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Abstract

Introduction: Cerebral palsy is the most common cause of disability among children. The main concerns of parents are the acquisition and improvement of gait. The aim of this study was to compare long-term results of the effect of two modalities of gait training.

Methods: Quantitative measurement of gait and clinical assessment of the gross motor function classification system and Modified Ashworth Scale were performed in 14 patients with cerebral palsy/spastic hemiplegia. Subjects were randomly assigned to two treatment groups: the first one using a driven gait orthosis (Lokomat) and the second, gait training on a long a rail within a hydrotherapy tank. Measurements and assessments as described above were performed immediately and 1 year after conclusion of treatment.

Results: A significant change was observed according to the gross motor function classification system (GMFCS) from II to I among children ($p = 0.042$) and a positive correlation between the functional shape of the gait and the GMFCS ($r = 0.54$, $p = 0.042$). Patients on Lokomat training improved on gait symmetry over patients on conventional therapy ($p \leq0.05$). After a 1-year follow-up, this intervention showed a tendency to retain the gait patterns only in patients treated with the Lokomat.

Conclusions: Benefit obtained with either modality was evident for both groups. However, residual effects observed in the group treated with the Lokomat, either in clinical assessment or gait parameters, were more promising than for patients undergoing conventional therapy. Due to the sample size used in this study, results are inconclusive and further long-term research is needed on this subject.

Key words: cerebral palsy, driven gait orthosis.

Introduction

Cerebral palsy (CP) describes a group of developmental disorders of movement and posture that are attributed to nonprogressive disturbances occurring in the brain during the fetal or infant phase with limitations in activity and motor function that are most affected and with alterations in gait patterns that depended on the site of injury and type and severity of brain damage. Neuromuscular abnormalities predispose muscle contractures, bone torsional deformities, and dynamics due to muscular imbalance.

Spastic hemiparesis affects intermediate postural phase “swing” that is manifested in posture, balance and gait with decreased speed and stride length and merits a greater contact of the foot with the ground. Most patients have the ability to walk without restrictions, although fine motor activities are compromised, particularly for using stairs and traveling on uneven terrain. According to these concepts, patients with spastic hemiparesis are ambulatory and are placed within group II of the classification of gross motor function, referring to independent walking with difficulty in running, jumping or walking on uneven terrain, with or without use of orthoses. The ideal goal of treatment would consist of placement within group I of the classification of gross motor function that refers to the skills used for running, jumping, and moving over rough terrain.

The Lokomat robotic orthosis (Lokomat Hocoma, Völketswil, Switzerland) consists of an electronic treadmill...
Methods

This prospective study included children with spastic hemiparesis CP and who met the following criteria: 4–14 years of age, either gender, without visual or hearing impairment (normal or corrected), without cognitive deficits and/or conduct disorders, and type II of the scale assessment of gross motor function. All subjects/guardians signed informed consent.

Patients were randomly assigned to either of the two treatment groups. Patients in the first group were subjected to a Lokomat orthosis robotic treatment whose management consisted of anthropometric measurements (weight, height, length of femoral and tibial segments, selection of harnesses) in an awareness session for use of orthoses, ten 30-min sessions for gait training using default settings for the equipment that was calculated based on weight, height and measurement of lower limb segments (femoral and tibial segment). A constant speed was adjusted with variations in the resistance provided by the orthosis treatment and the patient’s voluntary control. Patients in the second group received ten 30-min sessions with gait retraining in cycles within a therapeutic tank under the direction of a physical therapist and with the support of the patient’s caregiver.

Three evaluations were performed: 1) prior to beginning treatment, 2) at the end of the treatment and 3) 1 year after the initial assessment. Each patient in both groups was evaluated for clinical aspects that included lower limb muscle tone (modified Ashworth scale), gross motor function and spatiotemporal gait with the GaitRITE System. The following variables were analyzed: time differential between steps (expressed in seconds–STD) differential step length (expressed in centimeters–SLD), speed (cm/sec), gait cycle, stride length (cm) and stride (cm), and functional profile of the stride, which measures the gait efficiency and provides an overall score ranging from 0 to 100%, where 100% is the score that describes a highly efficient walk.

From the available electronic medical records in the intrahospital administration system, we obtained the information to develop a record of assessments and interventions conducted within areas of external consultation or treatment program in the intrahospital area during the period that included the term of the initial intervention and within 1 year of the final evaluation.

