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ORIGINAL REPORT

# EFFICACY OF ELECTROMECHANICALLY-ASSISTED REHABILITATION OF UPPER LIMB FUNCTION IN POST-STROKE PATIENTS: A RANDOMIZED CONTROLLED STUDY

Ji-Hyun KIM, PT, MS[1], Myoung-Hwan KO, MD, PhD[2], Jin Woo PARK, MD, PhD[3,4], Ho Jun LEE, MD, PhD[3,4], Ki Yeun NAM, MD, PhD[3,4], Yeon-Gyo NAM, PT, PhD[4], Chi-hun OH, OT[4], Joong Hee PARK, OT[4] and Bum Sun KWON, MD, PhD[3,4]

[1]*Department of Medical Device Industry, Graduate School of Dongguk University, Seoul, Republic of Korea*
[2]*Research Institute of Medical Science, and Research Institute of Clinical Medicine, Jeonbuk National University Medical School, Jeonju, Republic of Korea*
[3]*Department of Rehabilitation Medicine, Graduate School of Dongguk University, Seoul, Republic of Korea*
[4]*Department of Rehabilitation Medicine, Dongguk University Ilsan Hospital, Goyang, Republic of Korea*

***Objective:*** **To investigate the efficacy of electromechanically-assisted rehabilitation of upper limb function in post-stroke patients.**
***Design:*** **Randomized controlled trial.**
***Subjects:*** **Forty-eight stroke patients.**
**Methods: Patients were randomly assigned to control and experimental groups. The control group underwent occupational therapy training with conventional methods. The experimental group underwent electromechanically-assisted training using an end effector robot (Camillo®). Interventions were provided for 30 min per day, 5 days a week, for 4 weeks. Primary outcome was change in Fugl-Meyer Assessment (FMA) before and after training. Secondary outcomes were changes in hand function, upper limb strength, spasticity, mental status and quality of life.**
***Results:*** **Mean improvement in FMA was 1.17 (standard deviation (SD) 4.18) in the control group and 2.52 (SD 5.48) in the experimental group. Although FMA in the experimental group improved significantly after training, the improvement in FMA did not differ significantly between groups. Among the secondary outcomes, the Motricity Index (MI) improved significantly after training in the experimental group, and the change in MI between groups was statistically significant.**
***Conclusion:*** **Electromechanically-assisted rehabilitation using Camillo® was not more effective than conventional occupation therapy for upper arm function.**

*Key word:* stroke; rehabilitation; robotics; upper limb; hemiplegia

## LAY ABSTRACT

Electromechanically-assisted upper limb training is effective for stroke patients who need spontaneous exercise, because it provides highly precise and unlimited repetitive upper limb movements. In hemiplegic patients after stroke, upper limb function is important for daily life movements and working ability. The end effector robot, Camillo®, is an electromechanically-assisted upper limb training device that trains overall upper limb movement by inducing simultaneous motion of the shoulder, elbow and hand. This study evaluated the effect of rehabilitation using Camillo® by comparing it with conventional upper limb rehabilitation. In conclusion, electromechanically-assisted rehabilitation with Camillo® was not more effective than conventional occupational therapy for upper limb function.

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Correspondence address: Bum Sun Kwon, Department of Rehabilitation Medicine, Dongguk Ilsan Hospital, 27, Dongguk-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, Republic of Korea. E-mail: bskwon@dumc.or.kr

Hemiparesis/hemiplegia is the most common outcome of stroke, leading to movement deficits in the limbs contralateral to the side of the brain affected by the stroke (1). Movement disorder is the most common disorder after stroke, and acts as a major limiting factor in daily life. Among the movement disorders, upper limb function is highly related to the ability to perform daily


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activities, social activities, or recreational activities (2). The function of the upper limb and hand is most important for the performance and work ability of daily life movements, and upper limb dysfunction interferes with the independent performance of daily life movements and has a great influence on the prognosis of rehabilitation (3).

