Ocena treningu z wykorzystaniem zautomatyzowanej ortezy Lokomat (Hocoma)® w usprawnianiu dzieci i młodzieży z mózgowym porażeniem dziecięcym – doniesienie wstępne

Evaluation of training using Lokomat (Hocoma)® in physiotherapy process of children and adolescents with cerebral palsy – preliminary report

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STRESZCZENIE

Wstęp. Zaburzenia chodu skutkują często ograniczeniem niezależności i uczestnictwa w społeczeństwie. W grupie dzieci z mózgowym porażeniem dziecięcym (MPD) atrybuty prawidłowego chodu są często zaburzone. Dzięki swoim właściwościom zautomatyzowana orteza do reedukacji chodu – Lokomat (Hocoma) może stanowić uzupełnienie procesu leczenia usprawniającego skierowanego na poprawę funkcji chodu. Celem pracy była ocena wspomagania leczenia usprawniającego przy użyciu zautomatyzowanej ortezy Lokomat na mobilność dzieci z mózgowym porażeniem dziecięcym. **Materiał i metody.** Do badania włączono 20 dzieci (13 chłopców) z rozpoznaniem MPD (*diplegia spastica*) w wieku od 5. do 17. roku życia. Pacjenci podzieleni zostali na dwie grupy: kontrolną (n = 10) – objętą standardowym procesem leczenia usprawniającego 6 razy w tygodniu i eksperymentalną – uczestniczącą w terapii przy użyciu Lokomatu 3 razy w tygodniu oraz 3 razy w tygodniu bez terapii z użyciem ortezy Lokomat w standardowym programie rehabilitacji. Porównano obie grupy przed i po 4-tygodniowym turnusie rehabilitacyjnym pod względem wartości uzyskanych w 6-minutowym teście chodu (6min WT), teście Timed Up&Go (TUG) oraz 10-metrowym teście chodu (10MWT). Dokonano analizy porównawczej w skali GMFCS (Gross Motor Function Classification System) w grupie eksperymentalnej pomiędzy pacjentami na poziomie I–II a pacjentami ocenionymi na poziomie III–IV. **Wyniki.** Średni czas trwania 10-metrowego testu korytarzowego zmniejszył się w grupie eksperymentalnej i kontrolnej o kolejno 7,5 s oraz 2,4 s. Średni dystans pokonany w czasie 6-minutowego testu chodu zwiększył się istotnie w grupie eksperymentalnej i kontrolnej o kolejno 56,5 m oraz 24 m. Średni czas trwania testu TUG zmniejszył się istotnie w grupie eksperymentalnej i kontrolnej o kolejno 5,1 s i 6,0 s. Nie zanotowano istotnych statystycznie

ABSTRACT

Background. Gait disturbances often result in the reduction of independence and participation in society. In the group of children with cerebral palsy (CP) correct gait attributes are often disrupted. The automated gait orthosis – Lokomat (Hocoma) provides training that can complement the process of gait rehabilitation. The aim of the study was to evaluate the influence of supporting role of robotic orthosis – Lokomat on the mobility of children with cerebral palsy. **Material and Methods.** 20 children (13 boys) with a diagnosis of CP (spastic diplegia), aged 5 to 17, were enrolled in the study. Patients were divided into 2 groups: control (n = 10) which took part in a standard, complex rehabilitation program six times a week, and an experimental group with locomotion training using Lokomat orthosis three times a week in addition to standard, complex rehabilitation program. Groups were compared before and after 4-week rehabilitation program. Gait function was evaluated by the 6-minute walk test (6minWT), Timed Up & Go Test (TUG) and 10-meter walking test (10MWT). A comparative analysis using GMFCS (Gross Motor Function Classification System) in the experimental group between patients at I–II and III–IV levels was made.
Results. The mean duration of 10MWT decreased in the experimental group by 7.5 s and in the control group by 2.4 s. The average distance of 6MinWT increased significantly in the experimental group by 56.5 m and in the control group by 24 m. The mean duration of the TUG test decreased significantly in the experimental group by 5.1 s and in the control group by 6 s. There were no statistically significant differences between groups after a 4-week treatment program in any of the performed test. Patients classified on I and II GMFCS level significantly increased walking speed (10MWT: 1.26 ± 0,31 m/s before vs. 1.46 ± 0.33 m/s after; $p < 0.05$) and shortened TUG test duration (11.3 ± 3.9 s before vs. 8.2 ± 1.8 s after; p

