INTRODUCTION

The rehabilitation of stroke patients includes training the patients to do tasks that address their needs and to improve voluntary movements, thereby eliciting emotions such as joy and pleasure to maintain motivation for living. However, the selected task content varies according to patient needs, and it is difficult to verify the effects of different tasks. There are few reports on the comparison and verification of rehabilitative procedures in stroke patients.1–4) Wolf et al. reported that constraint-induced movement therapy, which was administered to stroke patients in the subacute to chronic stages, resulted in a significant improvement in upper limb function.5) Aisen et al. reported that robotic rehabilitation in acute stroke patients led to improved upper limb function.2) Kakuda et al. demonstrated the effect of repeated transcranial magnetic stimulation and intensive occupational therapy on improved upper limb function in stroke patients.3) However,
these studies did not provide enjoyable motivational therapy for patients. Our hospital has been working with companies, governments, and universities since 2016 in cooperation with the Hashimoto Screw Co., Ltd., and has been conducting occupational therapy with Screw Block® – a kit for creating three-dimensional objects such as animals and robots by combining various screws, according to the manufacturer’s instructions (Fig. 1). Each kit includes 18 types of screws and blocks, a spanner, and instructions to make 11 types of three-dimensional objects, with each step of the process explained through illustrations and short sentences (Fig. 2).

Screw Block® requires precise fingertip movement control and can be used for training and fun construction activities. However, the extent to which Screw Block® affects upper limb function in stroke patients is unclear.

This study was conducted to examine the effect of training with Screw Block® on the upper limb function and emotional state of stroke patients with hemiplegia.

Fig. 1. Assembled Screw Block® – Duck, Helicopter, Dog 2.

Fig. 2. Parts and assembly of the Screw Block® kit.
MATERIALS AND METHODS

Study Design
This single-center, quasi-randomized, controlled trial was conducted at the Hamamatsu Rehabilitation Hospital in accordance with the guidelines of the CONSORT 2010 Statement. Informed consent was obtained from all participants before starting the study experiments, which were approved by the Ethics Committee of the Hamamatsu Rehabilitation Hospital (protocol approval no. 16–86, approval date February 9, 2017). This trial was registered with the University Hospital Medical Information Network Clinical Trial Registry (UMIN-CTR 000039969, registration date: April 6, 2020, https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000045523).

Participants
Thirty hemiplegic stroke patients aged more than 20 years who were admitted to our hospital between April 2017 and April 2019 participated in this study. The period from the onset of stroke was not defined. The sample size was set based on Julious et al.’s report, which recommended a minimum sample size of 12 participants per group for a pilot study. Considering a potential 20% drop-out rate, we recruited 15 participants in each group (a total of 30 study participants) in this study. Study eligibility was defined by the inclusion criteria, which included a degree of motor paralysis of the upper limb of at least 7 on Ueda’s 12-grade hemiplegic function test or of at least Brunnstrom Recovery Stage (BRS) III for upper limb/fingers, as well as the ability to voluntarily grasp the Screw Block® kit items. The exclusion criteria were as follows: (1) recurrent or multiple brain lesions with unclear causative lesions; (2) Ueda’s 12-grade hemiplegic function test score ≤6 (≤BRS II); (3) dementia with an inability to communicate; (4) aphasia with difficulty in understanding commands; (5) sensory impairment (loss); and (6) severe physical agnosia. These were judged based on the attending physician’s diagnosis at the time of admission.

Experimental Procedures
Between April 3, 2017, and April 8, 2019, the total number of hospitalized patients was 3165 and the number of stroke patients was 919. Thirty-nine patients met the inclusion criteria. Of these, five refused to participate in this study, and four participants did not complete the interventions. As a result, 30 stroke patients were randomly assigned to the experimental group (EG) or the control group (CG), with the restriction that the maximum number of participants per group was 15. This study involved manual randomization in which the first author placed paper coupons numbered from 1 to 30 in an envelope. Occupational therapists unrelated to this study drew out a coupon from the envelope and randomly assigned patients to the study groups. To ensure blinding, outcome assessments were undertaken by an occupational therapist unrelated to this study. Participants in the EG received training with Screw Block® for 20 min in addition to conventional occupational therapy (20–40 min) (Fig. 1, Table 1). Conventional occupational therapy incorporates manual training such as repetitive exercises using tools including pegboards, training for daily necessities, and exercises for daily activities to facilitate voluntary movements. Participants in the CG underwent conventional occupational therapy, including upper limb functional training for 40–60 min, but without training using Screw Block®. In both groups, training was conducted for 5 days a week for 3 weeks (15 sessions in total). Participants and evaluators did not know to which group each participant had been assigned. In the EG, there were no restrictions on the timing of the Screw Block® training during the session. The blocks were constructed using both upper limbs in the ascending order of the number of steps in the instructions and were then deconstructed after completion. If the Screw Block® task was completed in time, then the subsequent scheduled tasks were performed. However, if the initial task was not completed in time, then the partially assembled object was not dismantled, and participants resumed assembly the next day. Tasks were selected in order from the minimum number of steps to the maximum number of steps. Patients in the EG were challenged with as difficult steps as possible. Patients in the CG received the same occupational therapy as that of the EG, except for Screw Block®, including upper limb.

