Effect of Intensive Training With a Spring-Assisted Hand Orthosis on Movement Smoothness in Upper Extremity Following Stroke: A Pilot Clinical Trial

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Background: A commercial splinting system is designed to permit quick training in opening and closing the affected hand in order to overcome the disadvantages of previous approaches. **Objective:** The purpose of this study was to assess the feasibility of intensive training using a spring-assisted hand orthosis on upper extremity in individuals with chronic hemiparetic stroke. **Design:** Five participants for the experimental group and 5 for the control group were recruited from a local rehabilitation hospital. Subjects in the experimental group participated in 4 weeks of training using a SaeboFlex orthosis for 1 hour per day, 5 times per week. Each subject in the control group wore the same orthosis for 1 hour per day without participating in upper extremity training. Outcome measures included the Fugl-Meyer Assessment, Box and Block Test, and Action Research Arm Test; kinematic parameters were collected using a 3-D motion analysis system. **Results:** The Fugl-Meyer assessment and the Box and Block Test score were increased significantly in the experimental group after the intervention. The resultant velocity of the wrist joint for the reach-to-grasp task decreased significantly, and the resultant velocity of the shoulder joint while performing a reach-to-grasp task at acromion height decreased significantly in the experimental group. **Conclusion:** A pilot clinical study of spring-assisted dynamic hand orthosis training is feasible in recovering the movement of the hemiparetic upper extremity. **Key words:** *hand orthosis, hemiparesis, resultant velocity, stroke, upper extremity*

Stroke is the leading cause of disability in adults and is the third leading cause of death in the United States.[1–3] Ninety percent of stroke survivors show permanent disabilities, and most of them develop hemiparesis or hemiplegia. Hemiparesis in the upper extremity is widely reported as the primary impairment in individuals after stroke. This impairment interferes with the movements required for basic daily activities and household chores as well as for work-related tasks.[4] Therefore, recovering voluntary movement in the upper extremity is the most important goal in rehabilitation and for research in these fields.

Various treatment approaches have been used for recovering the function of the hemiparetic upper extremity. However, previous studies have provided little or no evidence regarding the treatment effects of upper extremity training on muscle strength, muscle tone, dexterity, and activities of daily living.[5–7] Recently, task-oriented training has been shown to be a form of activity-dependent motor rehabilitation that facilitates the recovery process of upper extremity function.[8,9] This approach is based on the motor learning principles of practice and intermittent feedback and has the elements necessary for facilitating real-world activities.[10]

Constraint-induced movement therapy (CIMT) is a gold standard for recovering upper extremity function after stroke, and it is influenced by the task-oriented approach. It involves constraining

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the unaffected limb, influencing the behavior to increase the use of the affected limb, and, ultimately, massed training of the affected limb.[11] However, the CIMT protocol has strict inclusion criteria such as the ability to actively extend the limb by at least 10° at the metacarpophalangeal and interphalangeal joints and 20° at the wrist joint. Therefore, the CIMT is more effective than other currently available treatments for stroke patients with mild impairment, for example, impairment in the movements involved in opening the fist.[12]

A splint is applied under the forearm for improving the performance of the upper extremity by maintaining the more severely impaired upper limb in a preferred position for rehabilitation.[13] However, if stroke patients do not practice wearing static splints on the upper extremity, then the limited range of motion at the related joints will not improve.[14] Although static splinting supports the preferred position of the affected upper limb after stroke, the splint cannot be applied during exercise programs for improving upper extremity performance.[15,16]

A commercial splint system called the SaeboFlex orthosis (Saebo, Inc, Charlotte, North Carolina) has been developed to overcome the disadvantages of the remedial approaches described previously. This orthosis is a dynamic splint that is positioned in the functional grasp position and is used to assist patients who cannot voluntarily reopen their affected hands after functional grasping because of dominant flexor synergy in the upper extremity. Each finger sleeve is attached to springs by a high-tensile polymer line to provide assistance with finger extension; the orthosis does not have motor or electrical parts. The dorsal surface of the hand and forearm shell is made of lightweight plastic for ease-of-fit in the hemiparetic hand. The use of this material also allows the hemiparetic stroke patient to practice movement wearing the orthosis. Therefore, intensive repetitive training with the SaeboFlex orthosis may provide a new treatment approach for improving functional activities in individuals with more severe impairment of the upper extremity as a result of chronic hemiparetic stroke. Recent studies have supported the theory that this treatment approach will be beneficial for patients showing the effects of stroke.[13,17]