Stroke treatment includes drug therapy and rehabilitation. For hemiplegia, limb exercise or functional training through rehabilitation may be more effective (4). A previous study on hemiplegic patients reported that upper limb exercise was effective in improving upper limb function (3). The most important factor for neurological recovery after stroke is the patient's will and desire to perform spontaneous and repetitive exercise for afferent stimulation (5). However, in most patients, spontaneous exercise is often not possible, and constraint-induced movement therapy, electromyography-medicated electrical stimulation, and conventional rehabilitation treatment by a therapist is used (6).

Although conventional rehabilitation for upper limb function in stroke patients is known to be effective for motor function and independent daily life movements, a single therapist can treat only one person at a time. Hence, the efficacy of conventional rehabilitation treatment is low and the therapist's work intensity is high. A further limitation is that it is not possible to exercise at a consistent intensity, and it is difficult to obtain quantitative physiological information about the patient during exercise (6). In order to overcome this limitation, treatment using an electromechanically-assisted device has been developed recently, which is known to contribute to motor learning by helping the patient to repeatedly perform a purposeful movement of the upper limb at high intensity (6).

Camillo® (3DBT-61, Man&Tel Co. Ltd, Gumi, Republic of Korea) is an end effector type of electromechanically-assisted upper limb training device (**Fig. 1A**). The device was developed to perform various upper limb training protocols according to the exercise contents displayed on the screen. The patient's upper arm is placed on the device arm and fixed with a strap, and the patient holds a handle attached to the device. The occupational therapist can adjust the arm height of the device to suit the patient's height and set the positioning mode according to the patient's upper limb strength and neurological status. There are 3 positioning modes: horizontal, vertical, and inclined plane (**Fig. 1B**). The occupational therapist can apply the treatment programme according to the patient's needs and preferences.

The objective of this study is to investigate the clinical efficacy of electromechanically-assisted upper limb training using Camillo® compared with conventional occupational therapy.

## METHODS

### *Subjects*

From 11 September 2018 to 19 March 2020, 48 patients with hemiplegia due to stroke over the age of 19 years were recruited to this study. Inclusion criteria were: impaired upper limb dysfunction due to hemiplegia; ischaemia or haemorrhagic stroke confirmed by brain imaging; fair to good cognitive function in order to be able to follow instructions; ability to sit independently in a wheelchair or chair. Exclusion criteria were: bilateral upper limb dysfunction; impaired upper limb dysfunction due to osteoarthritis or pain; severe spasticity; inability to maintain the treatment due to any aetiology, heart or lung disease, etc.

### *Trial registration*

The study was approved by the Institutional Life Ethics Committee of Dongguk University Ilsan Hospital (number IRB 2018-03-032). It was registered in Clinical Research Information Service (CRIS Registration number KCT0003525). This randomized controlled trial (RCT) was designed according to the principles of the Declaration of Helsinki. Written consent to participate in the study was obtained from all subjects recruited.

