Improvement of walking abilities after robotic-assisted locomotion training in children with cerebral palsy

A Meyer-Heim,[1] C Ammann-Reiffer,[1] A Schmartz,[1] J Schäfer,[2] F H Sennhauser,[1] F Heinen,[2] B Knecht,[1] E Dabrowski,[3] I Borggraefe[2]

[1] Rehabilitation Centre, Affoltern am Albis, University Children's Hospital Zurich, Switzerland; [2] Department of Child Neurology and Developmental Medicine, Dr von Haunersches Children's Hospital, University of Munich, Germany; [3] Department of Pediatrics, Division of Physical Medicine and Rehabilitation, Children's Hospital of Michigan, Wayne State University, Detroit, Michigan, USA

Correspondence to: Andreas Meyer-Heim, Mühlebergstr. 104, University Children's Hospital Zurich, 8910 Affoltern am Albis – Switzerland; Andreas.Meyer-Heim@kispi.uzh.ch

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ABSTRACT

Objective: To measure functional gait improvements of robotic-assisted locomotion training in children with cerebral palsy (CP).

Design: Single-case experimental A-B design.

Settings: Rehabilitation Centre Affoltern am Albis, Children's University Hospital Zurich, Switzerland (inpatient group) and Neurology Department of the Dr von Haunersches Children's Hospital Munich, Germany (outpatient group).

Participants: 22 children (mean age 8.6 years, range 4.6–11.7) with CP and a Gross Motor Function Classification System level II to IV.

Interventions: 3 to 5 sessions of 45–60 minutes/week during a 3–5-week period of driven gait orthosis training.

Main outcome measures: 10-metre walk test (10MWT), 6-minute walk test (6MinWT), Gross Motor Function Measure (GMFM-66) dimension D (standing) and dimension E (walking), and Functional Ambulation Categories (FAC).

Results: The mean (SD) maximum gait speed (0.78 (0.57) to 0.91 (0.61) m/s; $p<0.01$) as well as the mean (SD) dimension D of the GMFM-66 (40.3% (31.3%) to 46.6% (28.7%); $p<0.05$) improved significantly after the intervention period. The mean (SD) 6MinWT (176.3 (141.8) to 199.5 (157.7) m), the mean FAC (2.6 (1.7) to 3.0 (1.6)) and the mean (SD) dimension E of the GMFM-66 (29.5% (30.3%) to 31.6% (29.2%)) also showed an increase, but did not reach a statistically significant level.

Conclusion: These results suggest that children with CP benefit from robotic-assisted gait training in improving functional gait parameters.

What is already known on this topic

- Driven gait orthosis training is a feasible treatment option in children with central gait impairment.
- Specific gait training with body weight-supported treadmill training improves certain gait parameters and gross motor function.

What this study adds

- Driven gait orthosis training offers a promising treatment option for improvement of walking abilities in children with cerebral palsy.
- The implementation of patient adaptive control strategies and an adapted biofeedback system for children will be crucial factors to assure active participation.

Cerebral palsy (CP) is currently defined as a group of non-progressive, permanent disorders which affect movement and posture that are attributed to disturbances occurring in the developing fetal or infant brain.[1] The incidence of CP in Europe is 2–3 per 1000 live births.[2] CP is the most frequent cause of motor, sensory and cognitive disability in childhood.[3 4] The main symptoms of CP are weakness, spasticity and its sequelae, deformities and contractures. Treatment options include non-surgical therapies such as physiotherapy, occupational therapy, hippotherapy, orthotics/casting and postural management and oral, regional or focally administered medications as well as orthopaedic and neurosurgical procedures.[5]

In recent years, authors have increasingly placed emphasis on promoting active therapies, including intensive, repetitive and task-specific training to enhance neuroplasticity.[6 7] There is increasing evidence that intensive functional training is effective in improving the motor abilities and muscle strength of children with CP. However, task-specific aspects of the training and its outcome have rarely been investigated in this population.[8 9] In adult patients with stroke, body weight-supported treadmill training (BWSTT) has been proven to be effective in several level I studies.[10] There is also an increasing body of evidence that BWSTT improves walking ability, speed and endurance in children with mild-to-moderate CP.[11–13]