The purpose of this experiment was to determine the feasibility of intensive training with the SaeboFlex orthosis in individuals with chronic hemiparetic stroke by assessing the movement smoothness and clinical assessment score of the upper extremity. To determine the resultant velocity with respect to movement smoothness, the Box and Block Test (BBT), Action Research Arm Test (ARAT), and the Fugl-Meyer Assessment (FMA) were conducted for hemiparetic upper extremity function.

Method

Participants

This study applied a randomized pretest-posttest control group design with a 4-week intervention. The outcome measures were performed the day before and the day after the 4-week intervention. During the intervention, the experimental group was involved in SaeboFlex orthosis (**Figure 1**) training, and the members of the control group wore a SaeboFlex orthosis to control for the possible placebo effect of wearing a splint. The outcome measures were performed by 2 certified and experienced therapists, and the SaeboFlex orthosis training was performed by different experienced therapists after they were randomly (by coin toss) allocated to a group. All the participants received regular physical therapy for 1 hour per day. For this study, 15 stroke patients (7 for the experimental group and 8 for the control group) were recruited from a rehabilitation hospital

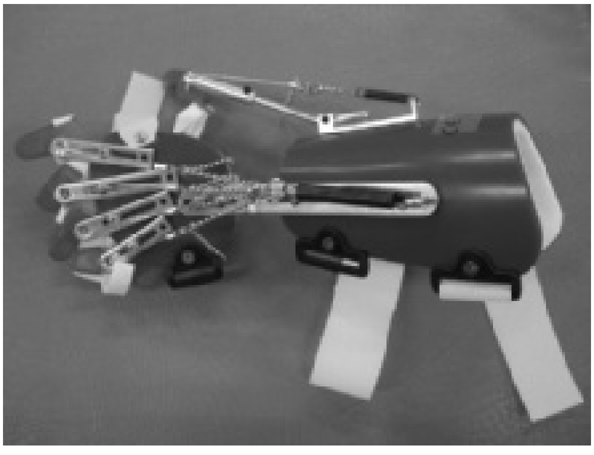

Figure 1. SaeboFlex orthosis.

in the Republic of Korea, and they were randomly allocated into the experimental and control groups by tossing a coin 3 times. This project was approved by the Institutional Review Board of the Yonsei University Wonju College of Medicine; all the patients agreed to participate in this study and signed an informed consent form. Two stroke patients in the experimental group and 3 stroke patients in the control group dropped out before completing the posttest evaluation (**Figure 2**). Three stroke patients (2 in the experimental group and 1 in the control group) did not complete the training because they were discharged from the hospital. In addition, 2 stroke patients in the control group were excluded because they had taken medication that affected the hypertonicity of the affected hand.

The following patients were included in the study: (1) patients with unilateral hemiparesis for more than 6 months after the stroke; (2) patients with a Mini-Mental State Examination (MMSE) – (Korean version) score of ≥23; and (3) patients who could perform at least some active voluntary movement (ie, 10° shoulder flexion/abduction, 10° elbow flexion/extension, and 30° interphalangeal proximal joints or 20° movement at the interphalangeal distal joints during volitional finger flexion that occurs when the hand is in the wrist and finger extension position) (**Table 1**).