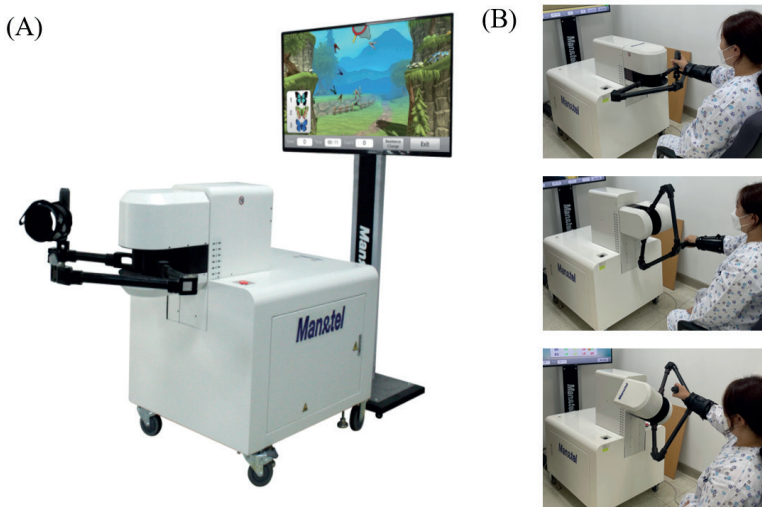


**Fig. 1.** (A) Camillo® set up (3DBT-61, Man&Tel Co. Ltd, Gumi, Republic of Korea), an end effector type of electromehanically-assisted upper limb training device. (B) Three positioning modes of training; horizontal, vertical and inclined plane

*Randomization and blinding*

The study was conducted as a prospective, randomized controlled clinical trial. Patients were randomly assigned to control and experimental groups using random check. "Block size 4" randomization was used, using the random number function of the Excel program. Randomization category A was assigned to the test group and B to the control group. Randomization was performed by a third party who did not participate in treatment or evaluation, and an assignment table was created. The control group performed occupational therapist-assisted upper limb training using a conventional method. The experimental group performed electromechanically-assisted upper limb training using Camillo®. The intervention was performed under the guidance of occupational therapists with more than 3 years of experience, who were not involved in the evaluation, in order to minimize the bias and increase the reliability of evaluation. This is a single-blind study in which the outcome assessors were blind and were not involved in patient enrollment, randomization, or intervention. They did not know which intervention patients were undergoing when they assessed them at the endpoints. In addition, the patients were instructed not to disclose their allocation to the assessors. The investigators who performed randomized data analysis were not involved in evaluation and training.

*Intervention*

The control group performed occupational therapist-assisted upper limb training using a conventional method; a treatment that involves stretching and joint exercise for the major joints of the upper extremities, and performing tasks to improve muscle strength and upper extremity motions, tailored to the subject's ability. The aim of this treatment is to improve sensory function, joint movement, balance, and motor control ability by applying task performance tools based on medical knowledge about the structure and function of the nervous and muscular systems. The conventional method included joint range of motion exercise, strengthening exercise, and goal-directed functional exercise.

The experimental group performed electromechanically-assisted upper limb training using Camillo®. The training program for this device was chosen according to the patient's preference and cognitive function. The programs that we provided were named "turtle catching", "window cleaning", "clay shooting", "jumping", "fish breeding" and "collecting". The positioning mode was chosen by the occupational therapist according to the patient's upper limb strength and neurological status. The possible positioning modes were "horizontal", "vertical" and "inclined" planes.

Both groups performed the therapeutic intervention for 30 min a day, 5 days a week, for 4 weeks. All patients in both groups underwent additional therapy for activities of daily living (ADL) for 30 min daily during the study period.

After a 4-week intervention a 10-item satisfaction questionnaire was applied to the experimental group. The items were: (*i*) appropriateness of training time; (*ii*) increased confidence in ADL; (*iii*) increased motivation; (*iv*) increased energy in daily life; (*v*) decreased stress in daily life; (*vi*) improvement in depression; (*vii*) improvement in nervousness; (*viii*) increased rehabilitation concentration; (*ix*) increased desire to continue the training; and (*x*) recommending this training to other patients. The patient answered the questionnaire based on a 5-level Likert scale of 1–5, with scores indicating the patient's response (strongly disagree, disagree, neither agree nor disagree, agree, strongly agree).

*Outcome measures*

The primary outcome measure was Fugl-Meyer Assessment (FMA) (7). Secondary outcome measures were: Box and Block Test (BBT) (8), Purdue Peg Board test (PPBT) (9), Motricity Index (MI) (10), hand grip strength (11), modified Ashworth scale (MAS) (12), Mini Mental State Examination (MMSE) (13), Beck Depressive Inventory (BDI) (14), and EuroQoL 5-dimension 5-level (EQ-5D-5L) (15).

