

Article

Evaluation of Short-Term Clinical Effects of a Novel Repetitive Facilitation Exercise Training Program Using a Hemiplegic Elbow Extension Rehabilitation System

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Abstract: Repetitive Facilitation Exercise (RFE) is known as an effective rehabilitation method that can elicit brain plasticity. In our previous study, we developed a hemiplegic upper limb rehabilitation system that can train the elbow and shoulder based on RFE theory. The system consists of a selective Arm-DoF constrainable mechanism and a multiple facilitative stimulus timing and duration control system. The selective Arm-DoF constrainable mechanism has three DoF, making it possible to selectively restrict a DoF of the shoulder or elbow. The multiple facilitative stimulation timing and duration control system only has an electrical stimulation source and a vibrator and no large actuators to perform the training exercise. In this study, we undertook an evaluation of the short-term clinical effects of a proposed elbow training program using the hemiplegic upper limb rehabilitation system. The training method consists of two sets, each involving 50 repetitions of the elbow extension exercise programmed in our system. We evaluated the short-term training effects through clinical trials for five stroke patients using the above method. In the evaluation, 10 repetitions of pre/post-tests without any facilitative stimulus were performed before and after the two sets of training. As a result, the maximum angular velocities or the average angular velocities of the elbow extensions improved significantly in most subjects. These results indicate that the quickness or the smoothness of elbow extension movements in the hemiplegic limb improved. Therefore, our clinical experiments support the short-term clinical benefits of the proposed method as well as the practicality of quantitative evaluation using our system.

Keywords: hemiplegic upper limb rehabilitation system; Repetitive Facilitation Exercise; hemiplegic elbow extension; facilitative stimulus



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1. Introduction

Hemiplegia is paralysis that affects only one side of the body, and it is caused by brain damage after a stroke. It is a common condition, and the number of affected patients continues to increase. Conventionally, it has been considered that if damaged nerve cells in the brain are not recovered, the treatment of paralysis is impossible. However, a level of “brain plasticity” has been found, aiding in the effectiveness of rehabilitation. This is a phenomenon in which the surrounding brain neurons make a new neural network, acting in place of the dead ones [1–4].

Functional recovery in a hemiplegic stroke patient is directly related to the improvement of quality of life (QOL) and activities of daily living (ADL). Training involving upper extremity exercises is particularly important in sub-acute rehabilitation after stroke [5]. In particular, the training of elbow extension directly improves ADL, such as drinking water, pushing a button, and changing clothes [4–7]. In order to improve paralysis in the hemiplegic limb, “Repetitive Facilitation Exercise” (RFE; Kawahira method) is considered

an effective rehabilitation method that can elicit brain plasticity [8–11]. The aim of RFE is to induce brain plasticity; it involves two stages: separating the targeted movement from synergic movement with the application of facilitative stimulations and performing 100 repetitions. Facilitative stimulations include the stretch reflex, the skin muscular reflex, shrinkable electrical stimulation (SES) [12], vibratory stimulation (VS), auditory stimulation, and visual stimulation. However, there are some issues that make it difficult to train therapists in RFE techniques; accordingly, there is a shortage of therapists who can perform RFE treatment. Therefore, improving both the quality and the quantity of treatment applications is necessary by developing rehabilitation devices that can perform RFE treatment [5,13,14].

Concerning the research on rehabilitation training using RFE, Amano et al. [15] assessed the feasibility of applying a robot to improve the motor control and function of the hemiparetic upper extremity in patients who had suffered a chronic stroke, with neuromuscular electrical stimulation and vibratory stimulation applied to facilitate agonist muscle contraction. However, this rehabilitation method cannot completely separate the synergic movements between the elbow and shoulder joints.

Previously, most rehabilitation devices have employed passive power assistance provided by actuators, such as motors or artificial muscles [16–19]. There are a few studies that have focused on separating voluntary movement from the synergic movement of hemiplegic limbs. Although our rehabilitation system does not use actuators such as power-assist robots, it can separate the synergic movement and thus isolate the joint movements of the hemiplegic upper limb [4–6]. Because we set the RFE training posture as a supine position, our device does not require any actuators because the passive elbow flexion required to trigger the stretch reflex can be assisted by gravity acting on the patient's arm [4,6].