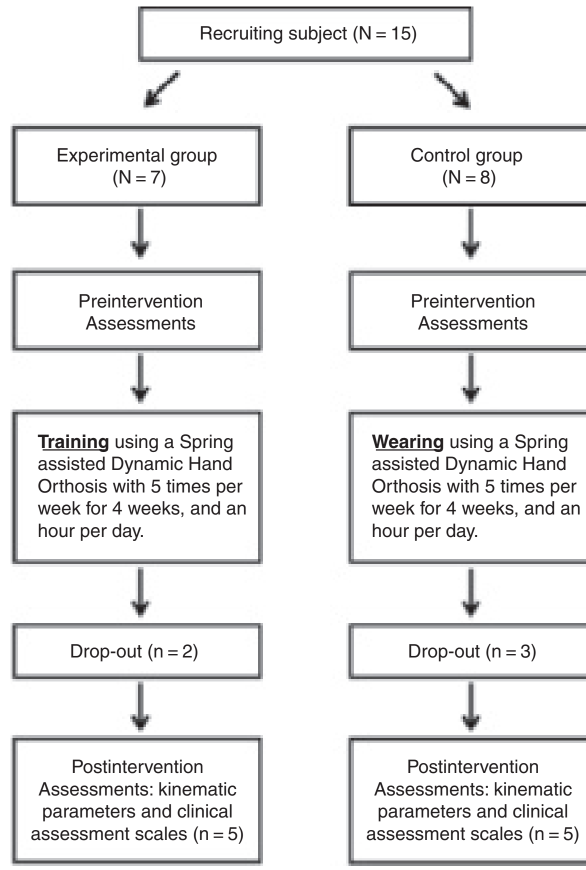

Figure 2. Flow of participants through the intervention.

Intervention

The participants of the experimental group performed training activities wearing the SaeboFlex orthosis. The training activities for the experimental group consisted of 20 sessions (5 times per week), and each session typically lasted for 1 hour. Each session consisted of 9 task-oriented practice sessions involving the hemiparetic arm.

Table 1. General characteristics of participants

	Experimental group					Control group				
Subjects	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**
Sex[a]	F	M	M	M	F	M	M	M	M	F
Age, years	73	49	53	40	40	39	57	38	55	67
Height, cm	150	179	168	170	157	168	170	181	168	157
Weight, kg	64	105	69	70	75	70	67	77	65	57
Arm length, cm	42	53	49	47	44	48	49	50	48	45
Hemiparetic side[b]	L	R	R	L	L	R	R	L	R	L
MMSE score	28	30	30	26	30	26	30	30	30	30
Brunnstrom's stage	4	2	2	3	4	3	2	2	4	3
Poststroke duration, months	36	40	32	21	19	48	42	17	10	21

Note: MMSE = Mini-Mental State Examination.
[a]F = female; M = male.
[b]L = left, R = right.

The practice tasks were conducted with patients wearing the SaeboFlex orthosis.

The tasks for the training program were as follows: (1) moving a soft ball from the side of the affected foot toward the table while sitting; (2) moving a soft ball diagonally from the less-affected side to the affected side while standing; (3) moving a soft ball diagonally from the affected side to the less affected side while standing; (4) moving a soft ball from the left to the right side on the table while standing; (5) moving a soft ball from a box, situated at knee height on the affected side, to a table while standing; (6) moving a soft ball through the target from the left to right side while standing; (7) grasping and releasing a soft ball for straight forward and backward transfer on the table while standing; (8) grasping and releasing a soft ball for diagonal forward and backward transfer on the table while standing; and (9) moving a soft ball from one cup to another cup on the table while standing.

The members of the control group wore a SaeboFlex orthosis to control for the possible placebo effect while wearing a splint and to practice the motions of the elbow and shoulder joints, without grasping activity; all the members sat and stood for the same period. All the participants of the control group received regular physical therapy for 1 hour per day.

Outcome measures

The rehabilitation outcomes of patients should be assessed at all 3 levels described in the International Classification of Functioning, Disability and Health (ICF) model: body functions and structures (impairment), activities (limitation), and participation (restriction). According to the ICF model, which is commonly related to upper extremity function, the FMA can be used to assess the level of body functions and structures. The ARAT and BBT can be used to assess the activities and participation level.[18] In this study, the outcome measures for clinical assessments were the ARAT, FMA, and BBT. The test-retest reliability (intraclass correlation [ICC]) value of ARAT reported in an ARAT-related study with 50 stroke patients was 0.98.[19] We also used the upper extremity subtest of the FMA, and the total score for the upper extremity was 66.[20] The interrater reliability reported in an FMA-related study with 37 stroke patients was 0.99, and their test-retest reliability was 0.97.[21] The interrater reliability reported in a BBT-related study of 37 stroke patients was 0.99, and the test-retest reliability was 0.96.[21]

Data regarding spatiotemporal parameters were collected using a 3-D motion analysis system and workstation software (Vicon MX system; Oxford Metrics, UK) for evaluating movement smoothness for qualitative measurement. A 6-infrared camera Vicon MX system obtained kinematic data at 60 Hz, which was processed by Nexus 1.4 software. A total of 28 spherical retro-reflective surface markers were placed at bony landmarks directly on the skin, according to the guidelines of the Vicon "upper limb" model marker set.

