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Effects of Constraint-induced Movement Therapy on Patients with Post-cerebrovascular Disease Hemiplegia in the Maintenance Phase: Evaluation of Gait Improving Effects by Biomechanical Analysis

Shosaku Okuda
Department of Rehabilitation, Shonan University of Medical Sciences Graduate School of Health Sciences, Yokohama, Kanagawa, Japan and Department of Judo Therapy, Meiji University of Integrative Medicine, Nantan, Kyoto, Japan

Hirofumi Tanabe
Department of Rehabilitation, Shonan University of Medical Sciences Graduate School of Health Sciences, Yokohama, Kanagawa, Japan

Hiroshi Tanabe
Department of Rehabilitation, Shonan University of Medical Sciences Graduate School of Health Sciences, Yokohama, Kanagawa, Japan

Shibasaka Ryoya
Department of Electrical and Mechanical Engineering, Nagoya Institute of Technology, Aichi, Japan

Yoshimi Sakurai
Department of Rehabilitation, Shonan University of Medical Sciences Graduate School of Health Sciences, Yokohama, Kanagawa, Japan

Yuichi Takata
Department of Physical Therapy, Hokkaido Bunkyo University, Eniwa, Hokkaido, Japan

ABSTRACT

In this study, a series of constraint-induced movement therapy for the lower extremity (LE-CIMT) was performed on patients with post-stroke hemiplegia, and biomechanical analyses were conducted on the effective changes in their gait to examine if any long-term improvement in walking functions was observed. Participants were seven patients with hemiplegia (five men and two women) in their maintenance phase who were independent in their daily lives. Assessments using Fugl-Meyer Assessment (FMA)-Lower Extremity, FMA-Balance, 10-Meter Walking Test If possible, please give the version of the software here. For example, this information could be Nexus 2.14 or Nexus 2.16. (10MWT), and Time Up and Go Test (TUG) were conducted at 1) five weeks before intervention (baseline); 2) before therapy implementation on Day 1 of intervention (pre); 3) on

the final day of intervention period [two weeks: post (2w)], and 4) on the day 16 weeks after the Day 1 of intervention [post (16w)], respectively. In addition, joint angles (at hip and ankle joints) and joint moment (at ankle joint) were measured at baseline and post (2w) using a three-dimensional motion analysis software (Nexus 2.12.1, Vicon Motion Systems Ltd, Oxford, UK) and a ground reaction force measurement device (AMTI BP400600, Advanced Mechanical Technology, Inc., Massachusetts, USA). The results indicated significant differences after the intervention, exhibiting an increase in hip joint extension angle, ankle joint dorsiflexion angle, and ankle joint plantar flexion moment on participants' paralyzed side extremities. Participants' gait propulsion on the paralyzed side also exhibited improvement from the angle increases, indicating evident improvements in 10MWT and TUG and suggesting that the effects of LE-CIMT were associated with the long-term effects observed in the participants.

Keywords: stroke, gait analysis, lower limb, constraint-induced movement therapy.

INTRODUCTION

Cerebral stroke is one of the primary causes of death in the world, and many of those who survive it suffer from hemiplegia, posing a significant medical and social issue[1)]. In Japan, the population aged 65 years and above had reached 36,236,000 in 2023[2)], which was approximately 29% of the national population. In this super-aging society, the prevalence rate of cerebral stroke has increased, with approximately 270,000 people suffering a cerebral stroke each year[3)], requiring long-term care after discharge from hospitals due to its sequela. The total medical expense in Japan is 47.3 trillion yen each year, among which the expense for those aged 75 years and above is 18.8 trillion yen[4)]. The medical expenses for cerebrovascular diseases (CVDs) had reached 1.8142 trillion yen in 2022, indicating a 4.2% increase from the previous year[4)]. The long-term care (LTC) expenses in 2022 had reached 11.5139 trillion yen, also indicating an increase of 2.9% from the previous year[5)]. The second most significant cause of conditions requiring nursing care is CVDs[6)]. CVD-related medical and LTC expenses have been increasing every year. A study reported a correlation between factors leading to conditions requiring long-term care and gait-speed decrease[7)], and another study reported that independence in walking would lead to early discharge from hospitals[8)]. Improving walking function is essential to reduce medical and LTC expenses.

