAC is a reliable and valid score to assess gait ability [23, 24]. The level of physical support needed while walking, irrespective of technical aids used, was assigned to one of six categories (0–5). Level 0 describes a patient unable to walk or requiring help of two or more people. At level 1, a patient needs continuous support from one person to carry weight or control balance; at level 2 a patient needs intermittent physical support, whereas at level 3 a patient needs only verbal support. Level 4 indicates that a patient is able to walk on even surfaces without help and level 5 means that a patient can walk independently everywhere, including stairs.
(2) Walking velocity was assessed by measuring the time a patient needed to walk a distance of 10 metres [25].
(3) Lower limb motor power was assessed by the Motricity Index leg score (score values range from 1–100). The Motricity Index assesses the motor power of the affected lower limb. Ankle dorsiflexion, knee extension and hip flexion of the affected limb or limbs are rated using the motor strength scale outlined by the Medical Research Council (ranging from 0 = no movement to 5 = normal power). This score is then converted to obtain a leg score ranging from 1 (plegic) to 100 (normal power). Because some subjects were diplegic, the Motricity Indices were added for both legs to achieve a sum score of 2–200 [26].
(4) The activity level was assessed by the Rivermead Mobility Index (0–15). This instrument

includes 15 mobility-related items, from turning over in bed to running. Items are assigned a value of 0 (unable to perform activity) or 1 (able to perform activity) [27].

(5) Posture control and balance were assessed using the Berg Balance Scale (BBS), which consists of 14 items pertaining to tasks commonly performed in everyday life. Items test the subjects' ability to maintain positions or perform movements of increasing difficulty by diminishing the base of support from sitting, standing on two legs to standing on one leg. The ability to change positions is also assessed. Each item is scored on a scale ranging from 0–4. The total score ranges from 0–56 points [28].

(6) The Modified Ashworth Scale (MAS) was used to document resistance to passive movement and, hence, muscle tone. Resistance is rated according to a 6-point scale (ranging from 0 = no increase of resistance to passive movement to 5 = maximal resistance to passive movement). The MAS was used to assess passive movements involving the ankle, knee and hip joints of both lower limbs. The results for each limb were added together (i.e. maximal score for both limbs = 30) [29].

These parameters were evaluated by trained therapists not involved in the study and therefore blind to pre- or post-intervention. Therapists administering the treatment had to complete a form after each therapy session, thereby providing information about the total distance walked, body-weight support, number of therapists needed for the treatment, necessity of physical assistance and the level of effort and complaints of patients and therapists. Effort was recorded as exhausting, high, moderate or low. Discomfort was recorded dichotomously (yes/no) and the type of discomfort described in short notes.

Statistical analysis

Patients' characteristics were first summarized with descriptive statistics. Differences between baseline and post-intervention were analysed with Fisher's exact tests for frequencies and dependent Student's *t*-tests for continuous variables [30].

To determine the patient's level of improvement after training, parametric statistics were applied after testing statistically with the Shapiro-Wilk Statistic for an approximated normal distribution [30]. The Student's *t*-tests for paired samples were used because of the test's greater power to detect statistical differences than non-parametric alternatives and therefore reduce beta error.

Fisher's exact tests were used for frequencies because the test is known to be independent of large-sample distribution assumptions and is suitable for sparse tables [30]. The alpha level was set at 0.05 for all comparisons. All calculations were performed using the SAS/STAT® software package 9.1.3 (SAS Institute Inc., Cary, NC, 2006).

Results

All patients completed the clinical trial. They tolerated the 30 minutes treatment time during the whole study period. No severe adverse events were observed during the locomotion training with LokoHelp.

Patients improved with regard to the Functional Ambulation Category (from mean 0.7 ± 1.6 to 2.5 ± 2.1, $p = 0.048$), Motricity Index (from mean 94 ± 50 to 111 ± 52 points, $p = 0.086$), Berg Balance Scale (from mean 20 ± 23 to 25 ± 23 points, $p = 0.168$) and Rivermead Mobility Index (from mean 5 ± 4 to 7 ± 5 points, $p = 0.033$), as shown in Table II.

Gait velocity was not evaluated statistically, because five of the six patients could not cover the test distance of 10 metres at baseline. This was also true for patient SP, although he scored high (39 points) on the BBS. He was unable to initiate the stand and swing phases of the paretic limb while at the same time he had very good compensatory postural adaptations of the unimpaired side at a high level. During the course of the study, his paretic limb's ability to bear weight improved considerably; hence, he scored better on the FAC, BBS and RMI.