Table 1. Number of processes and difficulty of Screw Block®

| Project name | Number of processes | Difficulty |
|--------------|---------------------|------------|
| Duck         | 5                   | Easy       |
| Horse        | 11                  |            |
| Giraffe      | 12                  |            |
| Pig          | 13                  |            |
| Helicopter   | 15                  |            |
| Dog 1        | 16                  | ↓          |
| Crane        | 20                  |            |
| Squirrel     | 22                  |            |
| Robot        | 24                  |            |
| Alpaca       | 27                  |            |
| Dog 2        | 28                  | Difficult  |
Outcomes

All outcomes were evaluated before and after the 3-week intervention. Ten experienced occupational therapists conducted the training and evaluation of stroke patients in this study. The primary outcome measure was the STEF score of the affected side (STEF AS).

Simple Test for Evaluating Hand Function

STEF is a widely used, well-validated test for functional motor assessment that reflects activities of daily living. STEF consists of 10 types of tests, and the time required to complete each test is divided into 10 stages (scoring from 1 to 10 points). The total score can be compared with the normal range for healthy people according to 17 age groups, from 3 years old to 80 years or older. The secondary outcomes were the results of Ueda’s 12-grade hemiplegic function test, the Jikei Assessment Scale for Motor Impairment in Daily Living (JASMID), the General Self-Efficacy Scale (GSES), the visual analogue scale (VAS), and the Functional Independence Measure (FIM).

Ueda’s 12-grade Hemiplegic Function Test

Ueda’s 12-grade Hemiplegia Function Test for the upper limb and hand/finger is an upper limb test that consists of 11 subtests and one preliminary test; the hand/fingers test comprises 9 subtests. The grade is determined by matching the results of inspection with the overall score that is determined. This test has become recognized as a comprehensive test for the assessment of the hemiplegic upper limb and hand/finger.

Jikei Assessment Scale for Motor Impairment in Daily Living

JASMID was used as an outcome measure to evaluate parameters including the extent of limb use in the paralyzed upper limbs, self-efficacy, and mood/emotional status. JASMID consists of a total of 20 two-handed and one-handed items. This is a subjective rating scale, and the assessors are required to listen out for the “amount of use” and “quality of movement” of the paralyzed hand based on an interview method and assigned scores.

General Self-efficacy Scale

GSES was used as an outcome parameter for determining self-efficacy. GSES consists of 16 questions with dichotomous scoring (“yes” or “no”); scores are in the range 0–16.

Visual Analogue Scale

VAS was used for the assessment of sadness, vitality, and pleasure.

Functional Independence Measure

FIM was used to evaluate the parameters of motor and cognitive function.

Statistical Analysis

To compare outcomes between the two groups, the two-sample t-test and Fisher’s exact test were conducted. In addition, Cohen’s d was calculated as a measure of the effect size. Statistical analyses were conducted using IBM SPSS 20.0 (IBM Japan Corp., Tokyo, Japan). Statistical significance was defined as P <0.05 for all comparisons.

RESULTS

Table 2 and 3 show the characteristics and outcomes of patients in the EG and CG groups. There were no significant intergroup differences in baseline characteristics such as age, stroke type, period from stroke onset, degree of motor paralysis, and number of occupational therapy units that were completed. Most of the patients were right-handed, and there was no significant difference in the number of dominant and non-dominant affected sides. This study was completed without any reported adverse events (Fig. 3).