Rehabilitation training is most effective when it promotes voluntary movements. It is necessary for post-stroke patients with upper limb hemiplegia to have specific synergic movements separated from voluntary movements in their individual joints. In order to be able to perform coordinated movement, it is important for hemiplegic patients to achieve this separation [4]. However, when a hemiplegic patient is training alone, voluntary movement tends to be accompanied by synergic movement. Training that does not separate these movements will cause adverse effects. Therefore, it is important for hemiplegic patients to separate voluntary from synergic movements in their training [7].

Hence, in our previous research, a selective Arm-DoF constrainable mechanism (Figure 1) and multiple facilitative stimulation timing and duration control systems for hemiplegic upper limb rehabilitation were developed, as introduced in [4,6]. Our rehabilitation system facilitates deliberate, voluntary movements in the patient using the two aforementioned devices. Moreover, preliminary clinical experiments on hemiplegic patients using this system were reported in [5]. In this paper, we report on the short-term clinical effects of a newly proposed training program using this system for hemiplegic elbow extension rehabilitation.

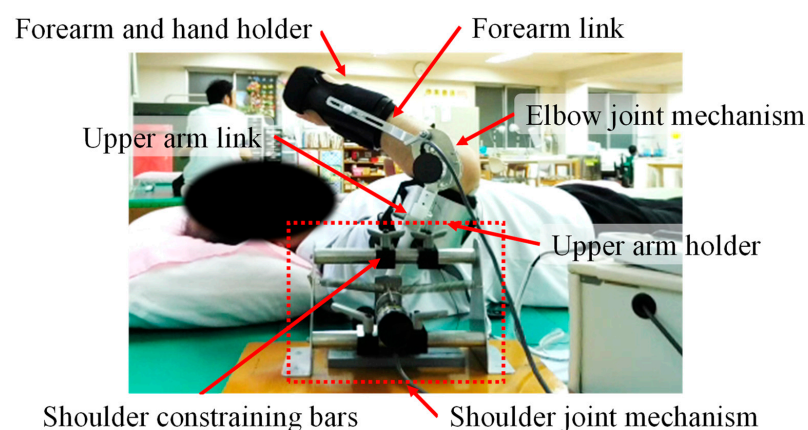


Figure 1. Selective Arm-DoF constrainable mechanism.

2. A Selective Arm-DoF Constrainable Mechanism and Multiple Facilitative Stimulation Control System

2.1. Selective Arm-DoF Constrainable Mechanism

Figure 1 shows the device mounted on the right arm of a patient. This device includes two link mechanisms that can only move in the DoF of purposeful movements of the shoulder and elbow joints. The upper arm and forearm are held by these links. The main structural materials of this device are an aluminum alloy and non-metallic materials, meaning the device is lightweight and not oppressive on the arm of the user [4]. The selective Arm-DoF constrainable mechanism is adjustable so that it can fit the width and length of the upper limb of any patient, and it is able to limit the movement direction and range depending on the training being given, besides being able to aid the movement of the elbow joint. In fixing the forearm to the link mechanism, a brace is used to establish an appropriate position for training [4]. The range of shoulder movement is adjustable in intervals set on the shoulder-constraining bar, and this bar can be fixed or adjusted. The range of movement of the elbow joint is constrained by the elbow joint mechanism [4].

2.2. Elbow Joint Mechanism

The elbow joint mechanism enables elbow rotation, and the range of motion of the elbow joint can be set independently. An encoder is built into the rotation axis of the elbow joint mechanism [4]. Figure 2 shows the movements applied in the elbow extension–flexion exercise. The elbow joint has only one DoF, either flexion or extension. To avoid damage of the elbow joint, the rotational angle of the elbow should be limited to within -10° extension to 100° flexion. This mechanism can aid in the training of both the right and left arms [4]. The training posture is the same as that used in manual RFE training; in this training posture, the weight of the upper arm accelerates the flexion motion of the elbow, which can induce a stretch reflex in the triceps' brachii muscle without any actuators.

