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Sustainability of motor performance after robotic-assisted treadmill therapy in children: an open, non-randomized baseline-treatment study

I. BORGGRAEFE [1], L. KIWULL [1], J. S. SCHAEFER [1], I. KOERTE [2], A. BLASCHEK [1], A. MEYER-HEIM [3], F. HEINEN [1]

[1]*Department of Pediatric Neurology and Developmental Medicine*
Dr. von Haunersches Children's Hospital
University of Munich, Munich, Germany
[2]*Institute of Clinical Radiology*
University of Munich, Munich, Germany
[3]*Rehabilitation Centre, Affoltern a. Albis*
University Children's Hospital Zurich, Zurich, Switzerland

Aim. **The aim of the study was to investigate the sustainability of motor improvements achieved after a three week trial of robotic assisted treadmill therapy in children and adolescents with central gait disorders within a follow up period of about six months.**

Methods. **Open, non-randomized, baseline-treatment study. Fourteen patients (mean age 8.2±5.4) underwent a trial of 12 sessions of robotic-assisted treadmill therapy using the Lokomat over a period of three weeks. Outcome measures were the dimensions D (standing) and E (walking) of the Gross Motor Function Measure, the ten meter walking test and the six minute walking test. Outcome variables were evaluated immediately before and after the trial and at a follow up of about six months.**

Results. **Improvements after the trial in the dimension D from 49.5% to 54.4% (P=0.008) and from 38.9% to 42.3% (P=0.012) in the dimension E of the GMFM were seen and are within the same range of previously published results. The mean score at the follow up after six months was 56.8% and 43.3% for dimension D and E, respectively. Gait speed improved from 0.80 m/s to 1.01 m/s (P=0.006) after the trial and was 1.11 m/s at the follow-up visit at six months. Similar results were obtained for endurance.**

Conclusion. **The improvements of motor function after a three-week trial of robotic-assisted treadmill therapy appear to be sustained after a mean period of six months.**

KEY WORDS: Body weight - Child - Motor skills.

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Corresponding author: I. Borggraefe, MD, Department of Pediatric Neurology and Developmental Medicine, Dr. von Haunersches Children's Hospital, University of Munich, Lindwurmstreet 4, 80337 Munich, Germany. E-mail: ingo.borggraefe@med.uni-muenchen.de

Current concepts of motor learning assume that repetitive task-specific practice can significantly improve motor functions.[1, 2] Locomotor therapy for regaining walking capacity using the principle of enhancing neuroplasticity by task specific training is effective in the rehabilitation process of patients with central gait disorders.[1, 3, 4] The approach of treadmill therapy offers a task specific approach to improve walking performance in the rehabilitation process of gait disorders. Trials of conventional body-weight-supported treadmill therapy have shown improvements of walking function, gait speed and endurance in pediatric patients.[5-8] The feasibility and efficacy of robotic-assisted body-weight-supported treadmill therapy in children and adolescents with central gait impairment enabled by the driven gait orthosis Lokomat was shown recently in a non-randomized trial revealing improvements in the subjects' gait velocity, endurance, and performance of functional motor tasks as walking and standing.[9-11] The use of a robotic device assists in achieving and maintaining a physiological walking pattern for extended periods of therapy and the impact of robotic approaches in the rehabilitation process in children has been described

TABLE I.—*Demographic data of the patients.*

Patient #	Diagnosis	Etiology	Gender	GMFCS	Device	Age
1	BS-CP	Prematurity	F	1	a	15.3
2	BS-CP	Prematurity	M	3	p	5
3	BS-CP	Prematurity	M	3	p	6.2
4	BS-CP	Unknown	F	2	p	4.3
5	BS-CP	Prematurity	M	3	p	6.8
6	BS-CP	Prematurity	M	3	p	4.3
7	SP	Unknown	M	1	a	19.1
8	BS-CP	Prematurity	M	4	p	7
9	BS-CP	Prematurity	F	1	p	6.4
10	BS-CP	Prematurity	M	3	p	5.5
11	BS-CP	Prematurity	M	4	p	6.5
12	BS-CP	Prematurity	M	2	p	4.5
13	BS-CP	Prematurity	M	4	p	5
14	BS-CP	Prematurity	M	2	a	19.2
Mean						8.2
SD						5.4

BS-CP=bilateral spastic cerebral palsy. SP=spinal paralysis; a= adult device. p=pediatric device; RPT=regular physiotherapy.

recently.[12, 13] No data are available regarding maintenance of improved motor functions achieved after a trial of treadmill therapy using either conventional body weight supported treadmill therapy or robotic assisted treadmill therapy.