różnic pomiędzy grupami w żadnym z mierzonych testów po 4-tygodniowym okresie terapii. Pacjenci sklasyfikowani w skali GMFCS na I oraz II poziomie znamiennie zwiększyli prędkości chodu (10MWT: 1,26 ± 0,31 m/s przed vs. 1,46 ± 0,33 m/s po; $p < 0,05$) oraz skrócili czas trwania testu TUG (11,3 ± 3,9 s przed vs. 8,2 ± 1,8 s po; $p < 0,05$). Rezultatów takich nie zaobserwowano wśród pacjentów sklasyfikowanych na III oraz IV poziomie GMFCS. **Wnioski.** Terapia z wykorzystaniem zautomatyzowanej ortezy Lokomat może służyć jako forma wspomagania standardowego procesu rehabilitacji pacjentów z MPD.
Słowa kluczowe: trening lokomotoryczny, chód, Lokomat

< 0.05). Such results were not observed among patients classified on III and IV GMFCS level.**Conclusions.** Therapy with the automated gait orthosis Lokomat can be used as a form of support to standard rehabilitation process of patients with CP.
Key words: locomotor therapy, gait, Lokomat

INTRODUCTION

The complex treatment of children with cerebral palsy (CP) requires therapeutic interventions aimed at the needs of the child and his family in relation to his optimal functioning in adulthood [1, 2]. Optimal functioning, among other aspects, is facilitated by the ability to independent gait. Disturbances in gait function often result in the reduction of independence and participation in the society [3, 4]. Inadequate muscle control and activity during gait lead to the development of compensatory mechanisms and pathological movement patterns observed in patients with CP [4, 5]. Gage indicated the most frequently observed gait abnormalities in patients with CP based on the comparison with healthy peers. They include, for instance, the instability in stance phase, insufficient lift of the foot in the swing phase, reduced stride length and insufficient energy expenditure during gait [7]. The frequent occurrence of these disorders in patients with cerebral palsy [7] makes the gait therapy one of the most important parts of the process of rehabilitation treatment [4, 8, 9]. With the development of robotics and computer technology, engineers, doctors and physiotherapists are designing equipments which can carry the therapeutic process in conditions of dynamic weight support. One such device is Lokomat proV5 (Hocoma). Lokomat is a driven gait orthosis (DGO) which facilitates gait reeducation and the development of motor skills by individualized training in a motivational environment of constant feedback, which increases engagement and the efficiency of rehabilitation [8, 10, 11]. Lokomat comprises an outer skeleton DGO which drives the lower limbs, a dynamic weight support system for the patient and the treadmill. During therapy session robot moves patient limbs according to a predetermined schedule and most physiologic gait pattern [12–15].

So far, there are no guidelines for the use of Lokomat training. There is also no consensus on the optimal duration, intensity, or the level of patient weight support during training. However, it is proven that the process of rehabilitation complemented by Lokomat training can positively affect the level of functional capacity in patients with CP [16–19].

The aim of this study was to evaluate the assistive role of robotic orthosis – Lokomat in the rehabilitation process of children with cerebral palsy.

MATERIAL AND METHODS

Participants

The study was conducted in the Mazovian Centre of Neuropsychiatry in Zagórze. The study included 20 patients (13 boys) with a diagnosis of cerebral palsy (spastic diplegia) aged from 5 to 17 years (mean 10.8 ± 4.4). The following inclusion criteria were established: patients able to move with or without the use of orthopedic equipment, ability to understand verbal instructions, no contraindications to participate in the training using Lokomat. Patients in the randomization process were divided into two groups. Patients from control group participated in the standard rehabilitation treatment process 6 times a week. Patients from experimental group participated in therapy using Lokomat proV5 (Hocoma) 3 times a week, and 3 times a week (without treatment with orthosis Lokomat) in a standard rehabilitation program. Detailed characteristics of the groups are presented in Table I. In addition, patients were compared according to Gross Motor Function Classification System (GMFCS). Experimental group was divided into GMFCS I–II (subgroup I–II) and patients, at III–IV GMFCS level (subgroup III-IV).

Procedure

During the 4-week rehabilitation program children in the experimental group participated in 12 training sessions (3 trainings/week) on Lokomat. For the rest of the week patients participated in a standard therapeutic rehabilitation program. Duration of therapy with the Lokomat was set for 45 minutes. Walking speed and the body weight support were determined individually for each participant during therapy. Patients in the control group participated in individually programmed therapeutic rehabilitation program. The duration of a single treatment session was set for 45 minutes in both groups. At the beginning of the rehabilitation program experienced physiotherapists set with the parent/guardian the therapeutic goal to improve gait function.