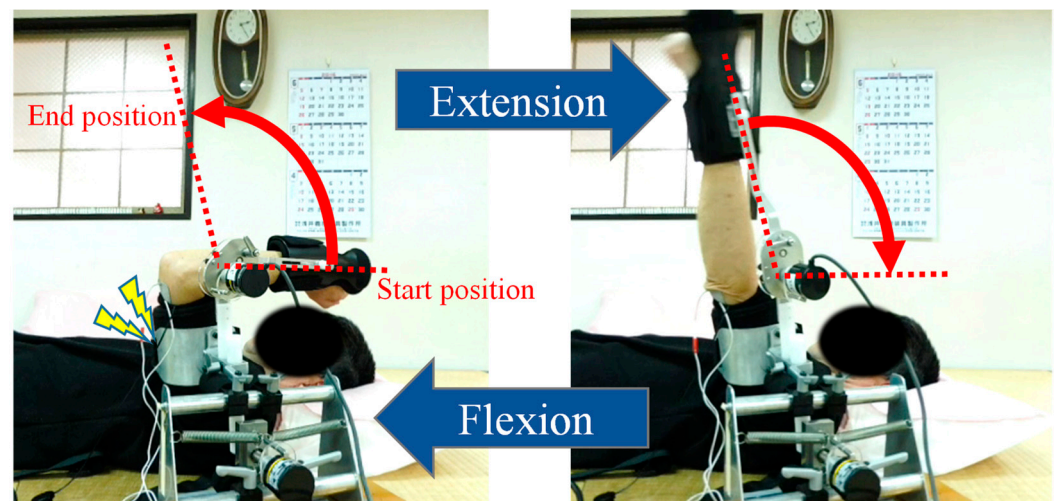


Figure 2. Elbow extension-flexion training exercise. SES and VS are given at predetermined timings during extension-flexion movements.

2.3. Multiple Facilitative Stimulation Timing and Duration Control System

An overview of the system configuration is shown in Figure 3. The encoder counter is connected to a laptop computer via a USB cable. The software on the laptop processes the count data provided by the rotary encoders set at each joint axis of the selective Arm-DoF constrainable mechanism. The computer records data on the joint angle and angular velocity. Based on the data regarding joint angle and angular velocity, it is possible to control the timing and duration of the SES and VS.

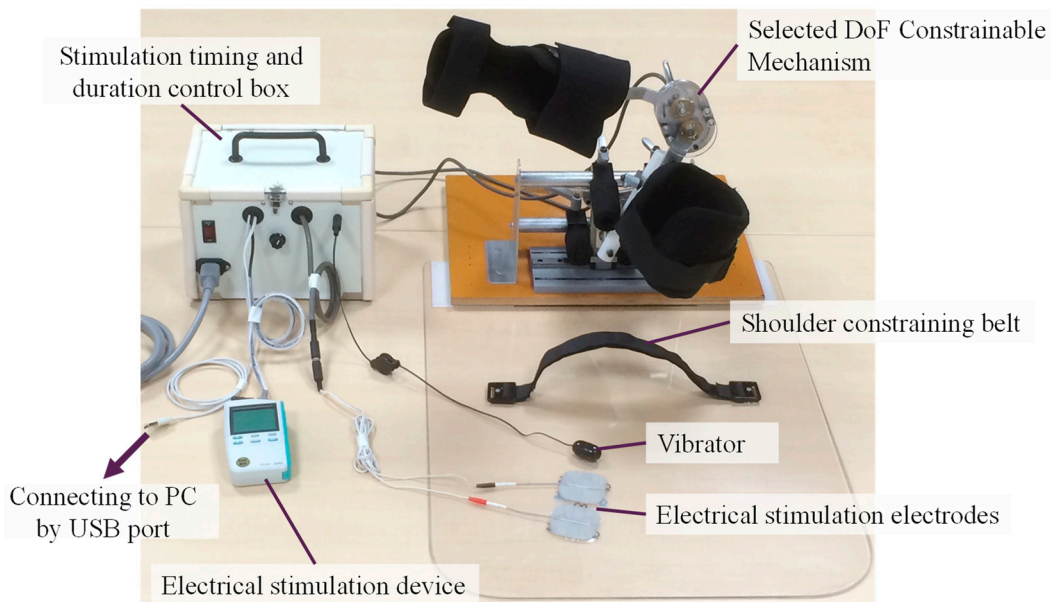


Figure 3. Configuration of the timing and duration control system for the SES and VS.

The points of stimulation of the SES and VS applied in the elbow extension training program are shown in Figure 4. Two electrodes are placed over the tricep brachii muscle [5]. The intervention timing and duration of the SES and VS are outlined in [5].

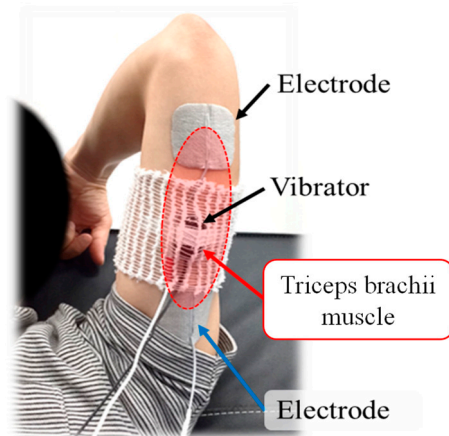


Figure 4. Stimulation points of the SES and VS.