There are cases reported in *Guideline 2021 for the Treatment of Stroke [Revised version 2023]* regarding patients in the post-cerebral stroke maintenance phase who exhibited walking function improvement and increased physical activities[9)]. Another study reported that implementing gait or upper extremity rehabilitation training on patients with post-stroke hemiplegia improved walking function and activities in daily living (ADLs) by the second year from the disease onset[10)]. The randomized controlled test (RCT) results in multiple studies indicated that the repetitive transcranial magnetic stimulation (rTMS) applied on exercises of non-paralyzed side extremities significantly improved participant's ADLs[11, 12)]. Several other studies also reported that rTMS effectively improved patients' walking abilities and lower limb motor functions in post-cerebral stroke acute and maintenance phases[13, 14)]. Although there are multiple meta-analyses that investigated the effects of transcranial direct current stimulation (tDCS) on walking functions, their conclusions differ from one another[15, 16)]. Nevertheless, gait training is essential for rehabilitation, but conducting training involving rTMS or tDCS at home is challenging.

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Constraint-Induced Movement Therapy (CIMT) is an evidence-based intervention method that does not require special equipment. It was initially developed as a treatment method for upper extremities for adult patients with hemiplegia by Taub et al. of the University of Alabama. Functional recovery of paralyzed side extremities by CIMT was reported by several studies to be based on brain plasticity, such as neural reconstruction in the brain[17, 18, 19)]. Later, the CIMT protocol for the lower extremity (LE-CIMT) was developed in 2015 at the University of Alabama. LE-CIMT protocol is different from the one for the upper extremities in the point that it aims to promote various activities in the paralyzed side lower limb by behavioral psychological interventions applying loads on the paralyzed side lower limb without constraining non-paralyzed side lower limb. Several studies investigated the efficacy of LE-CIMT, most of which suggested a protocol of promoting functional recovery of the paralyzed side lower limb by conducting tasks in a standing position and walking exercises upon constraining non-paralyzed side lower limb; reports that follow the original protocol of LE-CIMT are extremely rare. One such rare study was the comparison study by Tanabe et al., who conducted comparisons using 10-meter walking tests (10MWT), Time Up and Go (TUG), lower limb exercise items of Fugl-Meyer-assessment (FMA-LE), and lower limb Motor Activity Log (LE-MAL) regarding pre- and post-intervention results of three patients with hemiplegia in the maintenance phase[20)]. However, the study did not clarify changes in the qualities of walking action, including the improvement to better gait performance. In upper extremity cases, the movements of paralyzed side hands can be visually observed. As for the gait, one cannot subjectively confirm their own movements, especially those with reduced sensory functions. Motor function degradation would lead not only to the decline of muscle strength, balance function, and gait ability but also to the decline in motor imagery. A study reported that motor imagery decline would cause differences between predicted and measured values in stride, leading to falling risks when the difference becomes large enough[21)]. Therefore, modifying gait motor imagery using a motion analysis device is considered effective in preventing falls. This study aimed to conduct LE-CIMT on patients with post-stroke hemiplegia in the maintenance phase and evaluate the effective gait improvement by biomechanical analysis to clarify if the intervention effects of LE-CIMT would be sustained in the long term.

PARTICIPANTS AND METHODS

Participants

The seven participants (five men and two women) were selected from patients with post-cerebral stroke hemiplegia registered to a relevant patient association in the Kanto area (Nousocchu Katamahi Toujisha no Kai), who satisfied the criteria, including those in the maintenance phase with more than one year from disease onset, without any medical complications that prohibit the intensive exercise of paralyzed side extremities, scored 24 and above in the Mini-Mental State Examination (MMSE), and independent in performing ADLs and able to participate in the relevant tests for themselves using private cars or public transportation (Table 1). Their age was 55.3±12.2 years (mean ± standard deviation). Their orthosis included one short lower limb orthosis with a metal support pole, two with gait solution design, two with Orthop orthosis (AFO), two with elastic orthosis, and one with TurboMed orthosis; no one with an orthosis that fixed ankle joint.

Table 1: Clinical characteristics at baseline (n = 7)

Patient	Affected side	Gender	Age (years)	FMA-L/E	FMA-Balance	10-meter walk at a comfortable gait speed (m/s) w. orthosis	TUG (sec) w. orthosis
1	Right	Female	64	15	7	0.4	31.7
2	Left	Male	56	17	7	0.6	22.7
3	Right	Female	28	21	11	0.9	13
4	Left	Male	66	14	9	0.4	29.2
5	Left	Male	51	17	8	0.5	30.8
6	Right	Male	58	25	9	0.7	15.7
7	Right	Male	64	15	8	0.6	21.8

FMA-L/E: Fugl-Meyer-assessment lower limb exercise items. FMA-Balance: Fugl-Meyer-assessment balance function items

This study was conducted following the doctrine of the Helsinki Declaration in 1975. The participants received a detailed explanation of the research purpose and contents at Shonan University of Medical Sciences, and their consent was obtained before the research implementation. The study was conducted with approval from the Research Ethics Committee of Shonan University of Medical Sciences (Medical Research Ethics Committee Approval Number 24-007).