Descriptive and comparative statistics were used to identify significant differences between described, before and after treatment and between groups. We used Kolmogorov–Smirnov test to determine normality of the distributions and Wilcoxon test to compare spatiotemporal gait parameters. To quantify the degree of association we used Pearson and Spearman correlation tests, considering 95% CI; $p \leq 0.05$ was accepted as statistically significant.

Results

At the beginning of the study, patients had the following medical history: five patients (from from the Lokomat group and one from the therapeutic tank group) used an articulated ankle/foot orthosis. Three patients from the Lokomat group had a history of a surgical event in the affected lower limb (lengthening of the Achilles tendon) and four patients (one from the therapeutic tank group and three from the Lokomat group) had a history of an application of botulinum toxin to the affected lower limb during a time range of ≥6 months. Age distribution, gender, affected side, and type of treatment assignment are detailed in Table 1.

After treatment completion in all patients, clinical improvement was observed after changing the functional group from II to I of the scale measuring gross motor function in three patients of the group treated with Lokomat and one patient from the group treated with tank therapy ($p = 0.042$) (Figure 1). The affected ankle muscle tone improved in ten patients (five patients per group) at least one level of the modified Ashworth scale ($p = 0.008$) (Table 2). Kinematic analysis showed a significant improvement in the functional value profile of the gait (74.5% to 82.6%, $p = 0.024$), walking speed from 87.9 cm/sec to 75.08 cm/sec ($p = 0.008$) (Table 3). Overall, a significant correlation exists between the category of the rating scale of the gross motor function and the functional profile of gait ($r = 0.549, p = 0.042$).

In the patients assigned to the Lokomat group, ankle tone of the affected ankle was reduced in five patients ($p = 0.46$). The speed improved from 68.8 cm/sec (±48.6) to 65.8 cm/sec (± 8.3) ($p = 0.025$) and stride length of the left lower limb decreased from its initial value of 86.1 cm (±1.7) to 79.5 cm (±5.4) ($p = 0.025$). The percentage of the cycle of the intermediate postural phase improved, approaching values that correspond to a gait cycle without pathology of
45.8% (±13.6) of the gait cycle to 49.1% gait cycle (±11.8) 
\(p = 0.046\) of an expected 60% gait cycle. In addition, there 
was a correlation between the level of the rating scale of the 
gross motor function and functional profile of the resulting 
total sample \((r = 0.732, p = 0.039)\).

In patients from the therapeutic tank group, only chan-
ges in the tone of the affected ankle \((p = 0.050)\) and in the 
functional profile of the stride of 68.6% (±1.9) to 81.0% 
\((p = 0.026)\) were observed. In the remaining param-
eters, no statistically significant changes were observed  
(Table 3).

One year after the intervention was conducted, the total 
Lokomat group of patients \((n = 8)\) received follow-up visits 
for 1 year after treatment completion; 50% of the patients 
received an average of three outpatient visits per year and 
the remaining patients from the group received a variety of 
visits that ranged from one to four visits per year. Of this 
group of patients, 75% \((n = 6)\) were hospitalized within the 
Pediatric Unit for treatment with botulinum toxin. None of 
these patients was subjected to a surgical event during this 
time period.

At the end of the study, the number of patients using a 
variety of ankle–foot orthoses increased to five, indicating 
an increase of two patients using orthoses with respect to 
the three patients at the time of study initiation. Of the pa-
tients who were not hospitalized, one patient \((2.25\%)\) recei-
ved therapy within the institution for gait retraining.

Patients assigned to the therapeutic tank group had an 
assessment of values from outpatient evaluations that in-
creased to four, and only 33% of the patients \((n = 2)\) warran-
ted inpatient treatment for application of botulinum toxin; 
16.7% of the sample \((n = 1)\) warranted surgical treatment 
for a fixed deformity of the ankle affected in equinus (Achi-
illes tendon elongation). Half of the patients \((n = 3)\) used an 
ankle–foot orthosis at the end of the evaluation.