In this study, the conditions of the SES were as follows: The pulse width was 150 μ s, and the pulse frequency was 50 Hz. The current intensity was set at different values optimized for each patient so as to avoid pain and muscle stiffness, with reference to the SES method outlined in [5,10]. The intervening end angle of the SES was set to 95% of the maximum movement range in order to prevent muscle cramps. The frequency of the VS was approximately 100 Hz.

2.4. Method of Rehabilitation Training and Evaluation

Figure 5 shows the values of the parameters applied when evaluating the training effects. The maximum angular velocity refers to the celerity of the training exercise, while the average angular velocity refers to the smoothness of the training exercise. Because the first and last points of the exercise training data are not stable, they were not used for the evaluation of the training effects. As such, when the training exercise was carried out 10 times, the maximum angular velocity data were only collected for the second repetition to the ninth. The method applied to evaluate the training effects involved a comparison

of the median values of the maximum angular velocity, recorded pre-training and post-training [5]. The average angular velocity is defined as follows:

$$\text{Average angular velocity [deg/s]} = \frac{\text{Maximum angle [deg]}}{\text{Exercise time [s]}} \quad (1)$$

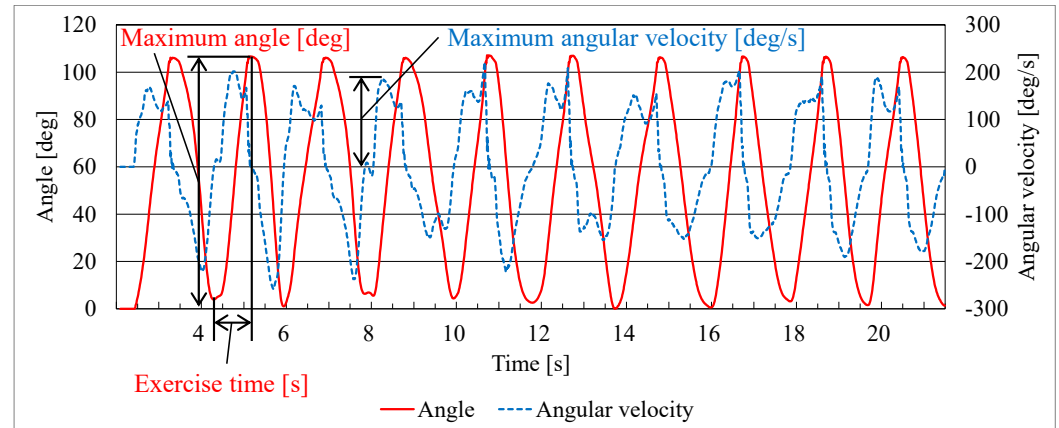


Figure 5. Definition of parameters on evaluations.

3. Clinical Experiments of Training

3.1. Aim of the Clinical Experiment

Our previous study showed that a combination of SES and VS is more effective than training without either. Furthermore, the study suggests that undertaking more than three sets of 10 repetitions, combined with SES and VS, significantly improved the training effects [5]. However, in previous studies, the number of repetitions of the training movement was as low as 10; thus, the effects of performing 100 repetitions, as in RFE, are unclear. Accordingly, in this study, we proposed a training program that involved a total of 100 repetitions of the training exercise, with repetitions increasing per set in combination with SES and VS, as inspired by RFE theory. The 100-repetition exercise was divided into two sets of 50 repetitions each to maintain the patient's concentration and prevent muscle fatigue. In these experiments, the number of training exercises in combination with SES and VS was set at 50 repetitions in each training set, and two sets were performed to determine the effects of repeated RFE training.

All study participants, or their legal guardians, provided informed written consent prior to study enrollment. In addition, we obtained approval from the Institutional Ethics Committee of the cooperating medical institution.

3.2. Methods of the Clinical Experiment

The configuration of the clinical experiment is shown in Table 1. The proposed training method comprises two training sets; one set comprises 50 repetitions of the purposeful training movement, as programmed into our system. In order to evaluate the effects of training, 10 repetitions were performed pre/post-test without any facilitative stimulations before and after the two sets of training. In the test set, for each set of 10 repetitions, the data regarding the maximum angular velocities and average angular velocities were collected from the second repetition to the ninth. In the training set, the data regarding the maximum angular velocities and average angular velocities were collected from the 2nd repetition to the 49th. The method applied for the evaluation of the effects of training was a comparison of the median values of the maximum and average angular velocities yielded in the test set before versus after the training set.