Assessment tools

To assess the functional capabilities of patients Gross Motor Function Classification System – GMFCS was used. To quantify gait selected walk tests were used: 10-meter walk test (10MWT), 6 minute walk test (6MWT) and test Timed Up & Go Test (TUG).

Table I. Patients characteristics

Variables	Experimental group (n =10)	Control group (n = 10)	p
Age (years)	11,2 ± 5,0 (5–17)	10,4 ± 3,9 (5–16)	0,73b
Body mass (kg)	40,4 ± 16 (18–58)	38,9 ± 13 (21–56)	0,82a
Height (cm)	140 ± 22 (105–167)	142 ± 16 (115–165)	0,85a
BMI	19,8 ± 4,0 (15,9–29,6)	18,9 ± 4,1 (12,0–24,9)	0,62b
Sex (n♂ / n♀)	7/3	6/4	0,18c
GMFCS*			
Level 1	1	2	0,81c
Level 2	5	4	
Level 3	2	3	
Level 4	2	1	
Orthotic devices			
Orthosis	5	6	0,27c
Walker	3	2	
Tripods	3	1	
None	2	3	

The values are expressed as mean ± standard deviation (range); p – level of significance; * – Gross Motor Function Classification System; a – t-tests; b – Mann-Whitney U test; c – Chi-square test

GMFCS classification

GMFCS is a five level classification used in assessment of motor skills in children with CP. GMFCS classification shortly can be defined as follows: Level I – patient moves without limitation, Level II – patient moves with some restrictions on uneven surfaces, inclines and in crowded areas, Level III – children walk indoors or outdoors on a level surface with assistive mobility device. Children may propel a wheelchair manually. Level IV – children may continue to walk for short distances on a walker or rely more on wheeled mobility at home and community. Patients classified at V level have restrictions in antigravity movement. All areas of motor function are limited [21, 22].

Walk tests

Tests used in the study (6MWT, 10MWT, TUG) are widely used in the evaluation of the effects of treatment and rehabilitation of patients with CP [23–26]. It has been proven that they are repeatable and reliable tools in the evaluation of functional mobility in group of patients with CP [27–28]. Before the test, while the subjects rested in a sitting position, an experienced therapist gave instruction how the test would be performed. Running during tests was not allowed.

10-meter walk test (10MWT)

Children's task was to walk 10-meter distance in a straight line. The time was counted from the command „start" until the tenth meter line was crossed.

6-minute walk test (6MWT)

After the command „start" children marched for 6 minutes at their own pace on the corridor prepared especially for this purpose. After 6 minutes the investigators measured the distance covered.

Timed Up and Go (TUG)

During the test the patient was sitting on a chair with a height adjusted to his height (full contact of feet with the floor). On the command „start" the patient raised and covered a distance of 3 meters in a straight line, turned and walked back to his chair and sat down.

The measurements in the 10MWT and TUG test were performed three times. Results used for statistical analysis were the mean values of 3 measurements. 6MWT was performed once. The tests were carried out on the first and the last day of the rehabilitation process in the following order: 10MWT, TUG, 6MWT. Between tests, patients rested in a sitting position for 10 minutes. During all tests time was measured in seconds with accuracy to the hundredth of a second. Patients performed tests in their customary orthopedic devices.

STATISTICAL ANALYSIS

Normality of the distribution of each variable was tested using the Shapiro-Wilk test. The Wilcoxon signed rank test or the paired Student's t-test were used to evaluate influence of the rehabilitation programs on measured variables. The

Student's t-test or the Mann-Whitney U tests were used in order to detect differences between groups. Intergroup differences were assessed by Chi-square analysis. We considered statistically significant differences at $p < 0.05$. The statistics were calculated using the software STATISTICA 10-StatSoft. Inc software (Tulsa, USA).