In this study, we assessed the movement smoothness during the reach-to-grasp task as a dependent variable to evaluate the effectiveness of the intervention. The dependent variables include resultant velocity for movement smoothness at the wrist, elbow, and shoulder joints. The resultant velocity (d_v) for movement smoothness combines the component velocities for each axis to determine the resultant velocity. Resultant velocity is the distance obtained in the Euclidean space. The Euclidean metric is the distance between any 2 or 3 points in space. The resultant velocity is calculated using the following formula[22,23]:

$$d_v = |T_v| = \sqrt{X_v^2 + Y_v^2 + Z_v^2}$$

In this formula, X_v represents the velocity of sagittal plane movement, Y_v is the velocity of coronal plane movement, and Z_v is the velocity of transverse plane movement at the shoulder, elbow, and wrist joints. We defined the start and end of movement by Hingtgen et al.[24] Start and end of movement were defined as elbow flexion (beginning) to elbow extension (end).

The patients performed 2 different reach-to-grasp tasks while seated in nonswivel, stationary chairs. The hand to be tested rested on a table on the ipsilateral side, such that the shoulder was at approximately 0° of flexion/extension and 0° of internal rotation. The elbow was at 90° of flexion; the wrist rested palm down on the table with the finger joints in slight flexion. The target used for the spherical grasping task was a soft (10-cm-diameter ball), and it was positioned for 2 different reach-to-grasp tasks: elbow and acromion heights. The first position for the reach-to-grasp task was directly in front of the tested arm at 100% length and at elbow height, and the other position was directly in front at shoulder joint (level with the acromion), also at a distance of 100% length. Participants were instructed to grasp at their preferred speed. In this study, arm length was defined as the distance from the anterior axillary fold to the distal wrist crease when the subject raised his or her arm as close to 90° elevation as possible and reached forward (without trunk movement) as far as possible. For each reach-to-grasp task, participants were provided with 3 practice trials prior to the actual tasks, and each task was repeated 5 times (for calculation of the mean data) with a 3 second rest between trials.

Statistical analysis

The parameters used for data analysis were ARAT, FMA of upper extremity function, and BBT of clinical assessments and the resultant velocity for movement smoothness for the shoulder, elbow, and wrist joints. A Mann-Whitney *U* test was used to ensure the initial equivalence of groups, and a Wilcoxon signed rank test was used to identify the training effects after the intervention. An alpha level of $P < .05$ was considered to be statistically significant. All statistical analyses were performed using the SPSS statistical package 15.0 (SPSS, Inc, Chicago, Illinois).

Results

Pre-intervention status between groups

There were no significant differences in the clinical assessment scores and resultant velocity before the intervention between groups ($P > .05$). The clinical assessment scores of the ARAT, FMA of upper extremity function, and BBT were not significantly different between groups. There was no significant difference in the resultant velocity between groups.

Clinical assessment score

Table 2 shows the effects of intervention on hemiparetic extremity function in 2 groups. In the experimental group, the FMA of upper extremity score increased significantly from 33.00 ± 15.98 pre intervention to 35.60 ± 15.50 post intervention ($P = .042$), and the BBT score increased from 6.00 ± 9.27 to 8.40 ± 10.69 ($P = .039$). However, in the control group, only the FMA of upper extremity score increased significantly from 29.80 ± 14.87 to 31.20 ± 14.54 ($P = .038$).

