#### **CME Objectives:**

Upon completion of this article, the reader should be able to: 1) Identify the leading cause of gait impairments in children with Cerebral Palsy; 2) Describe the potential benefits of repetitive locomotor training on gait mechanics in children with Cerebral Palsy; 3) Describe the potential effects of repetitive locomotor training on disability and energy expenditure during gait in children with Cerebral palsy.

#### Level: Advanced

**Accreditation:** The Association of Academic Physiatrists is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Association of Academic Physiatrists designates this activity for a maximum of 1.5 *AMA PRA Category 1 Credit(s)*<sup>TM</sup>. Physicians should only claim credit commensurate with the extent of their participation in the activity.

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Gait

CME ARTICLE • 2011 SERIES • NUMBER 2

## Improved Gait After Repetitive Locomotor Training in Children with Cerebral Palsy

### ABSTRACT

Smania N, Bonetti P, Gandolfi M, Cosentino A, Waldner A, Hesse S, Werner C, Bisoffi G, Geroin C, Munari D: Improved gait after repetitive locomotor training in children with cerebral palsy. Am J Phys Med Rehabil 2011;90:137–149.

**Objective:** The aim of this study was to evaluate the effectiveness of repetitive locomotor training with an electromechanical gait trainer in children with cerebral palsy.

**Design:** In this randomized controlled trial, 18 ambulatory children with diplegic or tetraplegic cerebral palsy were randomly assigned to an experimental group or a control group. The experimental group received 30 mins of repetitive locomotor training with an applied technology (Gait Trainer GT I) plus 10 mins of passive joint mobilization and stretching exercises. The control group received 40 mins of conventional physiotherapy. Each subject underwent a total of 10 treatment sessions over a 2-wk period. Performance on the 10-m walk test, 6-min walk test, WeeFIM scale, and gait analysis was evaluated by a blinded rater before and after treatment and at 1-mo follow-up.

**Results:** The experimental group showed significant posttreatment improvement on the 10-m walk test, 6-min walk test, hip kinematics, gait speed, and step length, all of which were maintained at the 1-mo follow-up assessment. No significant changes in performance parameters were observed in the control group.

**Conclusions:** Repetitive locomotor training with an electromechanical gait trainer may improve gait velocity, endurance, spatiotemporal, and kinematic gait parameters in patients with cerebral palsy.

**Key Words:** Development, Robotics, Rehabilitation, Brain Damage, Walking, Randomized Control Trial

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#### **Disclosures:**

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**C**erebral palsy (CP) describes a group of chronic conditions affecting body movement and muscle coordination caused by damage to one or more areas of the brain, usually occurring during fetal development or infancy.<sup>1</sup> The motor disorders of CP are often accompanied by disturbances of sensation, cognition, communication, perception, behavior, and/or a seizure disorder.<sup>2</sup> One of the most disabling mobility impairments in CP is gait impairment, clinically characterized by reduced speed and endurance, as well as reduced step, stride length, and toe clearance during gait.<sup>3,4</sup>

Recently, gait rehabilitation methods in patients with neurologic impairment have relied on technological devices, which drive the patient's gait in a body-weight support condition and emphasize the beneficial role of repetitive practice.<sup>5</sup> The rationale for these approaches originates from animal studies, which have shown that repetition of gait movements may enhance spinal and supraspinal locomotor circuits.<sup>6</sup>

Previous studies in gait rehabilitation in patients with CP were carried out by using partial body-weight support treadmill training (PBWSTT) and robotic-assisted treadmill therapy. Most of these studies consisted of single-case, small, or unselected patient samples and/or uncontrolled trials.7-11 In a recent randomized control trial study, Willoughby et al.<sup>12</sup> showed that PBWSTT was no more effective than overground walking for improving walking speed and endurance in children with CP. They concluded that the progressive reduction of body-weight support along with the addition of concurrent overground walking practice to a treadmill training protocol may increase the intensity of training and assist with carryover of improvements to overground walking.<sup>12</sup> Despite their potential, these technologies have practical limitations in their routine application: PBWSTT requires the assistance of one or two physiotherapists to control the patient's weight shift and lower limb position during training,<sup>13</sup> and proper placement of the patient onto the machine (Lokomat; Hokoma Inc, Volketswill, Switzerland) for roboticassisted treadmill training is time-consuming.<sup>14</sup>

More recently, several studies have focused on the use of a new electromechanical gait trainer (Gait Trainer GT I; Reha-Stim, Berlin, Germany)<sup>15</sup> in adult patients who have experienced a stroke. These studies have shown that training with this device may significantly improve gait performance.<sup>16,17</sup> Despite the clinical impact of this new rehabilitative procedure, to date, no studies have been conducted on its use in children with CP.

The primary aim of the present randomized controlled trial was to evaluate whether repetitive locomotor training with the Gait Trainer GT I can improve walking speed and endurance in tetraplegic or diplegic ambulatory children with CP. The secondary aim was to assess whether training can also have a positive impact on kinematic and spatiotemporal gait parameters and on disability.