In the assessment conducted 1 year after treatment, 
positive or negative effects of intervention at initiation 
were compared at the end, without finding any statistically

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (years)</th>
<th>Gender</th>
<th>GMFCS</th>
<th>Treatment group</th>
<th>Side affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6</td>
<td>Female</td>
<td>II</td>
<td>Lokomat</td>
<td>Right</td>
</tr>
<tr>
<td>2</td>
<td>7</td>
<td>Female</td>
<td>II</td>
<td>Lokomat</td>
<td>Right</td>
</tr>
<tr>
<td>3</td>
<td>7</td>
<td>Female</td>
<td>II</td>
<td>Lokomat</td>
<td>Right</td>
</tr>
<tr>
<td>4</td>
<td>7</td>
<td>Female</td>
<td>II</td>
<td>Lokomat</td>
<td>Right</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>Male</td>
<td>II</td>
<td>Therapeutic tank</td>
<td>Right</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
<td>Male</td>
<td>II</td>
<td>Therapeutic tank</td>
<td>Right</td>
</tr>
<tr>
<td>7</td>
<td>6</td>
<td>Male</td>
<td>II</td>
<td>Therapeutic tank</td>
<td>Right</td>
</tr>
<tr>
<td>8</td>
<td>12</td>
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<td>II</td>
<td>Lokomat</td>
<td>Left</td>
</tr>
<tr>
<td>9</td>
<td>9</td>
<td>Male</td>
<td>II</td>
<td>Therapeutic tank</td>
<td>Right</td>
</tr>
<tr>
<td>10</td>
<td>4</td>
<td>Male</td>
<td>II</td>
<td>Therapeutic tank</td>
<td>Right</td>
</tr>
<tr>
<td>11</td>
<td>5</td>
<td>Female</td>
<td>II</td>
<td>Lokomat</td>
<td>Left</td>
</tr>
<tr>
<td>12</td>
<td>6</td>
<td>Male</td>
<td>II</td>
<td>Lokomat</td>
<td>Left</td>
</tr>
<tr>
<td>13</td>
<td>12</td>
<td>Male</td>
<td>II</td>
<td>Lokomat</td>
<td>Left</td>
</tr>
<tr>
<td>14</td>
<td>9</td>
<td>Female</td>
<td>II</td>
<td>Therapeutic tank</td>
<td>Left</td>
</tr>
</tbody>
</table>

GMFCS = Gross Motor Function Classification System.
significant effects. During the annual re-evaluation there was no persistent change in rating scale of the gross motor function of level II to level I in patients of group A, although the level of the rating scale of the gross motor function remains at level II for the total sample. We compared initial, immediate and end of treatment results to the results obtained during the annual assessment. The annual assessment showed that in none of the cases were results lower at the time of intake for each patient; nevertheless, there were no statistically significant results for the variables studied. Similarly, we studied the trend in these patients to maintain post-treatment changes with a finding of the highest stability according to the following gait analysis variables: functional profile of gait, time differential between steps (shown in seconds) and differential of path length (shown in centimeters).

In the initial assessment of the functional walking profile of patients treated with Lokomat, the average score obtained was 77.5% (±1.5) with improvement to 83.2% (±1.4) after the initial treatment. During the annual re-evaluation of the functional walking profile, the result was 87.3% (±1.3) in contrast with the initial gain of patients treated in the therapeutic tank (68.6% ±1.9 to 80.2% ±1.4) and for functional gait profile at the end of 1 year of 82.6% (±7.0) (Figure 2).

As for the differential time between steps, Lokomat-treated patients had an average of 0.44 sec (±0.9) vs 0.43 sec (±0.7) in patients with therapeutic tank treatment. Initial improvement was most evident for patients with conventional therapy with a time differential between steps of 0.12 sec (±0.1) vs. 0.23 sec (±0.2) than patients in the other group; however, after the annual re-evaluation these patients showed a tendency to have a time differential between lower steps than the initial intervention with 0.16 sec (±0.1) vs. 0.21 sec (±7.6) of the patients in the therapeutic tank group (Figure 3).

In the case of the differential of the stride length, pre-intervention results for the Lokomat group were 21.6 cm (±5.2) and 33.9 cm (±5.6) for those treated in the therapeutic tank. After treatment we observed a decrease in the case of differential stride length, indicating greater symmetry during walking with 7.2 cm (±7.4) and 9.1 cm (±7.6) per group. Again, the trend in this case is the gradual decrease from baseline in patients treated with Lokomat with results of 4.9 cm (±5.7) and 9.1 cm (±7.1) for each group (Figure 4). For the remaining variables, it was not possible to determine a statistically significant trend, particularly in the case of stride length and symmetry of the gait cycle as observed after the initial treatment.