Based on the motor learning concept, robotic-assisted treadmill training conducted on a driven gait orthosis (DGO) was developed for adults in 2000.[14 15] DGO training in comparison with conventional over ground training (COGT) and BWSTT offers an increase in specific gait rehabilitation by a greater amount of stepping practice due to lower personal effort and costs, increased speed and longer walking distance during therapy sessions.[16] Because the parameters of each training session, including mileage, speed, step counts, guidance forces and body weight support, are well defined and continuously logged, gait training becomes easily comparable between different individuals and even different training settings. This, in turn, provides new opportunities not only for research but also for specific treatment planning and patient instructions. DGO training has

been found effective in improving walking abilities in adult patients with stroke and spinal cord injury (SCI).[17–19] Recently, robotic-assisted locomotion training has been introduced and found to be a feasible and promising therapeutic option in the paediatric setting as well.[20 21]

The aim of the current study was to examine the hypothesis that specific gait training on the DGO improves functional walking parameters in children with chronic gait impairment due to bilateral spastic CP.

METHODS

Participants

Patients were recruited from an inpatient setting (Rehabilitation Centre Affoltern am Albis, University Children's Hospital Zurich, Switzerland) and an outpatient setting (Department of Paediatric Neurology and Developmental Medicine of the Dr von Haunersches Children's Hospital, University Munich, Germany). Children with a diagnosis of bilateral spastic CP attributed to complications of prematurity, intracranial haemorrhage and periventricular leucomalacia according to the definition of Bax were enrolled in the study.[22] Of all the children with CP who had DGO training on the Lokomat® during 2006–2007 in the two centres, only those patients aged 4 to 12 years without additional treatment with Botulinum toxin or surgery within 3 months before onset of the Lokomat® training programme were included. Achieving or improving the ability to walk had to be a realistic goal of the rehabilitation programme for these children. For this reason, only children with Gross Motor Function Classification System (GMFCS) levels II to IV were included. Femur length had to be at least 21 cm, which correlates to children at approximately 4 years of age. Patients had to be able to signal pain, fear or discomfort reliably.

Exclusion criteria were severe lower extremity contractures, fractures, osseous instabilities, osteoporosis, severe disproportional bone growth, unhealed skin lesions in the lower extremities, thromboembolic diseases, cardiovascular instability and aggressive or self-harming behaviours. Mild scoliosis (Cobb angle $<20°$) was not considered as an exclusion criterion. Approval for the study was obtained from the local ethics committees and written consent was obtained from the parents.

Apparatus

Driven gait orthosis (Lokomat®)

Robotic-assisted locomotion training was performed using the commercially available DGO Lokomat®. For children with femur length <35 cm the therapy was performed on the paediatric module of the Lokomat®; for larger children the adult module was used (fig 1). The DGO consists of two exoskeletons which are adjustable to the anthropomorphy of the patient. Several braces are used to fasten the patient to the DGO. The legs of the DGO are connected to the frame of a body-weight support system by a four-bar linkage, which allows vertical movements and provides vertical stability. On each leg, two linear drives move the hip and knee joints of the orthosis. These drives are position controlled so that a kinematics — resembling a normal walking pattern — can be performed and synchronised with the treadmill. Walking speed can be set between 1.0 and 3.2 km/h. For body-weight support, a counter system with a harness is used. Several security measures provide safe training conditions. These include stop buttons for both therapist and patient, and a controller that limits both excessive force at the drives and deviations from the desired position of the joint angles, so that the DGO stops immediately if severe spasticity or dystonia occurs.[14]

Intervention

Specific locomotion training on the DGO Lokomat® was the main intervention for the children participating in the study. We strove for a total of 20 sessions of 45 minutes over a 4–5-week course on the DGO in the inpatient setting and for 12 sessions of 60 minutes over a 3–4-week course in the outpatient setting. In the inpatient group, additional therapeutic sessions of physiotherapy, speech therapy, occupational therapy and hippotherapy were individually scheduled according to the needs of each child. In the outpatient group, no further therapeutic sessions were scheduled.