## MATERIALS AND METHODS Subjects

Eighteen participants were recruited among 31 children with CP attending the Developmental Age Unit, "C. Santi," Polyfunctional Centre Don Calabria, Verona, Italy, from January 2009 to October 2009.

Inclusion criteria were bilateral lower limb (diplegic or tetraplegic) CP, 10 to 18 yrs of age, and Gross Motor Function Classification System<sup>18</sup> levels II to IV. The children needed to walk by themselves or with the use of an assistance device for at least 10 m, maintain a sitting position without assistance, follow instructions, and participate in the rehabilitative program. Exclusion criteria were lower limb spasticity of >2 or higher on the Modified Ashworth Scale,<sup>19</sup> severe lower limb contractures, cardiovascular diseases, orthopedic surgery or neurosurgery in the past 12 mos, or Botulinum toxin injections within 6 mos before the beginning of the study. Before the start of the study, participants were allocated to the experimental group or the control group via computerized randomization. The randomization sequence was generated by a research assistant not involved with the study, and the group allocation was concealed using sealed, numbered envelopes. The randomization list was locked in a desk drawer accessible only to the principal investigator.<sup>20</sup>

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Written informed consent was obtained from the children's parents and the children themselves. The ethics committee of the Department of Neurological and Vision Sciences, University of Verona, approved the study protocol.

#### Training

Before the start of the study, the authors designed experimental and control group treatment protocols and instructed two physiotherapists in their use. One physiotherapist treated the experimental group and the other treated the control group. The participants were treated individually on an outpatient basis in a rehabilitative gym at the C. Santi Medical Centre.

Both training programs consisted of ten 40-min daily sessions for 2 wks (5 days/wk).

During the study period, participants received no physiotherapy other than that scheduled in the study protocol.

#### **Experimental Group Training**

Each participant received 30 mins of repetitive locomotor therapy on the Gait Trainer GT I, followed by 10 mins of passive joint mobilization and stretching exercises by a physiotherapist.

#### The Gait Trainer GT I

The gait trainer consists of a double crank and rocker gear system, composed of two footplates positioned on two bars (coupler), two rockers, and two cranks that provide the propulsion. While using the gait trainer, individuals are secured in a harness and positioned on two footplates, whose movements simulate stance and swing phase, with a ratio of 60% to 40% between the two phases.<sup>15</sup> A servocontrolled motor assists gait movement by controlling the gear velocity and comparing it with the preselected velocity. The rotation of the planetary gear system, equaling one gait cycle, controls the movement of the center of mass (CoM) in the vertical and horizontal directions. Two cranks, one for the vertical and one for the horizontal movement CoM control, are attached to the planetary gear system. A transmission gear installed between the planetary gear and the crank controlling the vertical CoM displacement provides a double frequency of the vertical CoM movement within one gait cycle. A rope attached to the crank controlling the vertical CoM displacement served as the central suspension of the subject. A second rope connected to the crank controlling the horizontal CoM displacement was attached to the left lateral aspect of the subject harness at the level of the pelvic crest (Fig. 1).<sup>15</sup>



FIGURE 1 Training of a 6-yr-old on the Gangtrainer GT I.

#### **Training Procedures**

The child was positioned on the gait trainer. Step length and gait speed were individually set according to the gait parameters recorded at the pretreatment gait analysis. Walking speed was gradually increased over the course of the 2 wks if the children completed the last previous training session without discomfort or complaints of fatigue. The partial body-weight support was progressively decreased from 30% to 0% over the duration of the sessions. The criterion for the reduction was the child's ability to avoid his/her knee collapsing into flexion during the stance phase because of the increased load of body weight. Each participant was supervised during therapy sessions by only one physiotherapist who corrected knee motion manually, when needed. No patients required the assistance of two physiotherapists. The machine was stopped if pain or other problems such as muscle cramps occurred.

#### **Control Group Training**

Conventional training consisted of the repetition of three different sets of exercises: (1) passive joint mobilization and stretching of the lower limb muscles with the patient lying on a physiotherapy mat in the supine position; (2) strengthening exercises, including leg-press exercises and sit-tostand and stand-to-sit exercises. In the first session,

the correct performance of the leg-press exercise required strict supervision by the physiotherapist: the participants lay in the supine position and were asked to slowly push their feet against the physiotherapist's chest and to slowly bend them back again; in the subsequent sessions, these exercises were performed by using a leg-press machine with resistance specifically adapted for the child's ability; (3) balance and gait exercises. The balance exercises were carried out with the participant sitting on a bench and in the standing position, with a front support or against a wall. Gait exercises consisted of guided ground walking (e.g., side stepping) with the assistance of the physiotherapist. Each set of exercises lasted 10, 15, and 15 mins, respectively. During the entire sessions, the physiotherapist stood near the children to ensure safety and prevent potential falls.