Resultant velocity for movement smoothness

Table 3 shows the resultant velocity of the shoulder joint, at the height of the acromion, during reach-to-grasp task sessions decreased significantly in the experimental group from 68.94 ± 21.04 to 51.26 ± 13.49 ($P = .043$). The resultant velocity of the wrist joint in the experimental group during the reach-to-grasp task attempts at both elbow and acromion heights decreased

Table 2. Clinical assessment score after the intervention (n = 10)

	Experimental group (n = 5)				Control group (n = 5)			
Variables	**Pretest**	**Posttest**	***Z***	***P***	**Pretest**	**Posttest**	***Z***	***P***
Action Research Arm Test								
Grasp	7.0 ± 3.7	8.0 ± 3.2	–1.633	.102	6.8 ± 5.0	7.6 ± 5.8	–1.633	.102
Grip	4.4 ± 3.8	5.8 ± 3.0	–1.633	.102	4.8 ± 3.6	5.0 ± 3.5	–1.000	.317
Pinch	5.6 ± 6.7	6.6 ± 6.5	–1.633	.102	6.0 ± 5.7	6.6 ± 6.0	–1.732	.083
Gross movements	5.2 ± 2.4	5.4 ± 2.3	–1.000	.317	4.6 ± 2.5	4.8 ± 2.5	–1.000	.317
Total	22.2 ± 14.6	25.8 ± 13.3	–1.841	.066	22.2 ± 16.4	24.0 ± 17.5	–1.732	.083
Fugl-Meyer Assessment of Upper Extremity	33.0 ± 16.0	35.6 ± 15.5	–2.032	.042	29.8 ± 14.9	31.2 ± 14.5	–2.070	.038
Box and Block Test	6.0 ± 9.3	8.4 ± 10.7	–2.060	.039	3.8 ± 5.2	3.8 ± 2.9	–0.368	.713

Note: Values for pretest and posttest are given as mean ± *SD*.

Table 3. Resultant velocity after the intervention (n = 10)

		Experimental group (n = 5)				Control group (n = 5)			
Joint	**Task**[a]	**Pretest**	**Posttest**	***Z***	***P***	**Pretest**	**Posttest**	***Z***	***P***
Shoulder	A	37.8 ± 9.8	38.2 ± 12.1	–0.135	.893	60.1 ± 44.1	48.5 ± 26.7	–1.483	.138
	B	68.9 ± 21.0	51.3 ± 13.5	–2.023	.043	85.8 ± 68.1	71.5 ± 26.5	–0.405	.686
Elbow	A	52.5 ± 7.5	40.2 ± 22.4	–1.214	.225	48.1 ± 21.3	45.6 ± 23.5	–0.674	.500
	B	68.1 ± 20.6	51.0 ± 25.7	–1.214	.225	64.3 ± 25.9	54.2 ± 13.8	–0.674	.500
Wrist	A	30.0 ± 15.2	14.0 ± 4.0	–2.023	.043	29.9 ± 16.6	29.5 ± 11.2	–0.135	.893
	B	35.1 ± 9.0	15.7 ± 4.1	–2.023	.043	27.9 ± 21.8	27.9 ± 9.7	–0.674	.500

Note: The values for the pretest and posttest are given as mean ± *SD*.
[a]The target was located at elbow height (A) and acromion height (B) during reach–to–grasp task.

significantly from 30.04 ± 15.15 to 13.95 ± 4.01 and from 35.05 ± 9.03 to 15.69 ± 4.14, respectively (*P* = .043) (**Figure 3**). However, for all joints assessed in the control group, the resultant velocity did not significantly decrease after the intervention (*P* > .05) (**Figure 4**).

Discussion

The ARAT score, a measure of fine motor skill, did not differ after the intervention in either the experimental or the control groups. The ARAT and BBT were both used for measuring fine motor skill. The ARAT was used to test grasp and grip performance for different objects during each session, while the BBT tested performance in grasping similar objects. Although clinical assessment scores, before the intervention, were not statistically significantly different between the experimental and control groups, these results indicated that, after the intervention, the experimental group had better fine motor skill results.

In our study, we used resultant velocity as kinematic parameters for assessing movement smoothness at each joint of the upper extremity during reach-to-grasp tasks. The resultant velocity reflects the jerkiness of movement in all 3-D movements, whereas the jerkiness score evaluated the jerky movement in one direction. After the intervention, resultant velocity decreased in the wrist and shoulder joints. The resultant velocity of the wrist joint decreased at both height levels during the reach-to-grasp task. However, the resultant velocity of the shoulder joint decreased in reach-to-grasp task at acromion height. This result indicates that the resultant velocity of the shoulder joint, during the reach-to-grasp task, at elbow height did not change after the intervention, because there was a need for some shoulder movement during the task. In the experimental group, the resultant velocity for movement smoothness was improved after the intervention. The reach-to-grasp task of the upper extremity has provided a relatively simple model for studies of how movement is planned, produced, and coordinated,[25] and increased movement smoothness was a result of learned coordination for recovery from neural injury.[26] There was limited need for shoulder movement during the reach-to-grasp task at elbow height, therefore there was no significant change in the reach-to-grasp task at elbow height after the intervention, despite a difference in the experimental group.