Table 1. Configuration of the clinical experiment.

| | Test/Training | Contents of Implementation | Repetitions Times |
|-----|---------------|---|-------------------|
| (1) | Pre-test | One set of exercises without SES and VS | 10 |
| (2) | 1st training | One set of training with SES and VS | 50 |
| (3) | Mid-test | One set of exercises without SES and VS | 10 |
| (4) | 2nd training | One set of training with SES and VS | 50 |
| (5) | Post-test | One set of exercises without SES and VS | 10 |

3.3. Subjects of the Clinical Experiment

We evaluated the short-term training effects through clinical trials involving five stroke patients using the above method. These subjects comprised two convalescent stroke patients and three chronic stroke patients. The details of these subjects are shown in Table 2.

Table 2. Details of the subjects used in the clinical experiment.

| Subjects | Age | Gender | Affected Side | Brunnstrom Stage | Sensory Impairment | Limited Motion Range | Period from Onset Date |
|----------|------|--------|---------------|------------------|--------------------|----------------------|------------------------|
| A | 50 s | Man | Right | III | Severe Hypesthesia | Have | 6 years |
| B | 60 s | Man | Left | V | Have | Not | 1 month |
| C | 80 s | Woman | Left | IV | Not | Not | 3 months |
| D | 60 s | Man | Left | IV | Have | Not | 2 years |
| E | 70 s | Man | Right | V | Have | Have | 1 years |

3.4. Results of the Clinical Experiment

The results of the experiment for subjects A–E are shown in Table 3. Figures 6–10 show the results for the maximum angular velocities and average angular velocities in each set. These results show that the maximum angular velocities of elbow extension improved significantly in most subjects after training with a combination of SES and VS. In addition, in almost all cases, we observed significant improvements in terms of the change observed in the rate of average angular velocities between the pre-test and post-test periods. As these results show, the improvements in the maximum angular velocity in the first set are greater than those in the second set. The change rate of the maximum angular velocity between the mid-test and post-test periods did not improve much, even over 50 repetitions. In some cases (for example, in subjects D and E), improvements in either the maximum angular velocity or average angular velocity were seen, but not both. Interestingly, in subject C, we saw no significant change in the maximum angular velocity. However, in the results for the average angular velocity, we can note a significant difference in the improvement rate of the average angular velocity in the evaluation test from before to after the first training set.

Table 3. The result of clinical experiments.

| Subjects | Gender | Brs Stage | Period from Onset Date | Change Rate of Angular Velocities between Pre-Test and Post-Test | |
|----------|--------|-----------|------------------------|--|-----------------------|
| | | | | Maximum Values | Average Values |
| A | Man | III | 6 years | 47.2% ($p < 0.01$) | 179.7% ($p < 0.01$) |
| B | Man | V | 1 month | 35.0% ($p < 0.01$) | 41.0% ($p < 0.01$) |
| C | Woman | IV | 3 months | 16.1% ($p < 0.01$) | 19.2% ($p < 0.01$) |
| D | Man | IV | 2 years | 36.3% ($p < 0.01$) | 0.2% ($p = 0.77$) |
| E | Man | V | 1 years | 6.6% ($p = 0.47$) | 52.1% ($p < 0.01$) |