Measurement

The values of FMA-LE, FMA-Balance, 10MWT, and TUG were measured in the first author's university at 1) five weeks before intervention (baseline); 2) before therapy implementation on Day 1 of intervention (pre); 3) on the final day of intervention period [two weeks: post (2w)]; and 4) on the day 16 weeks after the Day 1 of intervention [post (16w)], respectively. Each participant used orthosis for walking outdoors; they performed ADLs barefoot indoors. Regarding the measurement, 10MWT was measured in two conditions, with and without orthosis, at a comfortable gait speed because those with post-stroke hemiplegia often perform ADLs without orthosis at home. TUG was also measured in the same two conditions. The measurement of 10MWT was performed according to the procedure proposed by Kinugasa et al[22). Distances of approach walk and slowdown were set as two meters each, and participants performed a 14-meter walk exercise, in which the measurement was made starting after two meters of approach to 12 meters before the slowdown. The measurement of TUG was conducted using a method by Podsiadlo et al.[23) at a speed as fast as possible. The measurement was made twice, of which the smallest one was set as the representative value.

A three-dimensional motion analysis software [Nexus, Vicon Motion Systems Ltd, Oxford, UK, with eight infrared cameras (T20) and two motion capture cameras (VICON Vero)] and six plates of ground reaction force measurement device (AMTI BP400600, Advanced Mechanical Technology, Inc., Massachusetts, USA) were used for the motion analysis. The sampling frequency was set at 100 Hz; the left and right directions were set on the *x*-axis (right direction: +), forward and backward directions on the *y*-axis (forward direction: +), and vertical direction on the *z*-axis (upward direction: +), respectively. The exercise was conducted at a gait speed that participants felt comfortable. Reflective markers were applied on the following body metrics according to the plug-in-gait model: at temples on both sides, two points on the occipital region, sternocervical notch, spinous process, seventh cervical vertebrae, tenth thoracic vertebrae, inferior angle of right shoulder plate, as well as on both sides of scapuloclavicular joint, lateral center of upper wrist, upper lateral supraspinatus of the upper carpal bone, center of dorsal forearm, radial styloid process, ulnar stromal process, second middle hand bone, superior colliculus, posterior superior iliac spine, lateral femur, lateral knee joint, medial knee joint, lateral lower leg, medial and lateral malleolus, between second and third metatarsus bone heads, and calcaneal tuber. Joint angles (at hip and ankle joints) and joint moment (at ankle joint) were measured at baseline and post (2w). The participants were instructed to walk straight for 10 meters in the measurement room, where the measurement was made at the center of the course.

Intervention

The LE-CIMT program was implemented according to the original protocol for two weeks. The protocol consisted of the following four items: 1) Motor Activity Log-Lower Limb (LE-MAL) management; 2) Home Diary (HD); 3) Behavioral Contract-LE (LE-BC); and 4) Home Skill Assignment-LE (HSA-LE).

The participants performed the program at home, aside from the measurement. The primary investigator (PI) conducted a 20-minute Zoom meeting every day with each participant to prevent incidents of injury or falling, as well as to confirm if the exercise was performed properly.

In the Zoom meeting, the PI collected MAL-LE from the participants to compare the results with the previous scores. When the obtained score exceeded the previous record, the PI praised the participants for their positive use of the paralyzed side lower limb and made additional comments. During the Zoom meeting, the PI and participants watched the HD video recorded by the participants on their performances in tasks in a standing position and walking exercises, which were agreed upon according to the behavioral contract to check if the tasks and exercises were performed safely without feeling any pains, and discussed modifications if necessary. Tasks assigned in HSA-LE were also monitored during the meeting, and the PI praised the participants for the tasks well done, providing advice when necessary.

Analysis

Scores of multi-baselines were analyzed using a multiple-comparison analysis method. Relevant evaluation analysis data in the single-case experimental design at baseline, pre, post (2w), and post (16w) were measured and comparatively examined. A statistical analysis software, SPSS Statistics27 (IBM Japan, Ltd., Tokyo, Japan), was used for the statistical analysis, with a 5% significance level.