The aim of the present study was to investigate the sustainability of motor functions achieved after a three week trial of robotic assisted treadmill therapy in children and adolescents with central gait disorders.

Materials and methods

Study population

Fourteen patients (mean age 8.2±5.4) with central gait disorders (N.=13: bilateral spastic cerebral palsy, N.=1: spinal paralysis, Table I) participated in this study. Motor impairment was determined by the Gross Motor Function classification System (GMFCS).[14] Inclusion criteria were the diagnosis of a central gait disorder, the need for functional therapy with the aim of improving over ground walking, written informed consent from the patient's parents or guardians and patients themselves if applicable. Exclusion criteria included any change in concomitant treatment 12 weeks prior to the study. Exclusion criteria were severe lower-extremity contractures, fractures, osseous instabilities, osteoporosis, contraindication of full body load due to previous surgeries, severe disproportional bone growth, unhealed skin lesions in the lower-extremities, thromboembolic diseases, cardiovascular instability, acute or progressive neurological disorders and aggressive behaviour.[10] Approval was obtained from the local ethical committee of the University of Munich and was in accordance with the guidelines set forth in the Declaration of Helsinki (1964).

Device

The DGO Lokomat consists of two leg orthoses adjustable to the anatomy of each patient and is manufactured by the Hocoma Inc. (Volketswil, Switzerland).[13] An adult device as well as a pediatric device are available. Dorsiflexion of the ankle joint is provided by an elastic foot strap. The legs of the DGO are connected to the frame of a body weight support system by a four bar linkage. Movements of the DGO are synchronized with the treadmill. Safety features include stop buttons for both the therapists and the patient and a controller that limits excessive forces as well as deviations from the desired position in the joint angles. A counter weight system is used for body weight support and allows body weight support within a range of 5 to 80 kg in 5 kg increments.

Intervention

Twelve therapy sessions of robotic assisted treadmill therapy were conducted over a three-week period (four sessions/week). Walking speed was initially

TABLE II.—*Overview of the distance and time walked during the three week trial of robotic assisted treadmill therapy.*

	Distance (meter)		Duration (minutes)		Leading force (%)
Patient#	Mean per session	Total per trial	Mean per session	Total per trial	Mean per session
1	1547	18563	504	42	53
2	906	10870	396	33	86
3	1149	10345	351	39	84
4	1105	13258	504	42	58
5	942	11299	432	36	74
6	924	11090	396	33	62
7	1473	17676	516	43	46
8	481	5771	288	24	97
9	1340	16078	504	42	76
10	927	11129	408	34	100
11	551	6616	300	25	100
12	1190	14285	492	41	59
13	837	10048	432	36	88
14	1600	19205	576	12	48
mean	1070	12588	436	34	74
SD	342	4146	85	9	19

set at 1.1 km/h and was gradually increased to 1.8 km/h. The duration of the therapy sessions was limited to 50:00 minutes. Body-weight support was started at 100% and then reduced as much as possible up to the point of when the knee started to collapse into flexion during stance. The leading force was continuously reduced from 100% until to much activity applied by the patient lead to activation of the control system of the Lokomat to stop the DGO. From this point, the leading force was set 5% higher allowing a leading force as low as possible and as high as necessary. In addition to general motivation during the training, the therapist provided encouragement to the child to take steps on their own and to try to recognize and correct unwanted gait patterns or postures. To maintain compliance during the therapy session the patients were allowed to watch a favourite cartoon on a DVD when verbal enhancement of the therapists was not sufficient anymore to sustain the therapy session.

Outcome measures

Outcome criteria were the dimensions D (standing) and E (walking, running, jumping) of the GMFM,[15] the gait speed as measured by the ten meter walking test and endurance as measured by the six minutes walking test.[16] Baseline measures were taken 1-2 days before the trial began (visit 1) and outcome measures were evaluated following completion of the three-week trial (visit 2). Another visit was scheduled after a follow up period of about six months (visit 3, 195 days ±64, range 81-343). The therapy regime during this follow period consisted on 1-2 sessions of regular physiotherapy/week with some patients (#1-7) receiving an additional therapy session of robotic assisted treadmill therapy (2-3 sessions/months).

Statistical analysis

Changes from the baseline measures (visit 1) between the outcome measures after the trial (visit 2) and after the follow up period (visit 3) were analyzed using the nonparametric Wilcoxon signed rank tests for paired samples. To investigate an effect of the additional therapy sessions of robotic assisted treadmill therapy during the follow-up period the differences of the outcome measures (% change) between the two subgroups (with and without an additional treatment) were analyzed using the Mann Whitney test for unpaired samples. Two-tailed significance was stated if p was <0.05. For statistical analysis SPSS15 (Chicago, IL, USA) was used.