Primary Outcomes

Table 3 shows the results of the analysis. In the EG, the mean STEF AS score increased by 13.1 ± 10.4 points after the intervention (61.0 ± 28.2) compared with the pre-intervention score (47.9 ± 28.9). In contrast, in the CG, the score increased by 5.1 ± 8.0 points after the intervention (51.0 ± 32.4) compared with the pre-intervention score (45.9 ± 33.0). The two-sample t-test revealed that the increase in the mean STEF AS score was significantly higher in the EG than in the CG (T=2.252, P=0.032, Cohen’s d=0.82). Table 4 shows the results of the analysis of STEF sub-items. There were no significant differences for any sub-item.

Secondary Outcomes

As shown in Table 3, there were no significant differences in the secondary outcomes (Ueda’s 12-grade, JASMID, GSES, VAS, and FIM) between the two groups.
DISCUSSION

In this study, we observed a significant improvement in the primary outcomes (evaluated using STEF) in the EG compared with that in the CG (P=0.032). Therefore, occupational therapy using Screw Block® for stroke patients is more effective than conventional training, including upper limb functional training. There were no significant intergroup differences in age, the time from onset, or the degree of motor paralysis. Patient conditions in both groups before this study were generally uniform (Tables 2 and 3). In addition to similar degrees of motor paralysis in both groups, there was no significant difference in the duration of the intervention, which implied the absence of differences in the effect of these two factors on the outcomes. Although there were no significant differences in the STEF sub-items, some items had large effect sizes, and this is considered to be the reason for the significant difference in the total STEF score. There were large differences between the mean values of STEF items 2 and 9 before and after intervention in the EG, and the two effects are considered to be large. Rather than simple repetitive tasks, it is a variety of upper limb movements, finger movements, and complicated repetitive movements that improve upper limb function. Conventional occupational therapy aims to facilitate the learning of desired movements efficiently by using manual treatments to develop voluntary movements. The therapy includes training with simple, repetitive movements using tools such as pegboards and everyday items. These interventions are generally considered to be effective and are widely used as the basis for occupational therapy in Japanese medical facilities. We speculated that training the upper limb on the paralyzed side using complicated movements (e.g., the manipulation of screws rather than simple repetitive movements) such as those required for assembling objects to create a tangible piece of work would be more effective in improving upper limb function. Nudo et al. reported that long-term practice of certain sensory motor skills caused functional reorganization in the associated cortical expression. Molina et al. stated that skilled exercises promoted better functional recovery than did simple repetitive exercises. Training using Screw Block® requires complex skills of the upper limbs and fingers. These skills include not only simple movements such as reaching, pinching, turning, and pushing but also perceptual movements for adjusting force and tilt and repeated coordinated movements. Furthermore, there are 11 levels of difficulty, and patients

| Table 2. Baseline characteristics of the participants |
|-----------------------------------------------|
| EG | CG | P-value |
|----|----|---------|
| **Sex (n)** | M:14, F:1 | M:14, F:1 | - |
| **Age (years)** | 64.4 ± 13.7 | 60.5 ± 13.8 | 0.468 |
| **Stroke** |  |  |  |
| Cerebral infarction | 12 | 7 | 0.060 |
| Cerebral hemorrhage | 3 | 8 | - |
| Duration from onset (days) | 75.0 ± 38.0 | 75.0 ± 25.9 | 0.604 |
| Dominant hand right | 14 | 15 | 1.000 |
| Dominant hand is affected | 6 | 10 | 0.272 |
| Occupational therapy units (15 days)* | 39.1 ± 3.8 | 40.3 ± 3.9 | 0.379 |
| **Comorbidity** |  |  |  |
| High blood pressure | 5 | 7 |  |
| Diabetes | 4 | 3 |  |
| Dyslipidemia | 1 | 2 |  |
| Hyperuricemia | 0 | 2 |  |
| Dysphagia | 1 | 2 |  |
| Arrhythmia | 2 | 0 |  |
| Hypokalemia | 0 | 1 |  |
| Physical therapy units (15 days)* | 63.3 ± 14.4 | 65.9 ± 15.5 | 0.637 |
| Speech therapy units (15 days)* | 20.9 ± 13.5 | 18.4 ± 11.7 | 0.597 |

Mean±SD values are reported from the analyses.
*1 unit=20 min. EG: experimental group, CG: control group.
Fig. 3. CONSORT flowchart showing the flow of patients through the trial.
can challenge themselves with difficult tasks if they wish. Of the 15 participants in the EG, 11 completed 11 sessions, 1 completed 10 sessions, 1 completed 9 sessions, 1 completed 8 sessions, and 1 completed 7 sessions. The results of this study suggest that performing repeated controlled movements with Screw Block® improved upper limb function, such as finger dexterity, and improved the score of the primary evaluation item (STEF) more than conventional training did.