RESULTS

Table 2 shows the changes in participants' body and walking functions before and after the intervention. No significant differences were observed at baseline and pre in all items. In addition, motor function at post (2w) and post (16w) indicated a declining trend in all items, but no significant differences were observed. The FMA-LE and FMA-Balance results did not indicate significant differences pre and post (2w). Regarding the results of 10MWT under the conditions with and without orthosis, significant differences were observed between pre and post (2w) and between pre and post (16w). As for the results of TUG under the conditions with and without orthosis, significant differences were also observed between pre and post (2w) and between pre and post (16w). As shown in the above results, most participants expressed their opinions that they could walk more steadily than before the intervention.

Table 2: Post-intervention changes in body and walking functions

	baseline	pre	Post (2w)	Post (16w)
FMA-L/E	17.7±3.7	18.0±4.0	19.1±3.6	18.9±3.2
FMA-Balance	8.4±1.3	8.9±1.1	11.0±1.5	10.7±1.4
10-meter walk at a comfortable gait speed with orthosis (m/s)	0.60±0.15	0.60±0.15	0.9±0.12＊	0.84±0.12＊
10-meter walk at the maximum speed with orthosis (m/s)	0.67±0.16	0.66±0.66	1.16±0.20＊	1.06±0.17＊
10-meter walk at a comfortable gait speed without orthosis (m/s)	0.50±0.16	0.52±0.18	0.80±0.15＊	0.76±0.13＊
10-meter walk at the maximum speed without orthosis (m/s)	0.56±0.16	0.55±0.16	0.99±0.18＊	0.91±0.14＊
TUG with orthosis (sec)	20.52±6.23	20.63±6.04	11.52±2.74＊	12.51±3.05＊
TUG without orthosis (sec)	23.53±6.85	23.39±6.83	13.03±2.34＊	14.12±2.70＊

Mean ± standard deviation *: $P < 0.05$.

Table 3 shows the changes in joint angles (in ankle joint plantar flexion and hip joint extension) and joint moments of ankle joint plantar flexion at terminal stance before and after the intervention [pre and post (2w)]. The ankle joint dorsiflexion angle of the paralyzed side extremity indicated a significant difference between pre and post (2w). Although the ankle joint dorsiflexion angle of the non-paralyzed side extremity showed increased angles, no statistical significance was observed. Regarding the hip joint extension angles, a significant difference was confirmed in the paralyzed side extremity between pre and post (2w). Also, no significant difference was confirmed in the non-paralyzed side extremity, though with increased angles. The joint moment of ankle joint plantar flexion indicated significant differences between pre and post (2w) in the paralyzed side extremity, whereas no significant difference was confirmed in the non-paralyzed side, though with increased moment.

Table 3: Changes between pre-and post-intervention in joint angles and moments in terminal stance

	baseline	Post (2w)
Paralyzed side terminal stance ankle joint dorsiflexion angle (deg)	1.5±5.3	7.0±1.2＊
Non-paralyzed side terminal stance ankle joint dorsiflexion angle (deg)	6.7±1.7	10.3±1.1＊
Paralyzed side terminal stance hip joint extension angle (deg)	4.1±4.4	14.6±3.9＊
Non-paralyzed side terminal stance hip joint extension angle (deg)	9.2±4.1	17.1±2.2＊
Paralyzed side maximum ankle joint plantar flexion moment (Nm)	415.5±163.0	639.8±146.2＊
Non-paralyzed side maximum ankle joint plantar flexion moment (Nm)	925.7±283.5	1116.8±117.9

*: $P < 0.05$.

DISCUSSION

This study aimed to implement LE-CIMT on patients with post-stroke hemiplegia in the maintenance phase and examine if the intervention effects would be sustained in the long term using a three-dimensional motion analysis software with relevant data collected from perspectives of gait kinematics and kinetics. Although significant improvements were observed in scores of FMA-LE and FMA-Balance before and after the intervention, no significant difference was observed in their fluctuations.

The result of 10MWT with orthosis before the intervention (pre) was approximately 0.60 m/s, while that of after the intervention [post (2w)] was approximately 0.90 m/s, indicating a significant difference in its fluctuation. The result at 16 weeks after the intervention [post (16w)] was 0.84 m/s, indicating no significant difference from the one previously measured at post (2w), though with a slight decline in speed. Thus, the results suggested that the intervention effects endured 16 weeks after the intervention. In addition, similar results were obtained in the evaluation without wearing orthosis before and after the intervention. According to the cut-off values in 10MWT for patients with post-stroke disabilities, those with 0.8 m/s are considered able to perform outdoor independent walking, those with 0.4 to less than 0.8 m/s are partially able to perform outdoor independent walking, and the walking capability of those with less than 0.4 m/s remains indoor[23)]. Therefore, participants in this study could perform outdoor independent walking before the intervention, and it is presumable that their walking performance became safer and stable than before because of the intervention effects.