Generally, movement increased jerkiness during the task in the hemiparetic upper extremity.[26,27] Therefore, the movement of upper limbs became smoother, less jerky, and more direct as recovery occurred in stroke patients.[28] Smoothness and directness have been shown to be characteristics of optimal performance during the performance of upper limb tasks and can be accurately observed in stroke patients.[25] In this study, movement smoothness improved, as measured by resultant velocity after the intervention. These results indicate that recovery continued in case of chronic stroke, and movements became less jerky and more coordinated during tasks. Arm movements in stroke patients had increased jerkiness, were longer, more variable, and had larger movement errors: elbow-shoulder coordination was disrupted

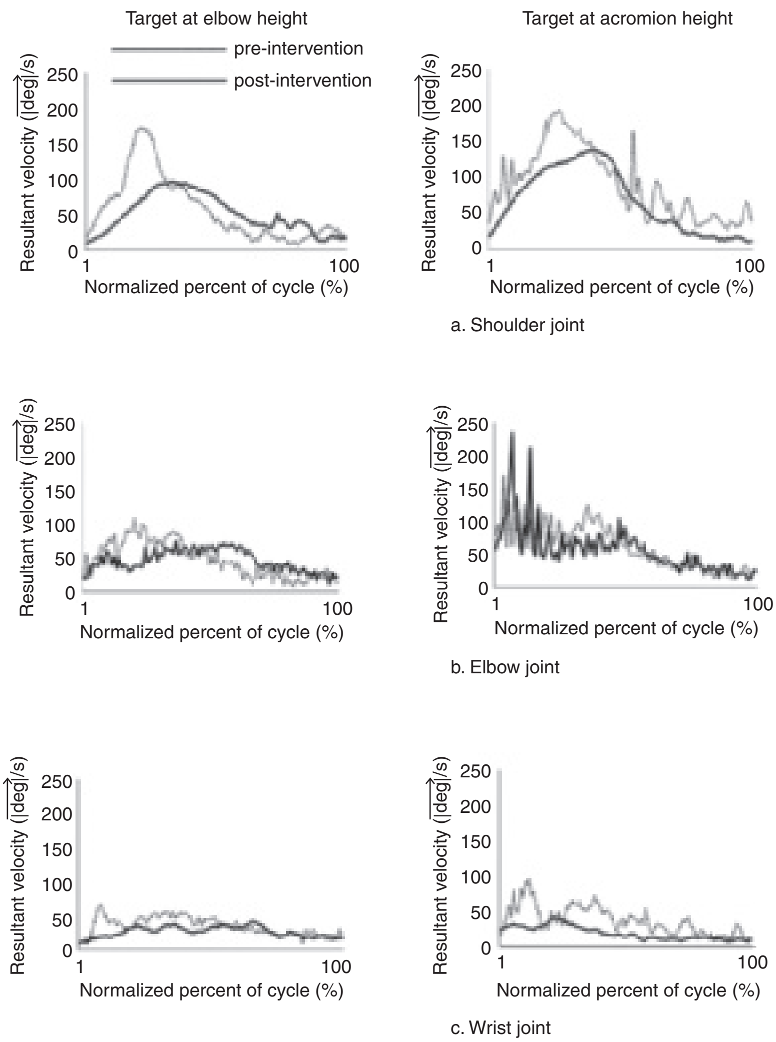

Figure 3. Resultant velocity in the experimental group.

and the range of active joint motion was decreased significantly compared with healthy subjects.[26,29,30]