#### Testing

Before and after treatment and at 1-mo followup, the participants were evaluated by the same examiner who was unaware of treatment allocation. The assessment procedures, consisting of clinical and instrumental evaluations, were carried out at the C. Santi Medical Centre: the clinical tests took place in a spacious and silent environment to avoid the child potentially becoming distracted, whereas the instrumented evaluations were conducted in the Gait Analysis Laboratory. All the assessments were administered in the same sequence (clinical and instrumented evaluations) and at the same time of day, in the afternoon, around 3 p.m. During testing, the participants were allowed to wear their usual footwear and orthoses and use their gait-assistive devices.

#### **Primary Outcomes** 10-m Walk Test:

This is a validated test for the clinical evaluation of walking speed.<sup>21</sup> The subject was asked to walk at her/his self-selected walking speed along the central 10 m of a 14-m linoleum-covered walkway. A digital stopwatch was used to time the walks.

#### 6-Min Walk Test:

This is a validated test for the clinical evaluation of walking endurance that involves respiratory, cardiovascular, skeletal, nervous, and muscular system competences/skills.<sup>22</sup> The subject was asked to walk at her/his self-selected walking speed in the gym along an oval track 20 m in length marked out with masking tape. The distance walked during the test was calculated with a tape measure.

#### Secondary Outcomes Functional Independence Measure for Children (WeeFIM):

This widely used scale for the evaluation of disability in children with  $CP^{23}$  investigates three main domains: self-care, mobility, and cognition (score, 18–126; high, best performance).

#### Gait Analysis:

Three-dimensional gait analysis (Vicon; Oxford Metrics, Oxford, UK) by means of a motion capture system consisting of six infrared cameras was carried out according to a standard marker placement protocol.<sup>24</sup> The participants were required to walk at their self-selected speeds. The data from at least four trials were collected. The gait parameters were sagittal plane kinematics (joint angles of the hip, knee, and ankle at initial contact; middle stance; and initial swing and middle swing) and spatiotemporal gait parameters (speed, cadence, and step length).

#### **Statistical Analysis**

We calculated effect sizes between the two independent groups (Cohen d) and used 95% confidence intervals. Because our data were not normally distributed (after visual and descriptive inspection), we used nonparametric tests for inferential statistics. The Mann-Whitney U test was used for testing differences between groups at baseline, the Friedman test was used to analyze changes in performance within groups, and Wilcoxon's signed rank tests were used to compare changes between groups from pretreatment/posttreatment and pretreatment/ follow-up measures. The Mann-Whitney U test was used for between-group comparisons. For this purpose, we computed the differences  $(\Delta)$  between pretreatment and posttreatment performance and between pretreatment and follow-up performance for all outcome measures. We set the alpha level for significance at 0.05; however, to adjust for multiple comparison, we used a Bonferroni<sup>25</sup> correction ( $\alpha = 0.025$ ). All statistical analysis was carried out using the SPSS for Macintosh statistical package, version 16.0.

#### RESULTS

No children withdrew from the study. Participant demographics and clinical characteristics are reported in Table 1.

At baseline, there were no statically significant differences between the two groups in age, performance on the 10-m walk test and the 6-min walk test, or WeeFIM scores (age, Z = -0.13, P = 0.89; 10-m walk test, Z = -0.08, P = 0.93; 6-min walk