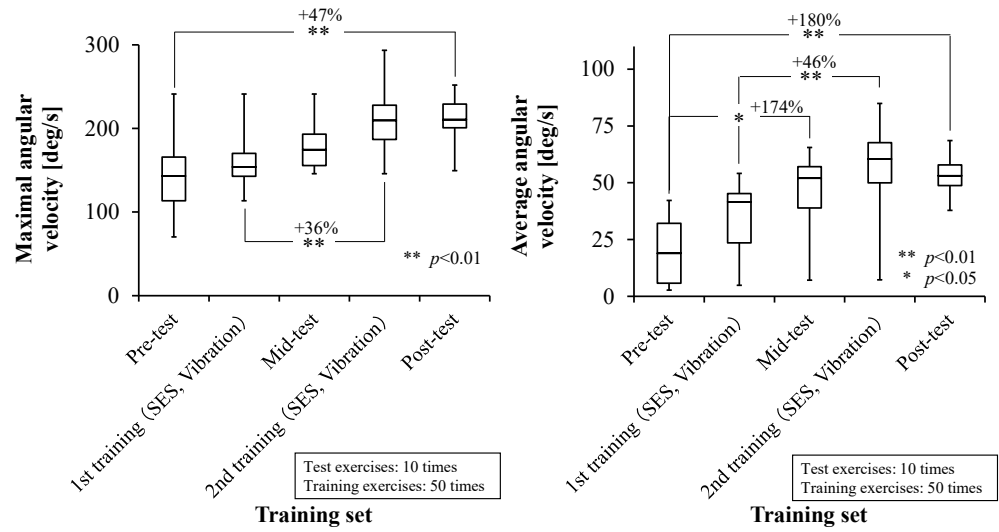


Figure 6. Maximum angular velocities (Left) and average angular velocities (Right) of subject A.

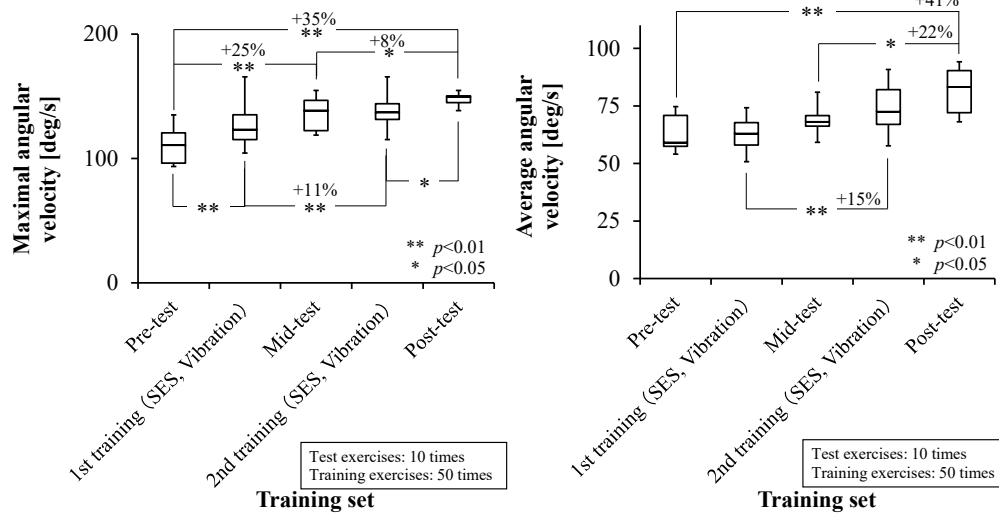


Figure 7. Maximum angular velocities (Left) and average angular velocities (Right) of subject B.

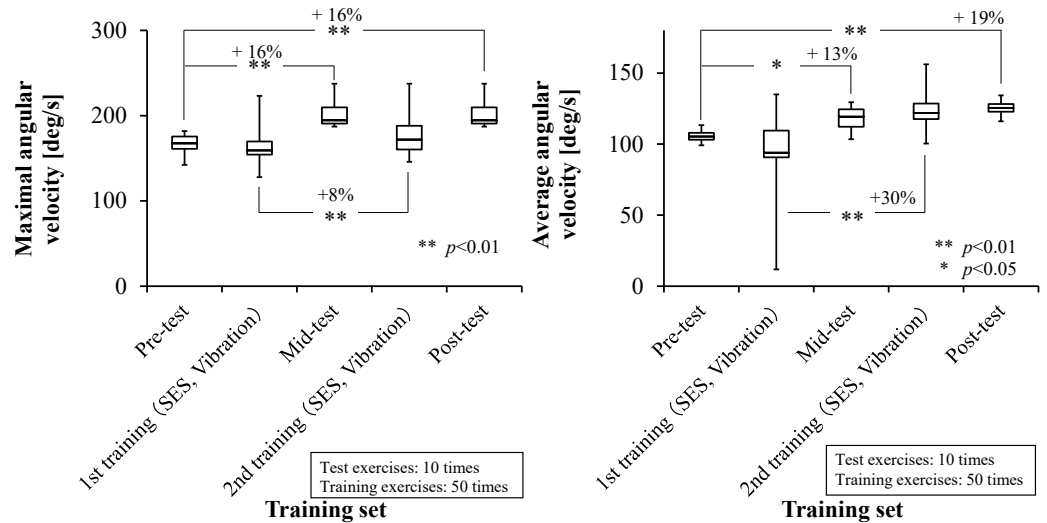


Figure 8. Maximum angular velocities (Left) and average angular velocities (Right) of subject C.