The secondary outcomes, evaluated using GSES, did not differ significantly (P=0.129) between the EG and CG, although the effect size was determined to have a d=0.57, which indicated a moderate effect. There was no significant difference in VAS (pleasure; P=0.127), but the effect level was moderate (d=0.57). With regard to pleasure and self-efficacy, Honke stated that pleasure is the comfort of a positive change in the body, thoughts, and emotions during work.14) In the present study, we presumed that the process of completing an assigned task would induce an improvement in upper limb function and confer a sense of accomplishment, leading to changes in mood and emotional state. There were no significant differences in the emotion and mood items between the two groups; however, moderate effect sizes in GSES and VAS (pleasure) were recognized. The reason for these results might be attributed to the small sample size.

Conventional training methods have been devised and practiced, and patients continue to work toward functional recovery with pleasure and self-efficacy. The fact that the introduction of Screw Block® resulted in an observable effect size with regard to pleasure suggests the importance of incorporating Screw Block® into rehabilitative training. However, it is necessary to verify these effects in a larger sample with higher statistical power.

In this study, we examined upper limb function and mood/emotion. However, we aimed to generalize the functional improvement using Screw Block® with regard to life and disability. We believe that it is necessary to clarify the issues associated with rehabilitative activities and participation and ensure greater patient involvement. The introduction of this

Table 3. Outcomes of the interventions

| Outcome | Before | After | Difference | T-value | P-value | Effect size |
|---------|--------|-------|------------|---------|---------|-------------|
| STEF AS | EG     | 47.9 ± 28.9 | 61.0 ± 28.2 | 13.1 ± 10.4 | 2.252 | 0.032 | 0.82 |
|         | CG     | 45.9 ± 33.0 | 51.0 ± 32.4 | 5.1 ± 8.0 |         |         |
| Ueda’s 12-grade |        |       |            |         |         |
| Upper limb | EG | 9.4 ± 2.7 | 10.0 ± 2.2 | 0.6 ± 0.8 | 1.364 | 0.183 | 0.49 |
|         | CG | 9.9 ± 1.3 | 10.2 ± 1.3 | 0.3 ± 0.4 |         |         |
| Fingers | EG | 9.5 ± 1.9 | 9.5 ± 1.9 | 0.1 ± 1.3 | 0.908 | 0.372 | 0.33 |
|         | CG | 9.2 ± 2.1 | 9.7 ± 1.7 | 0.5 ± 1.5 |         |         |
| JASMID |        |       |            |         |         |
| Amount | EG | 63.7 ± 21.9 | 69.5 ± 24.1 | 5.8 ± 9.5 | 0.456 | 0.652 | 0.17 |
|         | CG | 64.0 ± 20.3 | 68.0 ± 16.6 | 4.0 ± 11.3 |         |         |
| Quality | EG | 51.8 ± 16.3 | 62.1 ± 19.3 | 10.3 ± 7.6 | 1.103 | 0.279 | 0.4    |
|         | CG | 55.9 ± 21.8 | 62.7 ± 17.1 | 6.8 ± 8.8 |         |         |
| GSES | EG | 9.7 ± 4.6 | 10.7 ± 3.9 | 0.9 ± 1.6 | 1.562 | 0.129 | 0.57 |
|         | CG | 8.5 ± 3.1 | 8.0 ± 3.9 | −0.5 ± 2.9 |         |         |
| VAS |        |       |            |         |         |
| Sadness | EG | 2.5 ± 2.8 | 1.0 ± 1.5 | −0.5 ± 2.4 | −0.27 | 0.789 | 0.1   |
|         | CG | 4.5 ± 2.9 | 3.2 ± 2.2 | −1.3 ± 2.8 |         |         |
| Vitality | EG | 7.4 ± 2.5 | 8.3 ± 2.2 | 0.9 ± 2.7 | 0.695 | 0.493 | 0.25 |
|         | CG | 7.6 ± 2.4 | 7.9 ± 1.9 | 0.3 ± 1.7 |         |         |
| Pleasure | EG | 5.4 ± 2.4 | 6.8 ± 2.5 | 1.4 ± 3.0 | 1.574 | 0.127 | 0.57 |
|         | CG | 5.9 ± 2.5 | 5.7 ± 2.5 | −0.1 ± 2.1 |         |         |
| FIM |        |       |            |         |         |
| EG | 107.5 ± 12.3 | 112.3 ± 11.2 | 4.7 ± 5.8 | 0.116 | 0.909 | 0.04 |
|         | CG | 100.1 ± 15.8 | 104.6 ± 12.3 | 4.5 ± 6.4 |         |         |

Mean±SD values are reported from the analyses. Statistical analyses were performed on the differences between EG and CG.
Screw Block® training method, in addition to conventional occupational therapy, has great potential for future advances in occupational therapy. We believe that the search for novel training methods, such as this one, should be continued in occupational therapy.