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	-										
			10-m \	Walk Test,	m/sec	6-M	in Walk Test	, m		WeeFIM	
Sex Age, yr/mo Diagnosis	GMFCS	Walking Aids	Pre	Post	FU	Pre	Post	FU	Pre	Post	FU
F 11 ST F 11/1 ST M 14/4 ST M 14/4 SD F 13/2 SD F 13/2 SD F 10/1 SD F 13/2 SD M 17/6 ST F 10/1 SD M 17/8 SD M 17/8 SD F 15/4 SD F 15/4 SD F 15/4 SD F 15/4 SD F 15/4 SD F 15/8 S	I     I       I     I       I     I       I     I       I     I       I     I       I     I       I     I       I     I       I     I       I     I       I     I       I     I       I     I       I     I       I     I       I     I	None Walker None None None Walker None Walker, AFO None None Walker, AFO None Walker, AFO None Walker, AFO None None None Streatment;	0.99 0.76 1.35 1.12 1.12 1.10 0.83 0.53 0.53 0.53 0.53 0.53 0.53 0.53 0.5	1.05 0.77 1.54 1.54 1.16 1.32 0.68 0.68 0.68 0.68 0.63 0.63 0.63 0.63 0.91 0.63 0.91 0.91 0.91 0.91 0.92 0.91 0.63 0.88 0.93 0.88 0.93 0.63 0.63 0.63 0.77 0.63 0.63 0.63 0.63 0.63 0.63 0.63 0.63	$\begin{array}{c} 1.18\\ 0.75\\ 1.59\\ 1.59\\ 1.45\\ 0.77\\ 0.96\\ 0.60\\ 0.77\\ 0.60\\ 0.77\\ 0.54\\ 0.60\\ 0.60\\ 1.59\\ 0.60\\ 1.59\\ 0.39\\ 0.88\\ 0.88\\ 0.88\\ 0.88\\ 0.88\\ 0.88\\ 0.88\\ 0.88\\ 0.88\\ 0.88\\ 0.88\\ 0.88\\ 0.39\\ 1.10\\ 0.39\\ -1.10\\ 0.39\\ -1.10\\ 0.39\\ -1.10\\ 0.72\\ 0.$	308 205 451 451 400 368 302 300 90 414 300 90 451 322 317 403 317 403 317 319 317 322 319 317 322 319 317 318 322 317 318 322 318 317 318 322 318 317 322 318 322 318 322 317 322 317 322 322 317 322 322 322 317 322 322 322 322 322 322 322 322 322 32	393 262 590 462 442 362 360 180 590 378 180 590 370 370 331 284 284 290 312 332 331 331 331 331 331 331 331 331	395 550 550 462 462 423 378 190 190 386 190 386 186 550 186 550 318 318 318 318 318 318 318 318 318 319 318 319 319 319 317 322 317 319 319 316 316 560 0000000000000000000000000000000000	$\begin{array}{c} 115\\ 85\\ 94\\ 117\\ 85\\ 62\\ 112\\ 62\\ 102\\ 62\\ 102\\ 62\\ 117\\ 86\\ 111\\ 86\\ 111\\ 86\\ 111\\ 86\\ 111\\ 86\\ 111\\ 86\\ 111\\ 88\\ 111\\ 84\\ 112\\ 88\\ 112\\ 83\\ 83\\ 83\\ 94\\ 112\\ 84\\ 112\\ 84\\ 84\\ 112\\ 83\\ 83\\ 83\\ 94\\ 117\\ 84\\ 112\\ 84\\ 112\\ 84\\ 112\\ 83\\ 83\\ 83\\ 94\\ 117\\ 30\\ 84\\ 117\\ 84\\ 117\\ 84\\ 117\\ 84\\ 117\\ 84\\ 117\\ 84\\ 117\\ 84\\ 117\\ 84\\ 117\\ 117\\ 84\\ 117\\ 117\\ 117\\ 117\\ 117\\ 117\\ 117\\ 11$	$\begin{array}{c} 116\\ 85\\ 94\\ 117\\ 85\\ 63\\ 104\\ 62\\ 63\\ 104\\ 62\\ 104\\ 62\\ 117\\ 86\\ 112\\ 86\\ 112\\ 86\\ 112\\ 86\\ 112\\ 86\\ 112\\ 88\\ 112\\ 88\\ 113\\ 84\\ 113\\ 86\\ 94\\ 113\\ 86\\ 94\\ 113\\ 86\\ 94\\ 113\\ 86\\ 94\\ 113\\ 86\\ 94\\ 113\\ 86\\ 94\\ 113\\ 86\\ 94\\ 113\\ 86\\ 113\\ 86\\ 113\\ 86\\ 113\\ 86\\ 113\\ 86\\ 113\\ 86\\ 113\\ 86\\ 113\\ 86\\ 113\\ 86\\ 113\\ 86\\ 113\\ 86\\ 113\\ 86\\ 113\\ 122\\ 122\\ 122\\ 122\\ 122\\ 122\\ 122$	$\begin{array}{c} 116\\85\\85\\85\\84\\117\\84\\116\\63\\63\\104\\82\\104\\86\\117\\86\\117\\86\\112\\86\\117\\86\\117\\88\\113\\82\\81\\113\\82\\82\\83\\83\\83\\83\\83\\83\\83\\83\\83\\83\\83\\83\\83\\$