Most recommendations for treating upper extremities after neurological injury involve repetitive, task-oriented training of the impaired extremity for several hours a day, constraining patients to use the impaired extremity during waking hours. Selecting task activities is important as the movement is designed to transfer from the clinical setting to real-world activities.[31] The SaeboFlex orthosis was designed to provide splinting and repetitive task-oriented training, mimicking real-world activities for the hemiparetic upper extremity. Using the SaeboFlex orthosis has advantages in assisting finger extension for impaired grip opening caused by spasticity or flexor synergy. It allows the impaired hand to perform functional activities during training and is expected to facilitate use of the impaired extremity during functional tasks, which will carry over into the real-world activities of daily living. One of the limitations in this study was that we did not compare the change between the groups, because the equivalence of the groups was not ensured in the case of small sample size. However, it must be kept in mind that the clinical assessment scores and kinematic parameters of 3-D motion analysis were obtained under the laboratory environment. Therefore, the SaeboFlex orthosis training is considered to be an effective treatment option

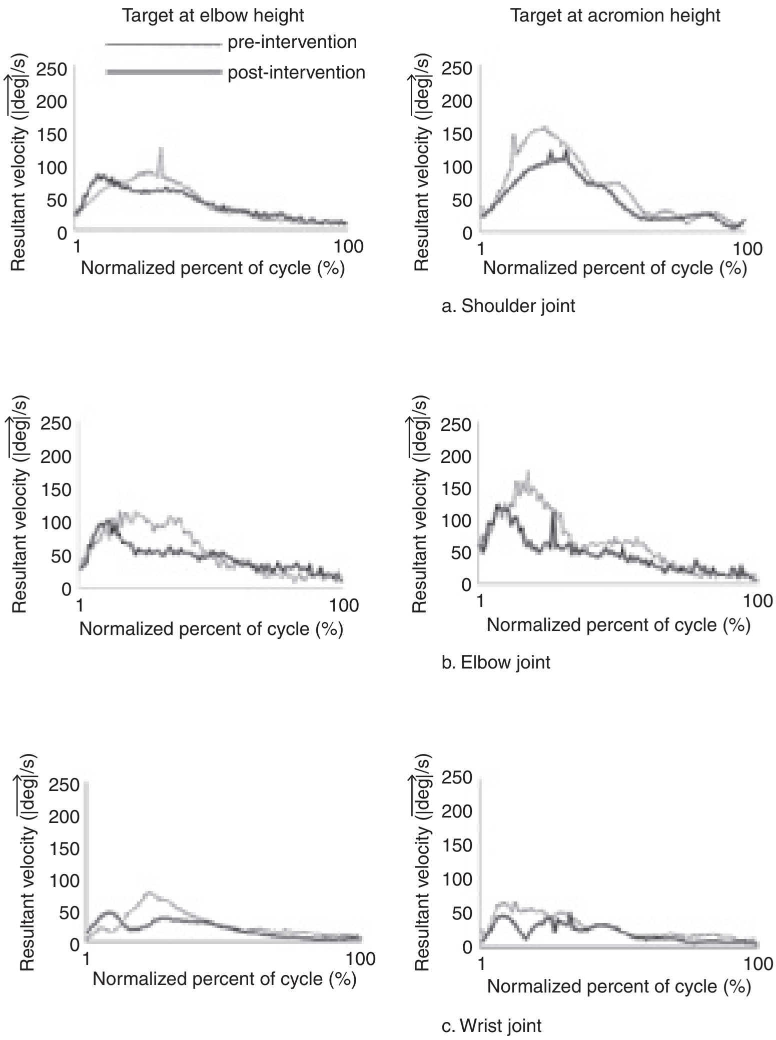

Figure 4. Resultant velocity in the control group.

for undertaking task-oriented activities, and it is considered to be an effective treatment option for providing repetitive task-oriented training and mimicking real-world activities for the hemiparetic upper extremity to perform functional training during rehabilitation.

The results of this study indicate that the spring-assisted dynamic hand orthosis training is effective in recovering the movement of the hemiparetic upper extremity of patients after stroke. The function of the upper extremity in clinical assessment scores increased in the experimental group but not in the control group. Parameters, such as resultant velocity for movement smoothness, also improved in the hemiparetic upper extremity. Therefore, the spring-assisted dynamic hand orthosis training is considered to be an effective treatment option for undertaking task-oriented activities. Further research is recommended using a greater variety of evaluation tools and a larger patient sample size.

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