Outcome measures

Maximum gait speed was assessed with the 10-metre walk test (10MWT) and gait endurance with the 6-minute walk test (6MinWT).[23 24] During pre- and postintervention assessments children wore their usual orthoses and footwear and utilised their regular walking aids.

Furthermore, the dimensions D (standing) and E (walking, running, jumping) of the Gross Motor Function Measure (GMFM-66) were assessed by GMFM-certified therapists. The GMFM-66 is a standardised observational instrument with good psychometric properties, categorising the 66 test items into five developmental dimensions to measure gross motor function in children with CP and other central disabilities.[25 26] Additionally, Functional Ambulation Categories (FAC) were collected before and at the end of the training cycle to gather information about the amount of walking assistance each required.[27]

Effective training time (minutes), walking distance (m) and mean walking velocity (m/s) of each session were logged by the Lokomat® system.

Statistical analyses

Because the assumptions of parametric statistical analyses were not satisfied, non-parametric test procedures were used. To assess differences between pre- and post-tests, the changes of all outcome parameters were analysed with Wilcoxon signed-rank tests. Additionally, the relative changes of gait speed and 6MinWT were calculated. To account for the differences concerning adjunctive therapies between the in- and the outpatient group, Mann–Whitney U tests were performed. To look for correlations between GMFCS level and training volume, Spearman's rank correlation (r_s) coefficient was calculated. A two-tailed level of significance was set at $p<0.05$ for all analyses, which were conducted using SPSS Version 15.0.

RESULTS

From the total of 67 children with CP who took part in DGO training during 2006–2007 in the two centres, 22 children (13 males, 9 females) with a GMFCS level II to IV and without additional treatment with Botulinum toxin or surgery within 3 months before start of the Lokomat® training programme, were included for data analysis. Eleven children and adolescents (mean (SD) age 9.7 (1.7) years, range 6.0–11.7 years) were from the inpatient (Zurich) setting and 11 patients (mean (SD) age 7.5 (2.0) years, range 4.6–10.9 years) were from the outpatient setting (Munich). Eighteen children utilised walking aids and/or orthoses on a regular basis in their daily lives. Further characteristics of the patients are listed in table 1.

Figure 1 Robotic-assisted locomotion training of a 12-year-old girl with cerebral palsy on the driven gait orthosis (Lokomat®).

In a mean (SD) of 15.1 (4.1) training sessions, patients walked a mean (SD) of 842 (291) m during a mean (SD) of 31.5 (7.1) minutes per session on the DGO. Individual details of the gait training data and of the outcome parameters are shown in tables 2 and 3.

The assessed outcome parameters improved in the entire study group as follows:

Mean (SD) maximum gait speed assessed with the 10MWT improved 0.12 (0.17) m/s from 0.78 to 0.91 m/s ($Z = -2.856$; $p<0.01$), signifying a relative increase of 15.9% (fig 2A).

The covered distance in the 6MinWT improved from mean (SD) 176.3 (141.8) m to 199.5 (157.7) m, representing a 13.1% increase, but this gain did not reach statistical significance ($Z = -1.678$; $p = 0.093$) (fig 2B).

The scores of the standing section (D) of the GMFM increased significantly by 6.3% from mean (SD) 40.3% (31.3%) to 46.6% (28.7%); $Z = -2.475$; $p<0.05$. The walking section (E) showed a non-significant improvement of 2.1% from mean (SD) 29.5% (30.3%) to 31.6% (29.2%); $Z = -1.376$; $p = 0.169$ (fig 2C).

The mean (SD) score of the FAC as a measure of the amount of necessary walking assistance increased from 2.6 (1.7) to 3.0 (1.6) ($Z = -1.857$; $p = 0.063$).