<ul> <li>174M</li> <li>13/88</li> <li>2.83</li> <li>2.84</li> <li>80</li> <li>80<td>IV III III III IV IV V V V V V V V V V</td><td>Walker, AFO Walker, AFO None None Walker Walker, AFO Walker, AFO Walker, AFO Walker, AFO Sune None</td><td>0.89 0.27 0.53–1.35 0.39 0.39 0.91 0.83 1.10 1.12 1.11 1.12 1.11 1.00 0.57 0.69 0.69 0.69 0.69 0.69 0.69 0.57 0.69 0.57 0.57 0.57 0.57 0.57 0.57 0.53 0.53 0.53 0.53 0.53 0.53 0.53 0.53</td><td>0.97 0.31 0.63-1.54 0.389 0.89 0.84 0.92 1.11 1.02 0.84 0.91 0.63 0.72 0.63 0.72 0.63 0.72 0.32 0.32 0.32 0.38-1.11</td><td><math display="block">\begin{array}{c} 1.01\\ 0.36\\ 0.60-1.59\\ 0.39\\ 0.38\\ 0.88\\ 0.88\\ 0.88\\ 0.84\\ 0.92\\ 1.10\\ 1.02\\ 0.85\\ 0.85\\ 0.62\\ 0.72\\ 0.72\\ 0.72\\ 0.72\\ 0.39-1.10\\ 0.39-1.10\\ 0.21\\ 0.39-1.10\\ 0.21\\ 0.39-1.10\\ 0.21</math></td><td>292 121.44 90-451 321 322 319 403 259 403 259 41.3 259-403 259-403 550, spastic c</td><td>360 128.71 180–590 403 312 312 284 290 284 290 321 321 321 321 33.60 321 33.60 270–403 iplegic; AFO, i</td><td>361 120.81 186–550 400 314 314 318 318 318 318 318 318 318 318 318 318</td><td>62–1 1 1 1 62– 62– 10sis.</td><td>92.66 20.94 117 111 111 111 111 112 88 88 88 88 88 88 88 83 83 83 83 83 83</td><td>92.66 93.44 17 62–117 86 85 86 11 112 85 86 94 117 84 84 17 117 84 84 17 117 83 83 83 85 94 17 17 84 84 84 84 13 13 85 94 117 13 85 94 117 117 85 85 94 117 117 85 85 94 117 117 85 85 85 85 85 85 85 85 85 85</td></li></ul>	IV III III III IV IV V V V V V V V V V	Walker, AFO Walker, AFO None None Walker Walker, AFO Walker, AFO Walker, AFO Walker, AFO Sune None	0.89 0.27 0.53–1.35 0.39 0.39 0.91 0.83 1.10 1.12 1.11 1.12 1.11 1.00 0.57 0.69 0.69 0.69 0.69 0.69 0.69 0.57 0.69 0.57 0.57 0.57 0.57 0.57 0.57 0.53 0.53 0.53 0.53 0.53 0.53 0.53 0.53	0.97 0.31 0.63-1.54 0.389 0.89 0.84 0.92 1.11 1.02 0.84 0.91 0.63 0.72 0.63 0.72 0.63 0.72 0.32 0.32 0.32 0.38-1.11	$\begin{array}{c} 1.01\\ 0.36\\ 0.60-1.59\\ 0.39\\ 0.38\\ 0.88\\ 0.88\\ 0.88\\ 0.84\\ 0.92\\ 1.10\\ 1.02\\ 0.85\\ 0.85\\ 0.62\\ 0.72\\ 0.72\\ 0.72\\ 0.72\\ 0.39-1.10\\ 0.39-1.10\\ 0.21\\ 0.39-1.10\\ 0.21\\ 0.39-1.10\\ 0.21$	292 121.44 90-451 321 322 319 403 259 403 259 41.3 259-403 259-403 550, spastic c	360 128.71 180–590 403 312 312 284 290 284 290 321 321 321 321 33.60 321 33.60 270–403 iplegic; AFO, i	361 120.81 186–550 400 314 314 318 318 318 318 318 318 318 318 318 318	62–1 1 1 1 62– 62– 10sis.	92.66 20.94 117 111 111 111 111 112 88 88 88 88 88 88 88 83 83 83 83 83 83	92.66 93.44 17 62–117 86 85 86 11 112 85 86 94 117 84 84 17 117 84 84 17 117 83 83 83 85 94 17 17 84 84 84 84 13 13 85 94 117 13 85 94 117 117 85 85 94 117 117 85 85 94 117 117 85 85 85 85 85 85 85 85 85 85