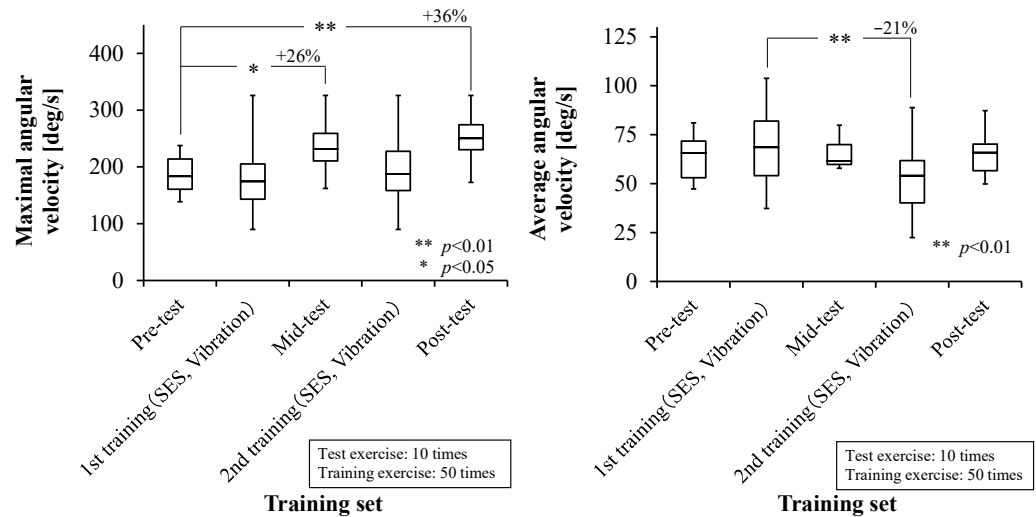


Figure 9. Maximum angular velocities (Left) and average angular velocities (Right) of subject D.

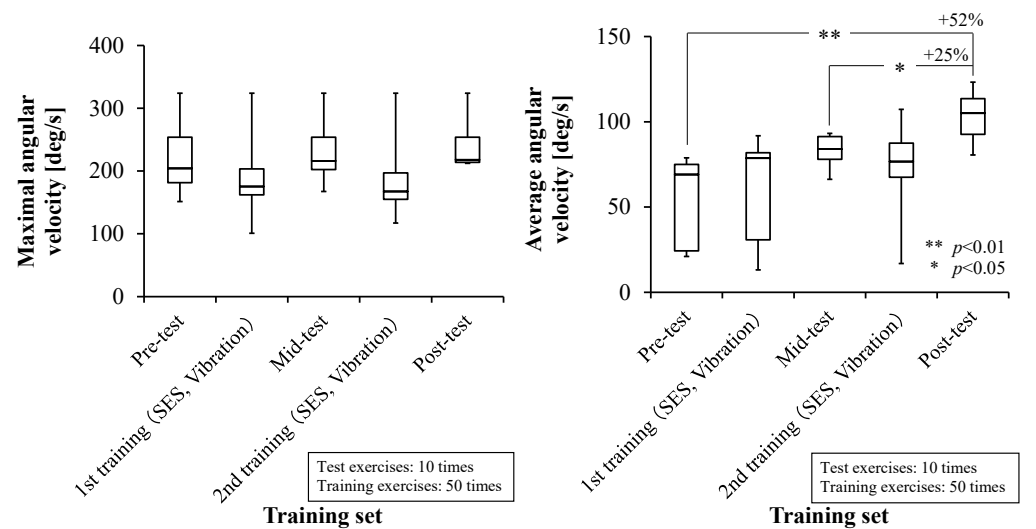


Figure 10. Maximum angular velocities (Left) and average angular velocities (Right) of subject E.

Surprisingly, large effects of the training were observed in chronic patients (over 6 months from stroke onset).

4. Discussion

As the results of these clinical experiments show, the combination of SES and VS yielded good effects, as seen in previous studies [4–6]. This demonstrates the effectiveness of the VS and SES combination when used as a facilitative stimulus applied in the hemiplegic rehabilitation of elbow extensions. These results also show that a tonic vibration reflex (TVR) related to VS was easily induced by increasing the biopotential excitation level of the target muscle attributed to SES. TVR is the phenomenon whereby a muscle contracts due to a spinal reflex, itself arising when a muscle spindle senses a stimulus resulting from a change in muscle length and shrinkage rate due to vibration [5,20]. Besides this, it is also considered that the training posture employed could induce a stretch reflex in the triceps' brachii muscle without the use of any actuator; this is due to the weight of the upper arm accelerating the flexion of the elbow.