Results

Training parameters

The mean of total distance walked per patient during the three week trial was 12 588 meters (±4 146)

TABLE III.—*Data of the outcome measures immediately before (V1. baseline) and after (V2) and after the mean follow up period (V3) of 195±64 days (range 81-343 days).*

	Gross Motor Function Measure						10 meter walking test			6 minutes walking test		
	D%			E%			Meter/second			Meter		
	V1	V2	V3	V1	V2	V3	V1	V2	V3	V1	V2	V3
1	87.2	87.2	92.3	81.9	83.3	86.1	2.16	2.22	1.81	500	500	493
2	38.5	51.3	56.4	18.1	18.1	19.4	0.78	1.02	1.35	120	190	245
3	28.2	33.3	48.7	15.3	15.3	15.3	0.36	0.50	0.43	108	130	170
4	82.1	92.3	87.2	65.3	68.1	68.1	1.58	1.66	nd	310	340	240
5	74.4	76.9	82.1	56.9	66.7	69.4	1.31	1.31	1.59	240	280	290
6	15.4	20.5	25.6	12.5	12.5	4.7	0.45	0.53	0.64	85	130	119
7	84.6	84.6	87.2	68.1	79.2	81.9	0.96	0.88	2.70	300	235	236
8	2.6	10.3	7.7	4.2	4.2	2.8	0.45	nd	0.35	nd	nd	101
9	94.9	94.9	97.4	91.7	94.4	97.2	0.83	1.30	2.50	nd	nd	310
10	12.8	25.6	23.1	12.5	13.9	15.3	0.25	0.60	0.57	55	115	152
11	5.1	5.1	2.6	4.2	4.2	4.2	0.11	0.14	0.17	34	46	69
12	79.5	89.7	87.2	59.7	69.4	72.2	1.11	1.77	1.38	256	420	330
13	5.1	7.7	15.4	4.2	4.2	4.2	0.05	0.23	0.23	22	63	60
14	82.1	82.1	82.1	50.0	58.3	65.3	0.84	0.93	0.74	213	262	266
Mean	49.5	54.4	56.8	38.9	42.3	43.3	0.80	1.01	1.11	187	226	220
SD	36.8	35.7	35.3	31.7	34.4	36.4	0.60	0.62	0.85	142	142	119

V: visits.

and the mean of walking distance per therapy session was 1 070 meters ±342). The mean of total time walked per patient was 436 minutes (±85) and the mean duration per therapy session was 34 minutes (±9) (Table II).

Immediate outcome

Immediate outcome (Table III, Figures 1-3) refers to the changes of the outcome measures from baseline to the evaluation after the trial (visit 1 to visit 2). Significant improvement was noted for the standing dimension (D) of the GMFM score from 49.5% (±36.8) to 54.4% (±35.7, P=0.008). Similar results were obtained for the dimension E (walking, running and climbing) with an improvement from 38.9% (±31.7) to 42.3% (± 34.4, P=0.012). The patient's gait speed increased from 0.80 meter per second (±0.60) to 1.01 meters per second (±0.62, P=0.006) and the endurance as measured as the time walked during six minutes from 187 meters (±142) to 226 meters (±142, P=0.033).

Short term outcome

Short term outcome (Table III, Figures 1-3) refers to the changes of the outcome measures from baseline to the follow-up evaluation at six moths (visit 1 to visit 3). The gain of the score of dimension D from visit 1 to visit 3 was 7.3% (from 49.5% to 56.6%, P=0.002). The same was true for the dimension E revealing an increase of 4.4 % (from 38.9% to 43.3%, P=0.033). In the evaluation of speed (ten meter walking test), two patients (# 4 and 8) could not complete the ten meter walking test according to exhaustion at visit 2 and 3. The patient's gait speed increased from 0.80 meters per second (±0.60) at visit 1 to 1.11 meters per second (±0.85) at visit 3 (P=0.046). Endurance (six minutes walking test) increased from visit 1 to visit 3 though not reaching a statistically significance (P=0.099, patient # 8 and 9 did not perform the test at visit 1 and 2 due to exhaustion).

Separate analysis of the patients who had robotic assisted treadmill therapy during the follow up period on a regular basis from those patients not having this additional treatment protocol revealed no statistically significant differences of changes of all outcome measures between visit 1 and 3.