FMA is a tool that evaluates motor function, based on Brunnstrom's 6-step recovery level, to measure the degree of functional recovery of stroke patients. FMA consists of: (A) shoulder/elbow/forearm, (B) wrist, (C) hand, and (D) coordination. The total score of the upper limb part (A–D) is 66 points, and the score for each item is on a 3-point scale (0: not possible, 1: partially capable, 2: capable of performing without defects).

The BBT was used to measure hand dexterity. It measures the number of blocks moved from one box to another in one min. The PPBT test is an evaluation tool that measures speed and accuracy when pinching, manipulating, and placing a small peg in a hole, to evaluate large-scale movement of the hand and arm and the agility of the hand. In this study, the results of the subject's affected side were used. MI was calculated only for the upper limb, to represent muscle strength. Shoulder abduction, elbow flexion, and pinch grip score were each assigned 0–33 points. The total MI score was recorded on the range 0–100 points, with 100 points consisting of the sum of arm points +1 point, with a higher number representing good muscle strength. In this study, the mean of each of the 3 scores evaluated was used. Hand grip strength was developed to measure the overall hand-grasp strength by dynamometer. In this study, the mean value of 3 trials was used after measuring the hand-grasp strength on the affected side. MAS is a popular spasticity evaluation tool in clinical practice; it is a semi-quantitative measure that evaluates muscle tone. MAS is classified as 0/1/1.5/2/3/4 according to the degree of muscle spasticity and tension. MMSE is a 30-point questionnaire that is widely used in clinical and research settings to measure cognitive impairment. BDI is a depression assessment scale used for screening and evaluating depression. The assessment consists of descriptions of symptoms and behavioural changes associated with depression. The question consists of a total of 21 questions, each of which has a different response depending on the severity of the symptoms. Each question is composed of a 4-point scale, scored from 0 to 3, with a total score of 0–63 points. EQ-5D-5L is a health-related quality of life questionnaire, which consists of 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The patient is asked to indicate their health state by ticking the box next to the most appropriate statement in each of the 5 dimensions.

*Data acquisition and analysis*

Assessments were conducted within one week before intervention (pre-training), and after intervention (post-training). All outcomes were assessed in the full analysis set (FAS), defined as all subjects who received at least one assessment. In the case of missing data in the FAS analysis, the last observation carried forward (LOCF) method was used. The baseline data and characteristics are presented as mean and standard deviation (SD) for continuous variables, and as numbers and percentages for categorical variables. The significance of changes between pre- and post-intervention in each group was assessed using a paired

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**Table I.** Baseline characteristics of control and experimental groups

| Characteristics | Control group ($n=24$) | Experimental group ($n=23$) |
|---|---|---|
| Sex, *n* (%) | | |
| Male | 15 (48.4) | 16 (51.6) |
| Female | 9 (56.3) | 7 (43.8) |
| Age, years, mean (SD) | 62.08 (12.42) | 57.17 (15.12) |
| Duration, days, mean (SD) | 813.67 (1,225.81) | 342.00 (635.07) |
| Height, cm, mean (SD) | 165.59 (10.19) | 167.48 (8.73) |
| Weight, kg, mean (SD) | 63.97 (11.22) | 68.68 (13.09) |
| MMSE, mean (SD) | 20.21 (6.28) | 22.87 (6.87) |
| MAS, mean (SD) | 0.60 (0.85) | 0.52 (0.76) |
| Affected side, *n* (%) | | |
| Right | 11 (45.8) | 10 (43.5) |
| Left | 13 (56.5) | 13 (56.5) |
| Type, *n* (%) | | |
| Infarction | 7 (58.3) | 5 (41.7) |
| Haemorrhage | 17 (48.6) | 18 (51.4) |

MMSE: Mini-Mental State Examination; MAS: modified Ashworth scale.

t-test, and the change in outcome between groups was analysed using an independent-samples *t*-test. Statistical significance level for the changes between groups at FMA levels (A–D) with the Bonferroni correction was set at $p<0.012$. One-way ANOVA was used to determine the difference in the mean of each of the FMA levels (A–D) within each group. The other statistical tests were performed as a 2-sided test, and significance was evaluated as valid when the probability of significance was $p<0.05$ with no adjustments for multiple comparisons. For statistical analysis, the SPSS Ver.18 (IBM Corporation, Chicago, IL, USA) program was used.