The mean training distance on the DGO correlated moderately with the GMFCS level ($r_s = -0.69$; $p<0.001$) which signifies that children with a lesser impairment level could cover more distance during a training period than children with greater impairment levels.

Between-group analyses did not reveal any significant differences between the results of the inpatient group and the outpatient group.

DISCUSSION

Cortical reorganisation enhanced by task-specific training is known to be related to the intensity and frequency of training.[28] Due to its ability to increase intensity and frequency, while maintaining a physiological gait pattern, DGO training offers nearly ideal conditions for a specific gait training.

This trial aimed to determine the functional gait improvements of a specific locomotion training programme in children and adolescents with CP performed on a DGO. The results of the 10MWT yielded a greater than 15% increase of gait speed. The standing dimension of the GMFM-66 improved by 6%, although this dimension is comprised of tasks that were not specifically trained during the intervention period.

Table 1 Clinical characteristics of the 22 participants

Mean (SD) age (years)	8.6 (2.1)
Sex (n)	
Female	9
Male	13
Mean (SD) height (cm)	122.5 (14.0)
Mean (SD) weight (kg)	26.0 (9.0)
Type of CP (n)	
Diplegic	10
Tetraplegic	12
GMFCS level (n)	
II	5
III	13
IV	4
Walking aids (n)	
Walker	9
Quad cane	3
Guided	3
None	7
Orthoses (n)	
FO	1
AFO	4
HKAFO	1
None	16
DGO type (n)	
CM	19
AM	3

AFO, ankle–foot orthosis; AM, adult module; CM, child module; CP, cerebral palsy; DGO, driven gait orthosis; FO, foot orthosis; GMFCS, Gross Motor Function Classification System; HKAFO, hip–knee–ankle–foot orthosis.

Two controlled studies of specific gait training on BWSTT in ambulatory children with CP have recently been conducted by Dodd *et al* and Cherng *et al*, which showed distinct improvements in gait parameters.[12 13] The participants (n = 7) of Dodd's trial underwent a 12 BWSTT-session programme during 6 weeks. Cherng's participants (n = 8) attended a 12-week programme including two to three sessions per week of BWSTT in addition to their regular therapeutic exercise programme.

Training parameters such as walking velocity and time walked per session are considerably higher during robotic-assisted treadmill training than can be achieved with BWSTT. The trainings lasted 20 minutes or less in both of the studies noted above, whereas the patients in our study reached a mean training duration of 31.5 minutes. Manpower requirements should also be taken into consideration, as they are often partially responsible for limited implementation of neurorehabilitative methods being put into practice.[29 30] For robotic-assisted treadmill training, only one therapist is usually necessary, whereas at least two are needed to ensure a physiological gait pattern in BWSTT. Though the Lokomat® indirectly allows drawing conclusions about the activity of the patient during the training, it does not react if the child's participation decreases. This may explain the lack of superior results compared with the BWSTT studies, despite longer training sessions in our trial. However, as study designs varied substantially among the present studies, further conclusions cannot be extrapolated.

Wang *et al* have stated in their study on responsiveness of the GMFM that an increase of 3.7% would be clinically meaningful.[31] Whereas dimension D of the GMFM showed a significant increase of 6.3%, dimension E improved just 2.1%