Discussion

The results from this study provide some data about the sustainability of motor improvements achieved after a three week trial of robotic assisted treadmill

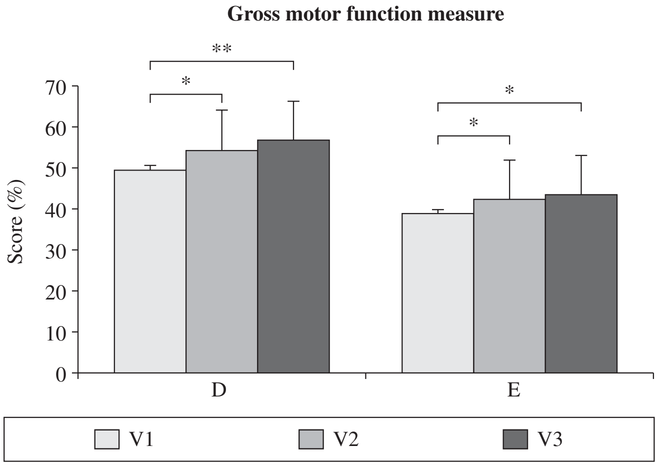

Figure 1.—Significant improvement of the dimensions D (standing) and E (walking) of the GMFM were achieved from visit 1 (V1, baseline) to visit 2 (V2, evaluation immediate after intervention). The improvement was still visible at visit 3 (V3, evaluation at six months follow up). **P<0.005, *P<0.05.

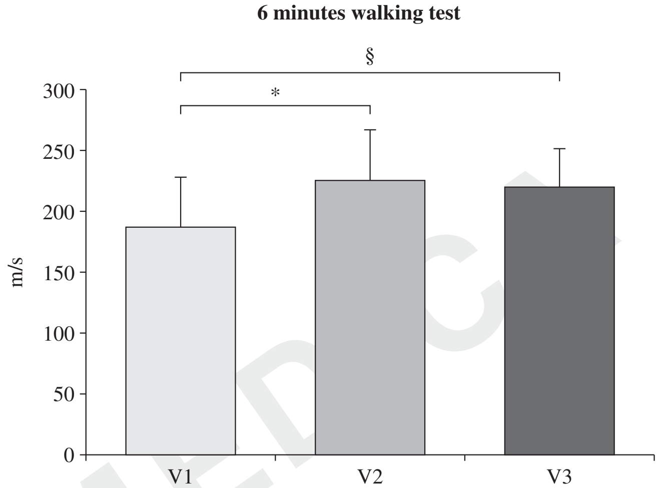

Figure 3.—Significant improvement of endurance as measured by the 6 minutes walking test was seen from visit 1 (V1, baseline)) to visit 2 (V2, evaluation immediate after intervention). The improvement was still evident at visit 3 (V3, evaluation at six months follow up) though not reaching statistical significance. *P<0.05, §not significant.

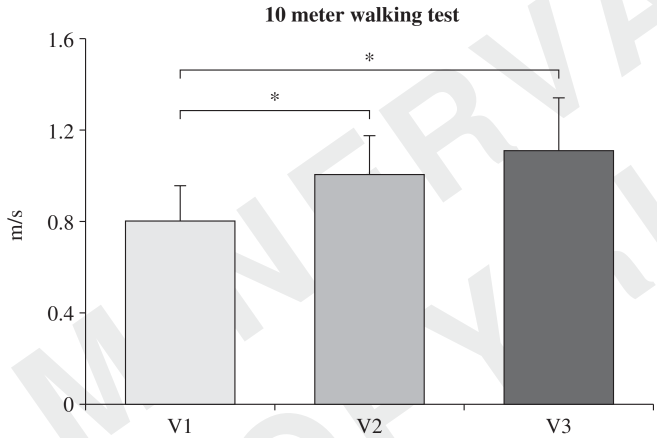

Figure 2.—Significant improvement of gait speed as measured by the 10 meter walking test was seen from visit 1 (V1, baseline) to visit 2 (V2, evaluation immediate after intervention). The improvement was still evident at visit 3 (V3, evaluation at six months of follow-up).

therapy in children and adolescents with central gait impairment. The short term motor improvements reflecting the changes between visit 1 and 2 achieved after this three week trial are consistent with previous findings using protocols with the similar intensity and subject selection.[10] The improvements of standing tasks (GMFM D) and walking tasks (GMFM E) as well as gait speed achieved after the trial were still evident after a follow-up period of about six months. This was also true for endurance though not reaching statistical significance. The considerable changes noted for the standing dimension (D) of the GMFM suggest an additional effect on the stabilization of posture beyond the task specific improvement of walking parameters (GMFM E, gait speed and endurance). The improvements of the outcome measures were consistent with the perception of the patients, parents and caregivers who most often reported increased endurance and enhanced ability to climb stairs.