The distances covered during one training session differed considerably between patients (range from 202–956 m). The average training distance in the first session was 377 m ± 111 SD, in the last session 600 m ± 171 SD. Figure 2 displays the development of the mean training distances (sum of four sessions) over the study period.

In their reports following each training session, patients described their efforts during training as ranging from low to exhausting (see Table III). Twenty-three cases of discomfort during training were reported. Most of these (11) were related to difficulties with the BWS-system (discomfort in the groin or armpit). The other cases varied: one case of discomfort in the right hip, one case of lower back pain, three cases of headache (reported by patient KG, who had often suffered from headaches before the trial began) and one case of menstrual cramps (also patient KG). In her fifth training session, patient FD complained about pain in the right knee after she had increased the training distance on the treadmill to more than 500 metres in that session. There was no swelling or instability. As the complaint recurred after the following sessions, her knee was bandaged and the speed reduced. As a

Table II. Pre- and post-intervention measures, listed for each patient.

	Impairments						Activity					
	Strength MRC		Balance BBS		Spasticity MAS		Walking ability FAC*		Gait velocity**		RMI	
Patient initials	B	FU	B	FU	B	FU	B	FU	B	FU	B	FU
AH	40	40	3	3	7	7	0	0	u	u	1	1
FD	71	126	3	22	1	9	0	3	u	0.7	4	6
KG	91	106	4	5	na	na	0	0	u	u	1	2
SP	110	129	39	52	6	3	0	4	u	0.5	6	11
JC	184	192	56	56	1	2	4	5	1.4	1.7	13	15
MB	67	73	13	13	0	0	0	3	u	0.2	5	7
Median	1	16	8.5	17.5	1	3	0	3	na		4.5	6.5
IQR	43	56	36	47	5	5	0	4			5	9
mean	3.8	11.0	19.7	25.2	3.0	4.2	0.7	2.5			5.0	7.0
SD	50.1	52.2	22.5	23.4	3.2	3.7	1.6	2.1			4.4	5.3
p (*t*-test)	0.086		0.168		0.547		0.048				0.033	

Notes: MRC = Motricity Index (sum score), BBS = Berg Balance Scale, MAS = Modified Ashworth Scale, FAC = Functional Ambulation Category, RMI = Rivermead Mobility Index, B = Baseline, FU = Follow-up, IQR = Interquartile range, SD = standard deviation, na = not applicable, p = probability for differences ($\alpha = 0.05$).
*Only patient MB used gait devices (two four-point crutches).
**Gait velocity: u = unable was allocated to patients who could not walk independently.

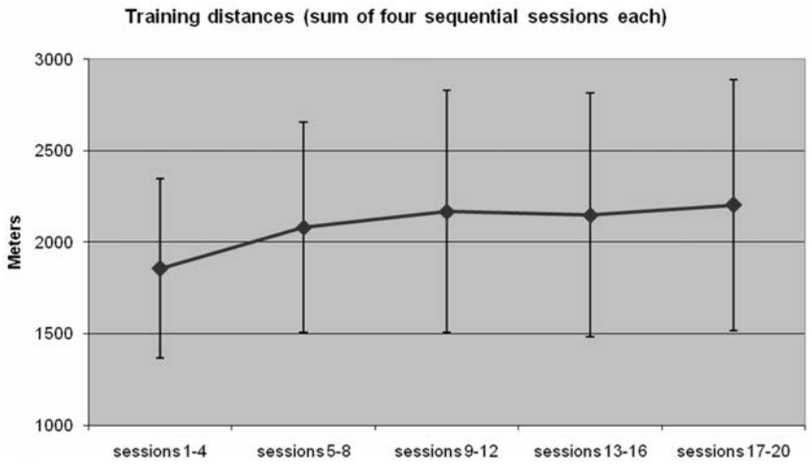

Figure 2. Training distances during the study period. The covered distances of four sequential sessions were summed for each patient. The figure shows the averages of the six patients ± standard deviation.

Table III. Frequencies of the various types of effort and occurrences of discomfort during the 20 training sessions reported by each patient and therapist.

	Patients described						Therapists described					
	Effort				Discomfort		Effort				Discomfort	
Initials	Exhausting	High	Moderate	Low	Yes	No	Exhausting	High	moderate	Low	Yes	No
AH	–	2	5	13	2	18	–	–	1	19	1	19
FD	–	1	2	17	7	13	–	–	–	20	–	20
KG	–	2	9	9	13	7	–	–	1	19	1	19
SP	4	14	2	–	–	20	–	–	–	20	–	20
JC	2	3	13	2	–	20	–	–	–	20	–	20
MB	–	7	9	4	1	19	–	–	–	20	–	20

result, the training distance decreased to 200 metres in that session. However, by the end of the study, the distance she walked increased to 392 metres without complaints.