### *Sample size estimation*

Calculation of the expected difference in FMA was based on a study by Lo et al. (2010) of the recovery of the upper limb function after stroke using In-Motion, a representative end effector type robot device (16). Based on the results of this previous study (16), the mean change in FMA for the primary outcome was 2.88. The SD was set as the mean of the SDs in studies by Vope (2000), Hesse (2005) and Lum (2006) (17–19). The expected difference in the mean value was 2.88, SD was 3.3, significance level (α):0.05, power (1–ß):0.8, and dropout rate 15%. To allow for a possible 15% dropout rate, 24 participants per group (total 48 participants) were randomized to each group. The selected sample size could achieve a power of 80% at the 5% level of significance.

## RESULTS

A total of 48 subjects were included in the study. Of these, 24 in the control group and 23 in the experimental group completed the initial outcome measures. One subject in the experimental group was excluded due to incomplete initial assessment. There were no differences in baseline characteristics between the control and experimental groups (**Table I**).

The primary outcome of total FMA in the control group was 24.8±21.7 pre-training and 26.0±22.3 post-training. The total FMA of the experimental group was 34.7±24.3 pre-training and 37.2±24.9 post-training. The change in total FMA between pre- and post-training was significant in the experimental group. Mean differences by FMA levels (A–D) within group were not statistically significant. Changes in FMA levels (A–D) between groups using Bonferroni corrections were not statistically significant. The change in total FMA also did not differ between groups (**Table II**).

Among the secondary outcomes, only the difference in the change in MI between groups was significant statistically between the 2 groups ($p=0.017$) (**Table III**).

Ten patients in the control group and 5 in the experimental group were excluded due to simple withdrawal or incomplete evaluation (Table SI). When per protocol set (PPS) analysis was applied, MMSE was 18.9±5.5 in the control group and 24.1±6.4 in the experimental group before intervention, in which the baseline of MMSE was different between 2 groups ($p=0.019$). The change of primary and secondary outcome measures were not significant (Table SII and Table SIII). The change in MI was not different between groups by analysis of covariance (ANCOVA) with MMSE as covariate ($p=0.075$) (Table SIV). No adverse events were found during training in either group.

The questionnaire on patient satisfaction with the upper limb rehabilitation robot training found that the overall satisfaction rate mean was 3.35 (SD 0.48). Mean satisfaction levels were: "increased motivation" 4.11 (SD 0.32), "to recommend this training to other patients" 3.95

**Table II.** Changes in primary outcome measures in control and experimental groups

| Measures | | Control group ($n=24$) | | | | Experimental group (n=23) | | | | *p*-value between groups |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Pre-training Mean (SD) | Post-training Mean (SD) | Difference (post-pre) Mean (SD) | *p*-value | Pre-training Mean (SD) | Post-training Mean (SD) | Difference (post-pre) Mean (SD) | *p*-value | |
| Fugl-Meyer Assessment | A | 15.00 (13.20) | 15.75 (13.50) | 0.75 (2.44) | 0.289[a] | 19.78 (12.77) | 21.39 (13.33) | 1.61 (3.68) | 0.062[a] | 0.348[c] |
| | B | 3.13 (3.23) | 3.29 (3.30) | 0.17 (0.64) | | 4.91 (4.17) | 5.22 (4.20) | 0.30 (0.64) | | 0.462[c] |
| | C | 5.29 (5.22) | 5.50 (5.23) | 0.21 (1.02) | | 7.78 (5.70) | 8.17 (5.74) | 0.39 (0.78) | | 0.495[c] |
| | D | 1.42 (1.93) | 1.46 (1.98) | 0.04 (0.20) | | 2.22 (2.41) | 2.43 (2.43) | 0.22 (1.04) | | 0.422[c] |
| | Total | 24.83 (21.71) | 26.00 (22.33) | 1.17 (4.18) | 0.184[b] | 34.70 (24.27) | 37.22 (24.87) | 2.52 (5.48) | 0.038[b]* | 0.344[d] |