RESULTS

Test groups did not differ significantly in terms of age ($p = 0.73$), weight ($p = 82$), height ($p = 85$), BMI ($p = 0.62$), sex ($p = 0.18$) GMFCS distribution ($p = 0.81$) and the use of assistive devices ($p = 0.72$) (Tab. I). The average total duration of 12 sessions with the Lokomat orthosis was 455 min (± 60 min; range: 382–544 min). The average duration of one workout was 42 min (± 2 min; range: 38–45 min). The average total distance covered during 12 training sessions was 10177 m (± 1924 m; range: 6846–12241 m), the average distance covered during a training was 922 m (± 131 m; range: 685–1113 m). Walking speed and the dynamic weight support was set by a therapist and individually adjusted to the patient. Training started at the speed of 1.0 km/h and 100% of patient weight support. The speed was systematically increased while weight support was consistently reduced with the individual progress achieved by the patient. The maximum speed reached in present study was 1.7 km/h (mean 1.3 ± 0.2), weight support was reduced to 0%. The average value of the weight support was 26% (± 37%).

The average values of walk tests before rehabilitation program did not differ significantly between groups. Both, control and experimental group achieved statistically significant improvement in all performed tests. A comparison of the results before and after rehabilitation is presented in Table II.

The average duration of a 10-meter walk test decreased in the experimental group and the control group respectively 7.5 s (~ 34%) and 2.4 s (~ 14%), which was consistent with a statistically significant increase in speed, successively by 0.25 m/s ($p < 0.01$) and 0.15 m/s ($p < 0.05$). The average distance covered in a 6-minute walking test increased significantly in the experimental and control group by 56.5 m (~ 19%) ($p < 0.05$) and 24 m (8%) ($p < 0.01$). The average duration of the TUG test decreased significantly in the experimental and control group by 5.1 s (~ 26%) and 6.0 s (~ 30%). There were no statistically significant differences between groups in any of the walk tests after 4-week treatment. Comparative analysis of the experimental group between patients classified at GMFCS level I–II (subgroup I–II) and patients classified at GMFCS III-IV (subgroup III–IV) showed no statistically significant differences in the following parameters of training: the average walking speed ($p = 0.68$, t-test), the total average walking distance (with $p = 0.91$, Mann Whitney, $p = 0.77$; t-test), the total duration of training ($p = 0.47$; t-test). The mean duration of training was significantly shorter in the I-II subgroup (40.0 min subgroup I–II vs. 43.6 min subgroup III–IV, $p < 0.01$; t-test). There were no statistically significant differences between subgroups in the walk tests, both before and after treatment. In the subgroup I–II we observed a statistically significant increase in walking speed (10MWT 1.26 ± 0.31 m/s before vs 1.46 ± 0.33 m/s after; $p < 0.05$) and shortening of the TUG test duration (11.3 ± 3.9 before vs 8.2 s ± 1.8 s after; $p < 0.05$). Such results were not found in the subgroup III–IV.

DISCUSSION

Based on presented results can be concluded that the use of Lokomat therapy can help in the rehabilitation process of patients with CP. In this study authors observed significant improvement in the results of walk tests in both groups: the experimental, after the training on Lokomat, as well as in control group, rehabilitated conventionally. Although no statistically significant difference was observed between groups, before or after a rehabilitation program, it should be noted that better results were obtained in a group where the training included the use of Lokomat. In addition, in the experimental group better results were observed among patients with small activity limitations, evaluated in GMFCS classification on level I–II.

The developed in Zurich Lokomat orthosis [15] is based on the relationship between physical activity and progressive changes in central nervous system in relation to the phenomenon of plasticity [29–31]. Potential changes caused by this form of therapy have become the subject of research in the groups of patients with spinal cord injury (SCI) [30], stroke [13], multiple sclerosis [33, 34] and CP [18, 35].

Table II. Summary of the results before and after therapy in the experimental group using robotic assisted Lokomat orthosis and the control group

Variables	Before therapy			After therapy		
	Lokomat	Control group	P	Lokomat	Control group	p
10MWT [m/s]	1,02 ± 0,50	1,05 ± 0,63	0,91a	1,27 ± 0,57**	1,20 ± 0,73*	0,81a
6MinWT [m]	300,1 ± 152,3	293,4 ± 188,9	0,93a	356,6 ± 170,1**	317,4 ± 188,4***	0,63a
Up&Go [s]	19,8 ± 23,0	20,1 ± 20,7	0,52b	14,7 ± 17,6††	14,1 ± 14,0††	0,47b

The values are expressed as mean ± standard deviation; Lokomat – an experimental group trained with the use of the Lokomat orthosis; Control group – standard physiotherapy program; a – Student's t-test for independent samples; b – U Mann-Whitney test to assess differences between the groups; * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$ – paired t-test; † $p < 0.05$; †† $p < 0.01$; - Wilcoxon signed rank test: to assess the effects of treatment

Currently there is no sufficient number of reports on the use of the Lokomat therapy in CP group to establish the guidelines for the most efficient frequency, intensity, and duration range of training in diverse group of patients with CP.