			Pre-Post			Pre-1 Mo FU	
	Group	95% CI, Mean (LB; UB)	Effect Size (BG)	P(Z)	95% CI, Mean (LB; UB)	Effect Size (BG)	P(Z)
10-m WT	Experimental	-0.08(-0.14; -0.02)	0.558	$0.008 (-2.67)^{a}$	-0.12(-0.21; -0.02)	0.644	$0.011 (-2.54)^{a}$
	Control	$0.02 \ (0.01; -0.06)$		$0.214 \ (-1.24)$	0.03 (0.01; 0.08)	a La C	$0.314 \ (-1.00)$
0-min W I	Experimental Control	-06.78 ( $-94.73$ ; $-42.82$ ) -0.67 ( $-45.92$ , $44.59$ )	0.438	0.008 (-2.00)	-09.33 ( $-90.04$ ; $-48.03$ ) -0.56 ( $-43.13$ ; 42.02)	0.474	0.008 (-2.66)
WeeFIM	Experimental	-0.78(-1.85; 0.29)	0.027	0.109(-1.60)	-0.78(-1.85; 0.29)	0.027	0.109(-1.60)
	Control	-0.22 $(-0.56; 0.12)$		0.157(-1.4)	-0.22 $(-0.56$ ; $0.12)$		0.157(-1.4)
Hip							
Initial contact	Experimental	$0.78 \ (-0.62; 2.20)$	0.192	0.109 (-1.60)	$2.71 \ (-1.88; \ -3.53)$	-0.12	$0.008 (-2.66)^{a}$
Middle stance	Exnerimental	2.02 (-2.12; 2.22) 2.02 (0.94: 3.1)	-0.023	0.214 (-1.24) $0.011 (-2.54)^{a}$	0.13 (-2.03; 2.34) 3.18 (1.11; 5.27)	-0.210	$(0.008 (-2.66)^{a}$
	Control	$0.22 \ (-0.03; 0.49)$		0.008 (-1.71)	0.091 (-0.21; 0.39)		0.441 (-0.77)
Initial swing	Experimental	0.93 $(0.03; 1.84)$	0.025	$0.024 (-2.24)^{a}$	2.25(0.92; 3.4)	0.114	$0.008 (-2.66)^a$
	Control	$0.08 \ (-0.01; \ 0.18)$		0.86(-1.71)	$0.01 \ (-0.40; \ 0.40)$		0.767 (-0.29)
Middle swing	Experimental	3.23 (0.13; 6.33)	-0.356	0.051 (-1.95)	3.32 (0.12; 6.76)	-0.335	0.066(-1.83)
17	Control	0.23 (-0.43; 0.89)		0.484 (-0.70)	-0.09(-0.34; 0.36)		0.374 (-0.89)
nnee	-					0 V V	1010 / 2100
Initial contact	Experimental	1.00(-2.33; 5.08)	-0.550	(21.1 - 0.249)	-0.46(-0.44; 5.54)	0.043	(01.0 - 1.01) (-0.10)
Middle stance	Collitoi Fynerimental	-0.02 (-0.23; 0.21) 1 82 (-0 47: 4 12)	-0.169	(00.0-) 411.0	-0.01(-0.25, 0.10) -0.17(-3.30, 9.953)	0.019	(16.1 - 121) 161.0
TIMUL JUNIT	Control	-0.12 ( $0.11$ ; $3.12$ )	01:0	0.130(-1.51)	-0.01(-0.18, 0.15)	01000	0.000 (-9.33)
Initial swing	Experimental	0.12 (-0.30, 0.03) 1.27 (-1.78; 4.34)	-0.045	(10.1 - 0.10)	2.38(-3.91; 8.67)	-0.158	0.735(-0.33)
D	Control	$0.07 \ (-0.11; \ 0.27)$		0.339(-0.95)	$0.11 \ (-0.06; \ 0.28)$	1	0.174(-1.36)
Middle swing	Experimental	2.06(-1.50; 5.61)	-0.116	0.172(-1.36)	$2.07 \ (-3.89; 8.05)$	-0.124	0.31 (-1.01)
	Control	-0.08(-0.25; 0.09)		0.349 (-0.93)	-0.03 (-0.20; 0.14)		0.776 (-0.28)
Ankle							
Initial contact	Experimental	2.83 (-1.64; 7.31) -0.06 (-0.41:0.28)	-0.371	0.285 (-1.06)	$3.04 \ (-1.8; 7.88)$ -0 14 (-0 46: 0 17)	-0.404	0.285 (-1.06)
Middle stance	CUILIUI Evensimental	0.00 ( 0.41, 0.40) 9 29 ( - 9 29:  - 2 46)	-0 363	0.973 (-1.00)	9.114(-0.140, 0.11) 9.20(-2.42, 10.02)	0 4 4 0	(10.0) $(-1.00)$
TALIANTE STATICE	Control	2.02(-2.02; -0.40) -0.08(-0.21; 0.04)	c0c.0_	0.167 (-1.38)	-0.21 ( $-0.32$ ; $-0.09$ )	-0.449	0.178(-1.09)
Initial swing	Experimental	1.88(2.72; -6.47)	-0.182	1.00(0.00)	1.98(-2.96; 6.92)	0.066	1.00(0.00)
	Control	-0.17 (-0.48; 0.15)		0.231 (-1.19)	$-0.17 \ (-0.43; \ 0.10)$		0.182(-1.33)
Middle swing	Experimental	2.69(-2.90; 8.28)	-0.250	0.109(-1.60)	2.71(-2.87; 8.29)	-0.244	0.144(-1.461)
	Control	-0.13(-0.25; -0.02)		0.036(-2.10)	-0.03(-0.17; 0.10)		0.570(-0.56)
Gait speed	Experimental	-0.05(-0.09; -0.01)	0.905	$0.028 (-2.19)^{4}$	-0.11 $(-0.16; -0.05)$	1.058	$0.008 (-2.26)^{a}$
	Control	$0.10 \ (0.07; 0.13)$		0.347 (-2.66)	0.10(0.07; 0.14)		0.198(-2.66)
Ladence	Experimental	0.70 (-4.36; 0.91) - $4.40 (-11.16; 0.18)$	107.0-	(90.0-) $(70.0)$	-1.53(-0.90; 5.54) -4.40(-11.16; 2.18)	cc0.0-	(20.0-) CIC.0
Sten length	Exnerimental	0.02 (0.4.0.00)	0 555	$0.024 (-2.25)^{a}$	$0.02 (0.04 \cdot 0.00)$	0.630	$0.111 (-2.53)^{a}$
ingun dass	Control	-0.0.1 ( $-0.02$ ; $0.00$ )		1 (0.00)	-0.01 (-0.03 -0.00)		1 (0.00)
D and 7 to Late	it mont boditucki onor	La Utilannada taat					
r allu z values v	, אבנה ומהווווושת ונטווו ר						
Pre, baseline; P(	st, posttreatment; FL	), follow-up; CI, confidence interval;	. LB, Iower bound; UB, upp	er bound; BG, between	groups; W1, walk test.		
<sup>a</sup> Statistically sig	nificant.						