### Table 2. Improvement in muscle tone of the affected ankle at the end of treatment according to group studied

<table>
<thead>
<tr>
<th>Muscle tone (MAS)</th>
<th>Lokomat (n = patients)</th>
<th>Therapeutic tank (n = patients)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0.008</td>
</tr>
<tr>
<td>1</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>1+</td>
<td>5</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

MAS, modified Ashworth scale, not including gradations 3 and 4 of the scale that implied fixed deformities and/or severe limitation of articular range evaluated.

### Table 3. Changes in gait analysis according to treatment group

<table>
<thead>
<tr>
<th></th>
<th>Lokomat</th>
<th>Therapeutic tank</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Average (± SD)</td>
<td>p Value</td>
</tr>
<tr>
<td></td>
<td>Initial</td>
<td>Final</td>
</tr>
<tr>
<td>Velocity (cm/sec)</td>
<td>68.8 (48.6)</td>
<td>65.8 (8.3)</td>
</tr>
<tr>
<td>Left stride (cm)</td>
<td>86.1 (1.7)</td>
<td>79.5 (5.4)</td>
</tr>
<tr>
<td>Postural intermediate (% GC)</td>
<td>45.8 (13.6)</td>
<td>49.1 (11.8)</td>
</tr>
<tr>
<td>FGP (%)</td>
<td>77.5 (1.5)</td>
<td>83.0 (1.4)</td>
</tr>
</tbody>
</table>

FGP, functional gait pattern; GC, gait cycle.
Discussion

It is well known that adult patients with hemiparesis effects of stroke presented changes in posture and gait symmetry with cycles near normal values expected for each individual after re-training for walking with a Lokomat robotic orthosis in 6- to 8-week treatment programs. To date, there are no reports of short treatment programs for non-institutionalized patients in both adult and pediatric populations.8,17

For pediatric patients, there are few studies that evaluate treatment interventions in a selected homogeneous group for gross motor function and topography of cerebral palsy. In the referenced literature, different treatment methods were not compared according to therapeutic effects in both the clinical as well as the quantitative areas. In our study, we selected patients with the variables of topography and pathological spastic hemiparesis.

As for re-education of gait in CP patients, there is only one study with a homogeneous sample of patients, which analyzes the variety of spastic diparesia (disease of the lower limbs, with varying degrees of affection of the trunk and upper extremities with involvement always less than in the lower limbs). Subjects trained on a treadmill for re-education of gait with varying speed according to the recommended therapeutic criteria, showing difficulties in standardizing treatment criteria that does not exceed the exercise tolerance of each child. In this case we did not only choose a uniform clinical manifestation, but also chose two treatment methods: a conventional one easily tolerated by the patient and responsible family (therapeutic tank) and a new method for the patient who at the beginning is sensitized, allowing the adjustment of intensity, duration and speed according to the characteristics of each patient.

The rating scale of gross motor function is the motor classification tool most often used in monitoring and evaluation of treatment of CP patients. In two of four published studies, positive changes were reported in range with the use of a robotic orthosis.12,13 The disadvantage was using a sample with a large variability of qualified patients within the rating scale of the gross motor function (from I–IV, ambulatory and nonambulatory) affecting the comparability in gross motor function and walking ability with patients included in this study, in addition to having a control group.

For the administered treatment characteristics, we dealt only with outpatients who had continuous sessions in a short time period (10 sessions/2 weeks). Changes were obtained similar to those described for in-hospital patients in rehabilitation centers with treatments applied three to four times/week with a duration of 45 min/session over a 2- to 3-week course.

In conclusion, the end of treatment assessment showed a clinical and functional improvement for the two treatment
modalities without reaching a definitive conclusion in regard to the superiority of one method over the other. At the end of 1 year, the statistical trend showed more permanent changes in gait symmetry for patients who received treatment with the robotic orthosis. We were unable to determine the long-term unique effect of a therapeutic intervention in children due to the evolving nature of CP and changes in terms of height and weight of each patient, requiring the rehabilitation specialist to review and provide constant adequate therapeutic interventions for each patient to maintain and/or improve patient’s status within the rating scale of gross motor function. Therefore, a larger sample size is necessary to observe consistency in the results and assess necessary treatment changes with regard to number and frequency of sessions.

References