Table 2 Individual training data

Patient no	Group*	GMFCS level	Number of training sessions	Mean walking distance (m)	Total walking distance (km)	Mean walking time (min)	Total walking time (min)	Mean walking velocity (m/s)
1	1	3	18	546	9.8	21.0	398.5	0.41
2	1	3	9	796	7.2	26.5	238.9	0.50
3	1	3	19	510	9.7	21.0	399.5	0.40
4	1	2	19	1000	19.0	30.4	577.4	0.55
5	1	3	19	844	16.0	35.2	669.3	0.40
6	1	3	21	683	14.3	28.1	590.4	0.40
7	1	3	18	397	7.1	22.9	411.3	0.29
8	1	4	22	656	14.4	30.7	674.7	0.36
9	1	3	17	951	16.2	31.2	530.7	0.51
10	1	4	20	394	7.9	25.7	513.8	0.26
11	1	3	20	870	17.4	31.6	632.0	0.46
12	2	3	12	1080	13.0	38.8	465.0	0.46
13	2	4	12	472	5.7	21.1	253.2	0.37
14	2	3	11	970	11.6	36.5	401.5	0.44
15	2	2	12	1463	17.6	43.8	525.0	0.56
16	2	2	12	1130	13.6	36.6	439.2	0.51
17	2	4	12	551	6.6	25.0	300.0	0.37
18	2	4	12	1190	14.3	41.2	493.8	0.48
19	2	2	12	1249	15.0	43.3	519.0	0.48
20	2	3	12	942	11.3	35.3	423.0	0.45
21	2	3	12	849	10.2	31.0	372.0	0.46
22	2	3	12	990	11.9	35.4	424.2	0.47

*1: inpatient, 2: outpatient.
GMFCS, Gross Motor Function Classification System.

without statistical significance. Previous results have shown that the walking dimension (E) in the GMFM was superior to changes in the standing dimension (D), which may emphasise the task-oriented specificity of the DGO training.[20] Interestingly, this finding was not replicated in this study. This observation may be somewhat surprising, because the dimension E was specifically trained during the intervention period. A possible explanation could be the fact that 18 of the 22 children utilised walking aids on a regular basis. However, the GMFM was administered without walking aids, making an improvement upon the initial score more difficult, especially in this dimension. The 15.9% improvement in gait speed could be

Table 3 Individual outcome parameters

Patient no	Gait speed pre (m/s)	Gait speed post (m/s)	6MinWT pre (m)	6MinWT post (m)	GMFM D pre (% value)	GMFM D post (% value)	GMFM E pre (% value)	GMFM E post (% value)
1	ND	ND	ND	ND	12.82	35.90	2.78	16.67
2	1.2	1.3	386	444	79.49	79.49	84.72	87.50
3	ND	ND	ND	104	7.69	38.46	2.78	22.22
4	2.1	2.1	370	350	87.18	87.18	84.72	87.50
5	0.6	0.7	136	164	7.69	2.56	5.56	0.00
6	1.0	1.2	ND	184	56.41	56.41	19.44	22.22
7	ND	ND	102	61	20.51	38.46	4.17	6.94
8	ND	ND	ND	ND	2.56	7.69	0.00	2.78
9	ND	ND	ND	ND	15.38	15.38	11.11	15.28
10	ND	ND	90	120	7.69	7.69	1.39	1.39
11	ND	ND	48	76	12.82	15.38	1.39	6.94
12	0.1	0.1	22	36	41.03	69.23	16.67	19.44
13	0.1	0.2	ND	ND	7.69	12.82	6.94	6.94
14	0.4	0.7	ND	ND	15.38	33.30	22.20	22.20
15	1.4	1.5	ND	ND	76.90	82.00	75.00	77.70
16	1.1	1.3	ND	ND	66.60	69.20	50.00	51.38
17	0.1	0.1	34	46	5.13	7.69	4.17	0.00
18	1.1	1.8	256	420	89.74	76.92	69.44	59.72
19	0.7	0.7	140	150	48.72	48.72	19.44	22.22
20	1.3	1.4	240	280	74.36	76.92	56.94	66.67
21	0.1	0.2	42	59	35.90	38.46	19.44	19.44
22	0.3	0.3	58	59	48.72	61.54	19.44	23.61

D, standing dimension; E, walking, running, jumping dimension; GMFM, Gross Motor Function Measure; 6MinWT, 6-minute walk test; ND, no data.