The TUG result with wearing orthosis before the intervention (pre) was approximately 20.52 seconds, and that of post-intervention [post (2w)] was improved to approximately 11.52 seconds, showing a significant difference. The result at 16 weeks after the intervention [post (16w)] was approximately 12.51 seconds without indicating a significant difference with that of post-intervention [post (2w)], though with a slight decline in speed. Thus, the results suggested that the intervention effects endured 16 weeks after the intervention. Similar results were also obtained in the evaluation without wearing orthosis. According to the TUG values associated with falling risk prediction in older adults, those with 13.5 seconds and above are considered to have a risk of falling, and those with 30 seconds and above require assistance in performing ADLs[22)]. Many of them remove orthosis in the house, where changes in directions in movements are frequent. The post-intervention TUG result was 13.5 seconds and less, indicating falling risk reduction.

The ankle joint dorsiflexion angle in the paralyzed side extremity at terminal stance before the intervention (pre) was approximately 1.5°, while that of the post-intervention was 7.0°, showing significant improvement and fluctuation. As for the hip joint extension angle in the paralyzed side extremity, the result of the post-intervention measurement [at post (2w)] showed a significant improvement and fluctuation with approximately 14.6°, compared to that of before the intervention (pre), which was approximately 4.1°. Likewise, the ankle joint plantar flexion moment in the paralyzed side extremity indicated a significant improvement and increase from approximately 415.5 Nm before the intervention (pre) to approximately 639.8 Nm after the intervention [post (2w)]. Several studies argue that the increase of trailing limb angle (TLA) is associated with the increase of gait propulsion in the paralyzed side extremity[24, 25, 26, 27)]. The influence of hip joint extension angle in consisting factors of TLA is considered significant[28]. The gait speed improvement observed in 10MWT and TUG in this study is probably due to the increases of the ankle joint dorsiflexion and hip joint extension angle in the paralyzed side extremity from the intervention effects of LE-CIMT implementation, thereby the ankle joint moment in the paralyzed side were increased, and as a result, gait propulsion in the paralyzed side was increased.

In the non-paralyzed side extremity, the ankle joint dorsiflexion angle at terminal stance before the intervention (pre) was approximately 6.7°, while that of the post-intervention [post (2w)] indicated a significant improvement and increase with the result of approximately 10.3°. Likewise, the hip joint extension angle in the non-paralyzed side in the post-intervention measurement [post (2w)] showed significant improvement and increase with the result of approximately 17.1°, compared to the one before the intervention (pre), which was approximately 9.2°. As for the ankle joint plantar flexion moment in the non-paralyzed extremity, though the result indicated an increase from approximately 925.7 Nm before (pre) to approximately 1116.8 Nm after the intervention [post (2w)], no significant difference was observed in the fluctuation. In terms of fluctuations, the ankle joint dorsiflexion angle at the terminal stance increased to 4.6 times on the paralyzed side and 1.5 times on the non-paralyzed side, the hip joint extension angle increased to 3.5 times on the paralyzed side and 1.8 times on the non-paralyzed side, and the ankle joint plantar flexion moment increased to 1.5 times in the paralyzed side and 1.1 times in the non-paralyzed side, all indicating significant improvements in the paralyzed side extremity.

Before the intervention, the gait propulsion in the paralyzed side extremity was weak, whereas that of the non-paralyzed side was strong enough to compensate for it. After the LE-CIMT implementation, the gait propulsion in the paralyzed side improved significantly, and the resulting minimization in gait propulsion difference between paralyzed and non-paralyzed sides probably led to efficient gait performances.

The walking patterns of those with post-cerebral stroke hemiplegia are categorized into several patterns, including buckling knee, stiff knee, extension thrust, and recurvatium knee patterns. As for a limitation of this study, the sample size was very small, with seven participants to conduct categorized statistical processing. Further investigation should be necessary in the future with a larger sample size to examine details according to the walking pattern categories.

CONCLUSION

The LE-CIMT intervention was implemented on patients with post-stroke hemiplegia in the maintenance phase to conduct biomechanical analysis regarding changes in effective gait performance and evaluate if the intervention effects should be sustained long-term.

The results showed substantial increases in the post-intervention measurements of hip joint extension angle, ankle joint dorsiflexion angle, and ankle joint plantar flexion moment in the paralyzed side extremity, indicating a significant difference. The intervention increased the participants' gait propulsion on the paralyzed side, showing evident improvements in both 10MWT and TUG. In addition, the effects endured 16 weeks after the intervention. The results of this study suggested that LE-CIMT intervention would provide long-term effects on walking function improvement.

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