Developmental curves established for children with cerebral palsy show that motor tasks defined by the GMFM improve during the first years of life.[17] However, these curves reach a plateau as early as 4 to 5 years of age. The present data might indicate that the achieved improvement of motor tasks after a trial of robotic assisted treadmill therapy as standing, walking, gait speed and endurance are sustained after a period of six months despite the fact that most of the patients had already reached their predicted plateau of motor performance. Data on the sustainability of improved motor function after functional therapy in the rehabilitation process of chronic pediatric gait disorders are mandatory. In adult patients with Parkinson Disease a treadmill trial with similar intensity of the intervention showed improved gait speed compared to the control group receiving regular physiotherapy.[18] This effect was still visible after a follow up period of six months. Although these results show some evidence of maintenance of motor tasks gained after a trial of treadmill therapy the comparability with our data is difficult as patients and diagnoses varied notably. Studies addressing the sustainability of achieved motor improvements using physiotherapy show contrary results. After a six-week trial of Bobath therapy patients aged two to six years improved significantly and this improvement sustained over a follow up of six weeks.[19] However, no improvement was seen in patients aged seven to ten years supporting the predictive impact of the developmental curves developed by Rosenbaum and others.[17, 20] Knox *et al*. investigated the effect of different approaches of physiotherapy regarding intensity and collected long term follow up data. No procedure was sufficient to show improvements beyond the normal developmental curves.[19] In light of the high costs for the robotic device, further investigations are needed comparing different types of functional therapies as *i.e.* conventional body weight supported treadmill therapy and robotic assisted treadmill therapy in a randomized approach. No general recommendations are yet available for either method making them not easy to compare. Trials involving similar patient groups with respect to age, impairment and diagnosis exhibit motor improvements comparable to the findings in robotic assisted treadmill therapy. However, relevant differences in treatment protocols and outcome measures exist between these studies making a comparison difficult.[5, 6, 8] For both methods, active participation of the patient is desirable. Cooperative strategies aim to enable the patients to contribute as much as possible to gait cycle. While the DGO provides a visual real time biofeedback system in three different graphical representations using the force sensors readily adaptable to adults,[21] the child's attention to this program lasts not longer than some minutes from our experience. For this reason, the patients were allowed to watch their favourite cartoon on a DVD at the point when neither verbal enhancement by the therapist to step actively nor the biofeedback system made the patient to walk longer. Thus, one might speculate that besides modulation of supraspinal motor control as well modulation of central pattern generators may play a role in the improvements achieved. In addition, the gain of endurance might support the hypothesis of changes in hemodynamic parameters (*i.e.*, energy consumption).[22] We state that continuing the therapy by allowing the children to watch a cartoon (after active participation could not be reached anymore) increased the applied dosage (*i.e.*, meter per session walked) of the intervention. This is believed to be justiefiebale as dose dependency is also an important concept of neurorehabilitation. Nevertheless, the importance of active participation during the learning of a motor task must be appreciated in the future and the implementation of more advanced and child adapted biofeedback systems in robotic-assisted treadmill therapy is an important next step in gait therapy for children. Recently, some efforts have been made to develop more advanced and child adapted biofeedback systems with enriched environments connected to the robotic device.[23, 24]

Some limitations of the present study must be acknowledged. First, the study was performed in single group design with pre and post evaluations without a control group. We, therefore, cannot exclude the impact of natural course of ongoing development on the results. However, the course of predictive developmental curves of motor performance suggests that the improvements are beyond the normal developmental curve.[17, 20] Second, the therapy during the follow up period was not standardized. The term regular physiotherapy as it was used in that context might have a wide definition. However, it most commonly based on regimes established by Bobath in our cohort. Third, the selection of patients was homogenous with the exception of one patient suffering from spinal paralysis. However, this may not necessarily change the trend that motor performance achieved after DGO therapy is sustained six months after the intervention in patients with central gait impairment; but a more homogenous group (*i.e.*, only patients with bilateral spastic cerebral palsy) in a randomized controlled approach is mandatory for further studies.

Conclusions

In summary, robotic-assisted treadmill therapy was easily performed in an outpatient setting in 14 patients with central gait disorders. Appreciable changes in motor performance after participation in a relatively short program of robotic-assisted treadmill therapy can be achieved and there is a sustainability of this effect over a period of 6 months. The improvement of gait parameters indicates that the paradigm of task-specific learning is adaptable to children with central gait disorders who never learned a normal physiological gait pattern. Superiority of this approach compared to other functional therapies cannot be extrapolated from this data.

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