In our study, similar to Borgraffe et al. [18, 19, 35] and Meyer-Heim et al. [17] (a group of patients from Munich) patients diagnosed with spastic diplegia participated in 12 training sessions using Lokomat orthosis. In contrast to mentioned research, with the 12 training sessions in 3 weeks, patients in our study participated in a 4-week training. The total duration of all training, and the average duration of a single session using the Lokomat, was the longest in our study as compared with those published by other authors. The average distance covered by the patients in our study during one training was 922 m, in other studies patients walked an average distance of 990 m [17], 1070 m [35] and 1149 m [19]. These results can be explained by the low, compared with other authors, average walking speed (1.3 km/h) set individually by the therapist and customized to the current needs of the patient. Low values of walking speed on a treadmill while using Lokomat can be attributed to the low pre-therapy values obtained by the patients during the 10-meter walking test. Results of walking speed during 10MWT are also lower in our study than in the so far published research. These results may indicate that in our experimental group patients were slower than the patients in the Borgraffe et al. [19, 35] and Meyer-Heim et al. study [17]. However, results obtained during the 6-minute walking test show that the patients in our study could endure more. The experimental group before the 4-week treatment, covered on average 300 m in 6MWT compared to 113 m in the study of Meyer-Heim et al., [17] and 187 m in the study Borgraffe et al. [35]. Such differences may result from individual activity limitations, limb length or severity of persisted gait pattern pathology.

Similarly to these studies, we also noted in our experimental group a significant improvement in walking speed and total walk distance. In contrast to mentioned works, in our study a control group was present. Results obtained after 4-week rehabilitation program in the experimental group, compared with the results of the control group, appear not to be statistically significant. Also, analysis of the results between groups before the treatment showed no significant difference, however, from a clinical point of view, it should be emphasized that the experimental group achieved nominally greater improvement in walking function after the treatment, expressed in a result of greater value in 10MWT and 6MWT. In the TUG test, the experimental group achieved a lower nominal effect, but the final results were better than these observed in the control group. This is probably due to the large difference in outcome between groups obtained before the rehabilitation program.

Borgraffe et al. [19] found that patients classified at GMFCS I-II level may gain better results using the Lokomat therapy than patients classified at level III-IV. Authors showed that patients with better functional capacity (GMFCS I–II) may benefit from Lokomat by the longer use of this automatic orthosis and, thus, to cover a longer distance during training. Greater improvement in the domain E (walking, running, jumping) in GMFM scale (Gross Motor Function Measure) was also observed in comparison with patients classified on GMFCS III–IV level. In our study, patients in the experimental group classified at the GMFCS level I–II achieved a significant improvement in walking speed (10MWT) and significantly improved result in TUG test. Among patients classified at III–IV GMFCS level there were no statistically significant results, but improvement was also observed in all of the performed tests. Results were even nominally higher than in the subgroup of patients at level I-II GMFCS. No statistical significance in this subgroup may result from small numbers of participants classified on GMFCS III–IV (4 patients).

In modern neurorehabilitation of patients with CP the use of virtual reality in the process of therapy is being emphasized [36]. In practice, the Lokomat orthosis allows for additional benefit of virtual reality using computer games so that patient can see his character on screen placed in front of him [37, 38]. Encouragement from therapist is also mentioned as a motivating factor [16]. In our study, in the experimental group, we used these two above-mentioned types of support.

The possibility of facilitating patterns similar to physiological movements, their precise multiple repetitions and the possibility of continuous training under certain conditions set by the therapist seem to be good conditions for remodeling the impaired gait function. Additional benefits from patient's increased motivation, willingness to take further efforts by utilizing the phenomenon of virtual reality help the therapist and the patient to achieve faster therapeutic goals. Despite the limitations of the use of Lokomat, resulting from the inability to set the robot motion in the transverse plane and the difficulty in working with patients with fixed deformities and contractures, Lokomat can complement standard program of rehabilitation treatment in children with CP. Moreover, it should be remembered that even the most perfect therapeutic robots are not able to work without the supervision of a physiotherapist and his participation in the rehabilitation process.

CONCLUSION

1. A series of training with the Lokomat robotic orthosis significantly improved the results of selected walk test in children with cerebral palsy.
2. Training with the use of the Lokomat orthosis can be used as a method of supporting the rehabilitation process of patients with a diagnosis of cerebral palsy – spastic diplegia.

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