Limitations
In this study, the proportion of male participants was considerably higher than that of women. Future research into this aspect needs to consider sex-specific effects and include training methods that are of interest to female patients.

Conclusion
In this pilot, quasi-randomized, controlled trial, improvement of the paralyzed upper limb function measured using STEF was significantly higher in participants who received occupational therapy using Screw Block® than in those who received only conventional occupational therapy. This result suggests that occupational therapy using Screw Block® might be effective in the improvement of upper limb function in stroke patients.

Table 4. Results for the Sub-item of STEF on the affected side

| Item no. | Sub-item        | Before | After  | Difference | T-value | P-value | Effect size |
|----------|-----------------|--------|--------|------------|---------|---------|-------------|
| 1        | Five large balls| EG     | 5.9 ± 3.3 | 6.9 ± 3.1 | 0.9 ± 1.8 | 0.689   | 0.496       | 0.29        |
|          |                 | CG     | 5.1 ± 3.6 | 5.5 ± 3.6 | 0.5 ± 1.4 |         |             |             |
| 2        | Six medium balls| EG     | 5.8 ± 2.9 | 7.1 ± 2.3 | 1.3 ± 2.1 | 0.000   | 1.000       | 0.81        |
|          |                 | CG     | 5.8 ± 3.4 | 5.8 ± 3.6 | 0.0 ± 0.8 |         |             |             |
| 3        | Five large cubes| EG     | 6.1 ± 3.2 | 7.1 ± 2.6 | 1.1 ± 1.8 | 0.514   | 0.612       | 0.66        |
|          |                 | CG     | 5.5 ± 3.2 | 5.6 ± 3.5 | 0.1 ± 1.0 |         |             |             |
| 4        | Six medium cubes| EG     | 5.3 ± 3.0 | 6.3 ± 2.9 | 0.9 ± 1.6 | 0.500   | 0.621       | 0.34        |
|          |                 | CG     | 5.2 ± 3.3 | 5.2 ± 3.3 | 0.5 ± 1.1 |         |             |             |
| 5        | Six wooden boards | EG    | 5.9 ± 3.1 | 7.1 ± 2.2 | 1.2 ± 2.2 | 0.845   | 0.405       | 0.32        |
|          |                 | CG     | 4.9 ± 3.3 | 5.6 ± 3.5 | 0.7 ± 1.9 |         |             |             |
| 6        | Six small cubes | EG     | 5.0 ± 3.2 | 6.2 ± 2.3 | 1.2 ± 1.7 | 0.877   | 0.388       | 0.41        |
|          |                 | CG     | 3.9 ± 3.5 | 4.5 ± 3.5 | 0.5 ± 1.6 |         |             |             |
| 7        | Six cloths      | EG     | 6.0 ± 2.5 | 7.1 ± 1.9 | 1.1 ± 1.2 | 0.730   | 0.472       | 0.55        |
|          |                 | CG     | 5.2 ± 3.4 | 5.4 ± 3.4 | 0.2 ± 1.9 |         |             |             |
| 8        | Six gold boards | EG     | 3.8 ± 3.3 | 5.2 ± 2.8 | 1.4 ± 3.1 | 0.253   | 0.802       | 0.44        |
|          |                 | CG     | 3.5 ± 3.9 | 3.8 ± 3.7 | 0.3 ± 1.5 |         |             |             |
| 9        | Six small balls | EG     | 5.4 ± 3.3 | 6.5 ± 3.2 | 1.1 ± 1.1 | 1.029   | 0.312       | 1.05        |
|          |                 | CG     | 3.9 ± 4.4 | 4.1 ± 4.6 | 0.2 ± 0.6 |         |             |             |
| 10       | Six pins        | EG     | 4.1 ± 3.7 | 6.0 ± 3.4 | 1.9 ± 2.6 | 0.230   | 0.820       | 0.59        |
|          |                 | CG     | 3.7 ± 4.2 | 4.3 ± 4.3 | 0.6 ± 1.8 |         |             |             |

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CONFLICTS OF INTEREST
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