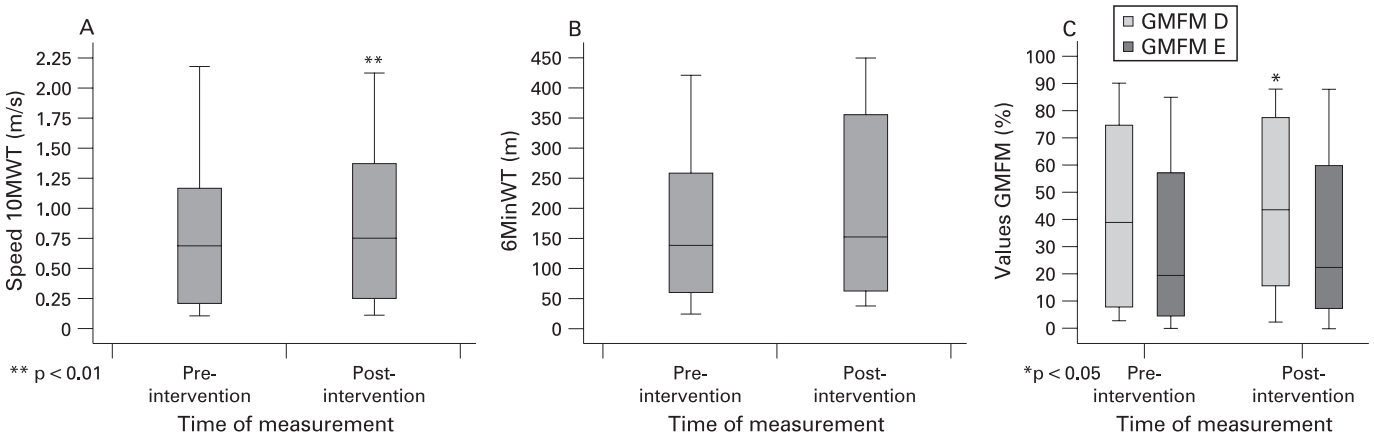

Figure 2 A. Comparison of the pre- and postintervention assessment of the 10-metre walk test (10MWT); B. the 6-minute walk test (6MinWT); C. the Gross Motor Function Measure (GMFM) sections D and E. *p<0.05; **p<0.01. D, standing dimension; E, walking, running, jumping dimension.

quite meaningful with regards to a child's participation in the community and interaction with peers, especially when walking short distances, such as changing between classrooms at school.

We are aware of several limitations of the present study. First, no control group was included and no baseline period was established, which makes it impossible to compare the described results to the natural course of children with CP within this time period. However, we do not expect a child with CP to improve in functional gait parameters noticeably within 3 to 5 weeks without therapy. The sample size was small, which may have reduced the power of this study. Even so, it is the largest sample of children with CP studied so far regarding either robotic-assisted or conventional BWSTT. Further, the outcome assessors were not blinded to the pre- and post-training condition. Only children aged 4–12 years were included in the study. We are aware that this selection criterion was arbitrary, but we wanted to prevent the biomechanical impact of the pubertal growth spurt. The in- and outpatient groups differed slightly from each other regarding the therapy protocol.

DGO training for children with CP may be an effective new therapy option to improve gait function, because the length of gait therapy can be increased thereby possibly enhancing neural reorganisation.

As stated earlier by Koenig *et al*[32] and as observed again during this study period, the implementation of patient adaptive control strategies and an adapted biofeedback system for children will be crucial factors to assure maximum participation in young children. Current projects aim to expand the existing biofeedback system of the Lokomat®, integrating technologies with walking in a virtual reality-based environment.[32] The potential benefit of these technologies as well as the effects of the DGO training and the optimal training parameters need to be further investigated in particular with controlled and randomised clinical trials and greater numbers of participants. For this reason, taking the comparability of DGO training into account, an international database (PeLoBASE) has been established to enhance international collaboration.

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Competing interests: AMH and IB have been reimbursed by Hocoma AG, the manufacturer of Pediatric Lokomat for attending two conferences as invited speakers and received a fee for speaking at one conference. Hocoma AG financed equipment for development and research of an augmented feedback system of the Pediatric Lokomat. AS has been employed by Hocoma AG during the submission of the paper to ADC.

Ethics approval: Approval for the study was obtained from the local ethics committees.

Patient consent: Parental consent obtained.

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