*$p<0.05$ by paired *t*-test between pre- and post-training outcome measures.
[a]No statistically significance differences were observed in difference test by level with one-way analysis of variance (ANOVA) analysis within groups ($p>0.05$).
[b]The *p*-value is paired *t*-test between pre- and post-training outcome measures
[c]No statistically significance differences were observed between groups with Bonferroni correction ($p>0.05/4$).
[d]No statistically significance differences were observed between groups with independent samples *t*-test ($p>0.05$).

**Table III.** Change in secondary outcome measures in control and experimental groups

| Measures | | Control group ($n = 24$) Pre-training Mean (SD) | Post-training Mean (SD) | Difference (post-pre) Mean (SD) | $p$-value | Experimental group ($n = 23$) Pre-training Mean (SD) | Post-training Mean (SD) | Difference (post-pre) Mean (SD) | $p$-value | $p$-value between groups |
|---|---|---|---|---|---|---|---|---|---|---|
| Box and Block Test | | 5.83 (9.69) | 6.96 (10.54) | 1.13 (4.88) | 0.270 | 15.04 (16.78) | 17.17 (19.08) | 2.13 (5.89) | 0.097 | 0.526 |
| Purdue Peg Board Test | | 0.75 (1.82) | 1.00 (1.89) | 0.25 (1.07) | 0.266 | 2.39 (3.85) | 3.09 (4.20) | 0.70 (1.49) | 0.036* | 0.244 |
| MI | | 38.38 (31.43) | 38.92 (31.88) | 0.54 (1.89) | 0.173 | 55.78 (28.15) | 61.52 (29.59) | 5.74 (9.49) | 0.008* | 0.017** |
| Hand grip strength | | 5.57 (10.56) | 7.13 (10.59) | 1.56 (4.07) | 0.073 | 16.61 (24.69) | 19.93 (28.32) | 3.32 (8.28) | 0.067 | 0.356 |
| MAS | Shoulder | 0.77 (0.79) | 0.73 (0.79) | 0.00 (0.29) | 1.000 | 0.57 (0.70) | 0.44 (0.65) | –0.13 (0.38) | 0.110 | 0.191 |
| | Elbow | 0.83 (0.79) | 0.83 (0.79) | 0.00 (0.29) | 1.000 | 0.83 (0.67) | 0.67 (0.65) | –0.15 (0.38) | 0.069 | 0.135 |
| | Wrist | 0.75 (0.82) | 0.71 (0.83) | –0.04 (0.20) | 0.328 | 0.76 (0.72) | 0.65 (0.68) | –0.11 (0.34) | 0.135 | 0.410 |
| MMSE | | 20.21 (6.28) | 20.33 (6.34) | 0.13 (1.08) | 0.575 | 22.87 (6.87) | 23.52 (6.31) | 0.65 (2.12) | 0.155 | 0.294 |
| Beck Depressive Inventory | | 8.75 (7.32) | 8.21 (7.03) | –0.54 (1.67) | 0.125 | 9.00 (6.33) | 9.22 (5.74) | 0.22 (6.10) | 0.866 | 0.560 |
| EQ-5D-5L index | | 0.28 (0.23) | 0.28 (0.24) | 0.00 (0.03) | 0.593 | 0.53 (0.20) | 0.54 (0.19) | 0.01 (0.06) | 0.397 | 0.570 |

*$p < 0.05$ by paired t-test between pre- and post-training outcome measures.
**$p < 0.05$ by independent samples $t$-test between groups difference
MI: Motricity Index in sitting position, Hand grip strength of affected side; MAS: Modified Ashworth scale; MMSE: Mini-Mental State Examination; QOL: quality of life; EQ-5D-5L index; EuroQol 5-Dimension 5-level.