In addition, it was suggested that increasing the number of repetitions per set could produce consistent improvements in the motion velocity after training. In manual RFE, the training movements are usually repeated 100 times; therefore, it was theorized that a greater training effect could be yielded by employing the RFE training method. Another significant

aspect of the above results reveals that by automating RFE training using mechatronics, it is possible to not only statistically verify the effectiveness of the training method itself but also to quantitatively evaluate the training's immediate effects, with a focus on the individual patient.

In most cases, when assessing the change rate of the maximum or average angular velocity pre-test versus post-test, we observed significant improvements. It is assumed that improvements in the maximum angular velocity indicate improved agility; on the other hand, improvements in the maximum angular velocity indicate improved smoothness of movement. However, there are some cases that showed no significant improvement in the maximum angular velocity. In these cases, we saw significant improvements in average angular velocity, and so these results suggest that only the smoothness of movement was improved. Thus, these results indicate that the speed of movement was broadly improved. As such, after observing both the maximum angular velocities and average angular velocities, we can infer the quality of the effects of training.

As shown by most of the results, the improvements in the maximum and average angular velocities achieved in the first training are greater than those achieved in the second training. This result suggests that the ratios of the training effects are not greatly improved over the 50 training exercises. Based on these facts, it seems that around 100 repetitions would be appropriate, and increasing the number of training repetitions to over 100 would be inefficient.

Furthermore, interestingly enough, large training effects were observed in patients in the chronic phase group for whom over 6 months had elapsed from stroke onset. This suggests that automatic training employing SES and VS in addition to RFE is effective even in chronic patients.

These results only indicate short-term training effects, and thus, we have yet to verify the more long-term training effects. Even if the effects imparted by the training increase movement momentarily, it is unclear what the long-term effects might be when training is continued daily for some weeks. A study by Amano et al. [15] showed medium-term training effects over two weeks derived from robotic rehabilitation using a combination of electrical stimulation and VS. Therefore, the approach in this study could yield not only short-term training effects but also medium- to long-term effects.

5. Conclusions

In this study, we proposed a hemiplegic upper limb rehabilitation system that can train the elbow and shoulder independently. The system consists of a selective Arm-DoF constrainable mechanism and a multiple facilitative stimulation timing and duration control system. The selective Arm-DoF constrainable mechanism enables the separation of synergic movements during elbow extension training by constraining each individual joint throughout the training exercise. Furthermore, this system permits control of the timings of the interventions and the duration of SES and VS according to the angle and angular velocity in the elbow joint. This system employs no actuators, such as power-assist robots, which improves safety and lowers costs.

Our previous study showed that using a combination of SES and VS is more effective than using neither. Furthermore, this study suggests that undertaking more than three training sets of 10 repetitions, combined with SES and VS, improved the training effects. Accordingly, in this study, we have proposed a training program comprising a total of 100 repetitions of the training exercise using the hemiplegic upper limb rehabilitation system. The proposed training method consists of two sets; each set comprises 50 repetitions of the elbow extension exercise, as programmed into our system. We evaluated the short-term training effects through clinical trials on five stroke patients using the above method. In order to evaluate the training effect, 10 repetitions of pre/post-tests without any facilitative stimuli were performed before and after the two sets of training.

Focusing on the evaluation of the instrumentation, the maximum angular velocities of elbow extensions improved significantly in most subjects. These results indicate that the

speed of the elbow extension movements in the hemiplegic limb improved. In addition, in most cases, we observed significant improvements in the change rate of the average angular velocities between the pre-test and post-test periods. These results indicate that the smoothness of the elbow extension movements in the hemiplegic limb improved. In particular, in some cases (for example, in subjects D and E), improvements in either the maximum angular velocities or average angular velocities were seen, but not both. These results demonstrate the value of the training, both in terms of the maximum angular velocity and average angular velocity. Interestingly, significant training effects were observed in chronic patients for whom over 6 months had elapsed since the stroke onset. The clinical experiments demonstrated the short-term clinical effects of the proposed method, as well as the practicality of the quantitative evaluations using our system.

In future research, it will be necessary to verify more long-term training effects, such as those for when training is continued daily for a number of weeks. Moreover, it is thought that quantitative evaluations of this system could be made more effective by evaluating correlations with data provided by existing rehabilitation evaluation methods, such as FMA (Fugl-Meyer Assessment), FIM (Functional Independence Measure), or ARAT (Action Research Arm Test).

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