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test: Z = -0.13, P = 0.89; WeeFIM, Z = -0.22, P = 0.82) (Table 1).

#### **Primary Outcomes**

In the experimental group, overall significant changes in performance in the different evaluation sessions were found in regard to all primary outcome measures (10-m walk test, df = 2, X = 11.56, P = 0.003; 6-min walk test, df = 2, X = 12.51, P = 0.001). Within-group comparisons showed that changes in performance were significant at both the posttreatment and follow-up evaluations (see Table 2 for details). In the control group, no significant changes in the primary outcome measures were found at any of the evaluation sessions (statistics in Table 2).

A between-group comparison showed that the effects of the experimental and the control treatments were significantly different in all primary outcome measures (see Table 3 for details).

#### **Secondary Outcomes**

No significant changes in WeeFIM scores were found in either group (see Table 2 for details).

In regard to gait analysis, the experimental group showed significant changes in the joint angles of the hip during initial contact, middle stance, and initial swing, as well as in gait speed and step length

TABLE 3         Comparison of treatment effects between the experimental and control groups					
	Pre-Post	Pre-1 Mo FU			
	P(Z)	P(Z)			
10-m WT	$0.007 (-2.69)^a$	$0.004 (-2.87)^a$			
6-min WT	$0.015(-2.43)^{a}$	$0.007 (-2.669)^a$			
WeeFIM	0.466(-0.72)	0.466(-0.72)			
Hip					
Initial contact	0.58(-1.89)	$0.005 (-2.78)^a$			
Middle stance	$0.009 (-2.60)^a$	$0.000 (-3.40)^a$			
Initial swing	0.03(-2.16)	$0.004 \ (-2.87)^a$			
Middle swing	0.85(-1.72)	$0.035 (-2.42)^a$			
Knee					
Initial contact	0.120(-1.55)	0.351(-0.93)			
Middle stance	0.529(-2.90)	0.855(-0.18)			
Initial swing	0.329(-0.97)	0.559(-0.58)			
Middle swing	0.045(-2.00)	0.184(-1.33)			
Ankle					
Initial contact	1.00(0.00)	0.380(-0.87)			
Middle stance	0.096(-1.66)	0.018(-2.37)			
Initial swing	0.236(-1.18)	0.466(-0.72)			
Middle swing	0.113(-2.48)	0.279(-1.08)			
Gait speed	$0.000 (-3.58)^a$	$0.000 (-3.58)^a$			
Cadence	0.145(-1.45)	0.757(-0.30)			
Step length	$0.004 \ (-2.89)^a$	$0.001 (-3.51)^a$			

from the Mann-Whitney U test.

Pre, baseline; Post, posttreatment; FU, follow-up.

<sup>a</sup>Statistically significant.

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Before-after comparisons showed improved hip extension at middle stance, initial swing, gait speed, and step length (see Table 2 for details). Beforefollow-up comparisons showed increased hip extension at different phases of the gait cycle and increased gait speed and step length. No changes in performance of the control group were seen (see Table 2 for details).

Between-groups analysis showed a significant difference in the rate of hip extension at different phases of the gait cycle, in gait speed, and in step length (see Table 2 for details).

#### DISCUSSION

Our results demonstrate that repetitive locomotor gait training with an electromechanical bodyweight support machine can significantly improve gait velocity and endurance in ambulatory children with diplegic and tetraplegic CP and that the improvements can be maintained for at least 1 mo posttreatment. Improvements were also seen in proximal lower limb gait kinematics and in spatiotemporal parameters (gait speed and step length). The results obtained displayed that the magnitude of treatment effect was small to medium among the primary outcomes, further supporting the value of our experimental approach. No changes were seen in disability. There was no adverse event that led to a missed training session. No joint pain or muscle spasms were reported during or after the GT I training program.

Our study showed that the children in the experimental group significantly improved their gait velocity after treatment (10-m walk test and gait analysis). There are several reasons for this effect of treatment. First, children showed significant posttreatment changes in hip kinematics in the sagittal plane, with increased hip extension during middle stance and initial swing. This may have been because of the fact that during training with the GT I machine, the footplates forced the children to extend their hips.<sup>15</sup> The leg movement imposed by the machine has a maximal fulcrum at the hip level, and backward pelvis displacements are blocked by a rear bar, thus forcing the patient to extend the hip joint. As a result, training might have progressively enhanced the extensibility of the hip flexor muscles and periarticular hip joint tissues, leading to increased hip movement. Another possible explanation for the improvement in gait velocity may have been the increased muscle strength present after training.<sup>26</sup> It has been demonstrated that muscle weakness is a primary limiting factor in ambulation in children with CP.<sup>26-28</sup> Although muscle strength was not specifically tested in this study, previous studies have shown that adult stroke patients trained with the GT I machine significantly increased their performance on the Motricity Index Test (lower limb section).<sup>13</sup> This effect on muscle strength is further confirmed by the fact that trained patients in previous studies usually experience a feeling of muscle fatigue after treatment, indicating that training on the GT I machine not only acts as a passive guide for movements but also requires active involvement of the lower limb muscles.<sup>15</sup>

A second main result of the present study was that the children in the experimental group had improved gait endurance after training. This improvement could have resulted from the previously described effects on gait kinematics and strength. However, a reduction in energy expenditure<sup>29</sup> related to the decrease in co-contraction muscle<sup>30,31</sup> and the improvement in movement efficacy during gait<sup>29</sup> may have also contributed to this improvement. This may lead to an optimization of cardiovascular performance. To date, no studies have investigated the effect of body-weight support gait-training approaches on energy expenditure in children with CP. Future research on this topic in the neuromotor rehabilitation of children with CP is needed.