Therapists described their efforts needed to carry out the training in 118 out of the 120 sessions as low and twice as moderate. There were no reports of high or exhausting effort (as shown in Table III). Discomfort during training occurred only twice: one complaint was related to the therapist's hand being squeezed in setting up the BWS-system and once the therapist reported pain in the lower back and in one hand after the treatment.

Discussion

This study found that locomotor training using an alternative electromechanical gait device may lead to a significant improvement in gait ability as measured with the FAC. This result confirms previous reports that gait rehabilitation following the guidelines of repetitive and task-oriented treatment might be beneficial to non-ambulatory patients with severe hemi-, para- and tetraparesis after acquired brain damage and incomplete spinal cord injury [8, 13–15, 20, 31, 32]. The distances walked during training sessions increased over the study period for all patients except one (FD). This means that there was an increase in the number of steps during training sessions. This high number of repetitions is crucial for relearning motor tasks [3].

Three of the patients with FAC of 0 at baseline attained a score of 3 or more at the end of the study, indicating that they were able to walk without physical assistance. Two patients with FAC of 0 remained unchanged. One of the patients (KG) continued the training with the electromechanical gait device after the end of the study and after ~40 training sessions, attained a FAC score of 3.

With respect to impairment, the patients' muscle strength and postural control improved; however, these improvements were not statistically significant. This might be due to the small sample of patients. Nevertheless, these results warrant further investigation with a larger sample. With respect to activity, gait velocity improved in the one patient who had been able to walk before the onset of training. This study observed a significant increase in the patients' RMIs, which reflected an improvement in carrying out daily life activities.

Since not all of the patients were in a chronic state, one cannot exclude the effects of spontaneous recovery. A randomized controlled study is currently being conducted to explore and further differentiate the effects of the intervention.

The improvement in FAC is comparable to the achieved amelioration with treadmill training with a body weight support system [14]. However, whereas treadmill training often requires two therapists [14], training with the LokoHelp is feasible with only one therapist.

The mean MAS score increased slightly. Patient FD's MAS score increased considerably. This increase may reflect the known development of spasticity which often takes place between 1–3 months after spinal cord injury. This study was conducted between 1–3 months after FD's spinal cord injury. Thus, the recorded increase might be the result of the known phenomena which occur after spinal cord injury and not of the intervention studied. It has been shown that repetitive training to improve upper limb function leads to a reduction of spasticity [33, 34]. Further studies must carefully examine the development of spasticity and its relationship to function.

The patients' descriptions about the effort needed to walk with the electromechanical gait device varied between low and exhausting. The fact that the two stroke patients described the therapy as being exhausting might be explained by the relatively high gait speed used during their training sessions. However, it should be kept in mind that recent guidelines have endorsed strenuous rehabilitative training for patients who have suffered stroke [35].

Finally, four out of six patients reported low numbers of complaints. Among the other two patients, one (FD) reported knee pain. However, no signs of knee injury were detected and the complaints decreased over the course of the treatment period. The other patient's (KG) complaints were related to the body weight support system. During the total 120 treatment sessions, no other unwanted side effects or complications occurred. Based on these findings, the described training methods can therefore be described as feasible and safe.

Therapists reported low levels of effort needed to carry out the treatment through all 120 therapy sessions. Two complained about wrist pain, whereby it should be noted that most of the patients had severe neurological impairments and were thus not easy to handle. Although previous studies have not quantitatively assessed therapists' complaints during treadmill training, the high level of effort required may explain why therapists do not like to implement the treatment, as Kosak and Reding [20] pointed out.

Taking all these facts together, it is concluded that task-oriented gait training with the newly developed mechanical gait device LokoHelp is a feasible and reasonable therapeutic approach, particularly for

patients with severe handicaps resulting from brain injury, stroke or spinal cord injury.

Some limitations of the study deserve mention. The most important shortcoming concerns the lack of a control group. Further studies using a randomized controlled design are necessary to clarify the effects of the intervention described here. Such findings must also be compared with those found using other task-oriented, repetitive approaches, in particular to gain further insights about which therapies are more likely to cause unwanted physical over-exertion of the therapists. Another important issue to be addressed in future research concerns how LokoHelp influences the kinematics of gait compared with treadmill training and over ground walking.

Conclusions

The combined use of an electromechanical device and treadmill training with body weight support is feasible in severely affected patients after brain injury, stroke and spinal cord injury. In addition, the results indicate that the alternative method of gait training described here may improve locomotor function and decrease effort and discomfort experienced by therapists who carry out the training.

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