(SD 0.52), "increased desire to continue this training" 3.84 (SD 0.60) , "appropriateness of training time" 3.58 (SD 0.61), "increased rehabilitation concentration" 3.16 (SD 0.60), "increased confidence in activities of daily life" 3.05 (SD 0.62), "increased energy in daily life" 3.05 (SD 0.52), "improvement in nervousness" 3.00 (SD 0.58), "improvement in depression" 2.95 (SD 0.62), and "decreased stress in daily life" 2.79 (SD 0.42).

## DISCUSSION

The objective of this study was to investigate the efficacy of the electromechanically-assisted rehabilitation of upper limb function in post-stroke patients compared with occupational therapist-assisted rehabilitation. Upper arm function, strength, spasticity, mental status and ADL were investigated, and there was no significantly statistical difference in the efficacy of the 2 types of rehabilitation, except for upper limb strength. The device was set up to enable inclined plane mode exercise for patients with proximal muscle weakness who cannot use the vertical plane mode exercise, but can use the horizontal plane easily. Those patients might benefit from strengthening their muscles. An increase in MI was expected in the experimental group, because MI represents upper arm strength. The difference in the change in MI between the 2 groups was statistically significant. FMA was subdivided into A, B, C and D, representing the movement and synergy of (A) shoulder/elbow/forearm, (B) wrist, (C) hand and (D) coordination. FMA A, B and C increased after rehabilitation in the experimental group and the difference in the FMA A was greatest among FMA A–D, which represented the effect of proximal muscle strengthening. An increase in BBT, PPBT and hand grip strength were also expected, representing upper arm function. However, only PPBT increased in the experimental group; the other measures did not. Because the mean post-stroke duration was 813.7 days (SD 1,225.8) in the control group and 342.0 days (SD 635.1) in the experimental group, further improvement in upper arm function could not be achieved.

The Camillo® device has 6 programs: "turtle catching", "window cleaning", "clay shooting", "jumping", "fish breeding" and "collecting". Each program has 3 levels of difficulty; "easy", "moderate", and "hard". The occupational therapist chose the program and level according to the patient's cognition and preference. Because "fish breeding" and "'collecting" requires a high level of cognition, the change in MMSE was measured after rehabilitation. However, MMSE did not improve in either group. Because the program was based on the game, and most patients showed a high satisfaction level, an improvement in BDI was expected. However, BDI did not improve either. The program thus requires further development to stimulate the patients' interest and cognitive function.

A total of 33 patients completed all training and outcome measurements. Five patients in the experimental group and 10 in the control group dropped out due to withdrawal from the intervention and incomplete evaluation. Due to the high risk of statistical bias using PPS analysis and because the sample size estimation reference used FAS analysis, FAS was conducted for a conservative approach analysis. However, in the PPS analysis, baseline measurement of MMSE was different between groups and the change in MI was also not different ($p = 0.075$) according to ANCOVA analysis with MMSE as covariate. The Camillo® device could provide the training in the inclined plane and might be effective for upper limb strengthening. However, the results should be interpreted with caution, since they depend on the MMSE mental state. Ten patients in the control group withdrew from the training or did not complete endpoint evaluation and might want to be enrolled in the experimental group. This was a single-blind study in which the assessors were blind. The patients were unaware of the study hypothesis and were instructed not to disclose their group allocation to assessors. However, the patients in the control group were more likely to withdraw from treatment or not complete the endpoint evaluation. The sample size estimation took into account a dropout rate of 15%. However, the dropout rate in the control group was higher. In the control group,

patients with good cognitive function and high MMSE score were eliminated because they preferred to belong to the experimental group at study inclusion. In addition, many subjects had difficulty with being treated every day for 4 weeks. There were many cases of incomplete testing schedules after the end of treatment. Patients' low compliance with intervention and evaluation reflected the real-world situation, and it was necessary to apply FAS in a conservative approach analysis.