The question arises as to the possible delayed effects of training. It is worth noting that at the 1-mo follow-up, the participants in the experimental group showed a trend toward continued improvement in gait kinematics and gait velocity. After training, the children may have been more motivated to practice gait during daily life activities. This hypothesis was supported by informal interviews conducted with the children's parents.

As shown by the WeeFIM results, the children in the experimental group showed no reduction in activities of daily life after training. Although gait is an important activity of daily life, this result may be explained by the fact that the WeeFIM is not sensitive enough to point out significant changes in the overall performance of activities of daily life. Furthermore, a potential ceiling effect may be an additional explanation of the small changes in score seen in children with higher scores in the WeeFIM.

No improvements in the primary and secondary outcomes were obtained in the control group. This could be because of the different level in the Gross Motor Function Classification System and in the gait-assistive devices required in the experimental and control group.

Most studies on body-weight support gaittraining techniques discuss the effects of PBWSTT and Lokomat robotic training. PBWSTT differs in several ways from the GT machine approach. The major disadvantage of PBWSST is that the trunk and the lower limbs are difficult to control during exercise. Hence, the more severe the mobility impairment, the more physical effort is demanded from the child. In addition, at least two physiotherapists are needed to assist trunk and limb movements during the gait cycle.<sup>13</sup> Two reviews<sup>7,8</sup> on the limited studies investigating the effect of PBWSTT on gait parameters in children with CP concluded that, currently, there is no evidence that children with CP benefit from PBWSTT. This lack of evidence was attributed to small sample size, disparate ability levels of participants, and low-quality experimental design.

A recently developed pediatric version of the Lokomat consists of a robotic-driven exoskeleton<sup>11</sup> that moves the lower limbs to reproduce normal walking. Lower limb movements are synchronized with a treadmill. The few studies examining the effect of this device on children with CP demonstrated positive effects on gait velocity and endurance in clinical tests.<sup>9–11</sup> However, these studies were limited because of small sample size, lack of a randomized control trial design, and lack of instrumental evaluations.

Some limitations of the present study must be acknowledged. First, no measure of muscle strength, energy expenditure, or quality-of-life was performed. Second, a longer session time (1 mo) could have led to a more significant improvement in children performances. Third, the fact that only one physiotherapist treated the control group and only one physiotherapist treated the treatment group makes it difficult to determine if group differences are related to the interventions or rather to a characteristic of the assigned therapist. Fourth, a great variability in the Gross Motor Function Classification System scores was evident in our sample of patients. Finally, a longer follow-up period (3-6 mos) is needed to determine the longterm effects of a gait-training program with this device. Nonetheless, our results strongly suggest that repetitive locomotor training on a bodyweight support electromechanical machine may improve gait speed and endurance in children with CP.

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## **CME Self-Assessment Exam Questions**

#### CME Article 2011 Series Number 2: N. Smania, et al.

- 1. In this study, which was used for repetitive locomotor training in children with Cerebral Palsy?
  - A. A robotic-driven exoskeleton
  - B. A treadmill device
  - C. An electromechanical body-weight support gait trainer
  - D. Lower limbs orthoses
- 2. In this study, which of the following may explain the velocity improvements after repetitive locomotor training?
  - A. Increased hip extension during the middle stance and initial swing
  - B. Increased knee flexion during swing phase
  - C. Decreased ankle dorsiflexion during swing phase
  - D. Increased ankle dorsiflexion during stance phase
- 3. Which of the following represent the scientific rationale for repetitive locomotor training in gait rehabilitation?
  - A. Repetition of gait movements may enhance supraspinal circuits
  - B. Repetition of gait movements may enhance spinal and supraspinal locomotor circuits

- C. Repetition of gait movements may increase the primary motor cortex excitability
- D. Repetition of gait movements may decrease lower limb spasticity
- 4. Which of the following represent gait impairment in children with Cerebral Palsy?
  - A. Increased step, stride length, toe clearance, gait speed and endurance.
  - B. Increased ankle dorsiflexion during phases of gait
  - C. Reduced step and stride length, toe clearance, gait speed and endurance.
  - D. Increase hip flexion, stride length, toe cleareance and endurance
- 5. In this study the improvement in gait endurance seen
  - in the experimental group may result from
  - A. Improved gait mechanics
  - B. Improved strength
  - C. Improved movement efficiency and reduction of energy expenditure
  - D. All of the above.

(Continued next page)

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