The change in FMA in the experimental group was 2.52 (SD 5.48), which was significant. However, it did not result in improvement in upper arm function, because the change was not sufficient for functional change. The minimally clinically important difference (MCID) in FMA of the upper extremity was 9–10 points for stroke subacute patient (20) and 5.3 points for chronic patients (21). In this study, the change in FMA did not reach the MCID score, and the difference in the change between the control and experimental groups was not significant, either. Until now the MCID score of MI had not been established. However, a study by Lambercy et al. (22), which investigated the effectiveness of robotic grasping, pronation, and abduction training in 13 patients with chronic stroke, showed that the change in MI score was 4.54, which was significant ($p=0.025$). When considering this MI result, we suggest that electromechanically-assisted rehabilitation for stroke patients can have an improved effect on upper limb muscle strength. However, the MI result should be interpreted with caution because it is only one significant secondary variable out of 10 with a non-significant primary variable.

The appearance of the device should be also considered when evaluating the treatment outcome. The electromechanically-assisted upper limb training device, Camillo®, is an end effector type model that implements the movement of the upper limb. In addition to the horizontal plane mode, the device has vertical and inclined plane modes, and we considered that the improvement in MI was associated with the characteristics of the device. The other electromechanically-assisted upper limb rehabilitation device or robot can only move in a planar direction or horizontal plane. Camillo® additionally provides oblique arm motion along the inclined plane, and could make a diagonal movement. Diagonal movement-induced complex movements of the shoulder, elbow and wrist could mimic ADLs and help with ADL therapy. Camillo® could provide training in the inclined plane, which might be effective for upper limb strengthening. However, it was not shown to be effective for upper limb function, because it depended on the patient's mental state.

A Cochrane review of electromechanical and robot-assisted upper limb training found that it improved arm function and daily activities, but did not improve arm strength (23). A systemic review of robotic-assisted arm training found that the outcomes of robotic-assisted arm training were comparable with conventional therapy (24). Indirect comparisons suggest that no single type of robotic device is any better or worse than any other device, providing no clear evidence to support the selection of specific types of robotic device to promote hand-arm recovery (24). However, the results of this study might have different effects on functions, daily activity, or strength, depending on the characteristics of the device.

High scores for satisfaction were obtained for the items "increased motivation" 4.11 (SD 0.32), "to recommend this training to other patients" 3.95 (SD 0.52), and "increased desire to continue this training" 3.84 (SD 0.60). In contrast, low scores for satisfaction were obtained for the items "improvement in depression", "'decreased stress in daily life", and "increased energy in daily life". There was also little improvement in MMSE, BDI and EQ-5D-5L index post-intervention. As the results of the questionnaire suggest, the content of the training needs further development in order to increase cognitive function and overcome depression and improve ADL.

### *Study limitations*

Study participants were recruited according to the inclusion criteria for use of the Camillo® device; hence the results are not representative of post-stroke hemiparetic patients. The mean durations of stroke were 813.7 (SD 1225.8) days in the control group and 342.0 (SD 635.1) days in the experimental group (Table I). The study should include acute and subacute stroke patients and sub-group analysis. The patients who withdrew had better cognitive function than those who completed the study. The baseline MMSE of all patients included in the control group was 22.1 (SD 8.5), and was not different from that in the experimental group. Because cognitive function could affect upper limb function, an additional incentive is needed for control subjects not to withdraw from the study, or a large sample size should be included based on the estimated high dropout rate.

### *Conclusion*

Electromechanically-assisted rehabilitation with Camillo® was not more effective than conventional occupational therapy for upper arm function.

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