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Feasibility and Therapeutic Effects of a Novel Magnet-Based Device for Hand Rehabilitation: a Pilot Study

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HIGHLIGHTS

- We developed a novel concept hand rehabilitation device using magnetic forces.
- Hand motor function and independence in the activities of daily living improved after rehabilitation therapy using this device.
- Magnetic-based hand rehabilitation devices can be a safe and beneficial therapeutic modality.

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ABSTRACT

The purpose of this study was to investigate the feasibility and therapeutic effects of a novel concept hand rehabilitation device based on magnetics for subacute stroke patients with hand motor impairment. We developed an end effector type device that can induce various movements of the fingers in accordance with a magnetic field direction using electromagnets and permanent magnets. Subacute stroke patients with hand motor impairments were recruited and divided into two rehabilitation groups. Conventional rehabilitation therapies were also conducted equally in both groups. Active-assisted training of the affected hand was additionally administered for 30 minutes per day for 4 weeks using the developed equipment in the intervention group. Hand motor function and the activities of daily living were evaluated before and after the intervention. The Manual Function Test score significantly increased in the intervention group after 4 weeks of treatment ($p = 0.039$), and there was a significant difference in the degree of improvement between the two groups ($p = 0.016$). The scores of the motor Fugl-Meyer Assessment of the upper limb, the Wolf Motor Function Test score and time, and the motor Functional Independence Measure also improved in both groups (all $p < 0.05$). In addition, the patients in the intervention group showed greater improvements in these outcome measures than those in the control group did (all $p < 0.05$). An adjuvant rehabilitation therapy using a magnetic based device can be helpful to improve the hand motor function and activities of daily life in subacute stroke patients.

Keywords: Hand; Rehabilitation; Robotics; Stroke; Upper Extremity

INTRODUCTION

Motor impairment, typically affecting movement of the face, arm, and leg of one side of the body, affects approximately 80% of stroke survivors [1]. Among them, upper limb motor impairments are often persistent and disabling. Only 20% to 56% of all stroke survivors regain useful upper limb function after three months, and of those with initial arm impairment, 50% have problems with arm function 4 years post stroke [2]. Hand functions are strongly related to performance in activities of daily living (ADL), and deficits in hand function seriously impact health-related quality of life [2,3]. Therapists have developed many

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Conflict of Interest
The authors have no potential conflicts of interest to disclose.

diverse techniques that aim to rehabilitate hand dysfunction [2], but recovery of hand motor function still remains a great challenge in stroke rehabilitation because the human hands are very complex and versatile [3].

New robotics have been used for stroke survivors to improve hand function and ADL in recent years. The exoskeleton hand using metals to provide a rigid framework to assist motor impairments were developed in the early stages of rehabilitation robotics [4-6]. However, the development of soft robotics fabricated from easily deformable materials such as fluids, gels, and soft polymers that have better biomimetic qualities is currently an active area of research. Soft hand robotics mainly use pneumatic, cable, and hydraulic systems as actuators and make glove-formed, wearable devices to increase compliance and versatility while conforming to the contours of the human body [7-10]. These robotics have shown some positive effects on hand motor recovery in stroke patients when applying conventional rehabilitation therapies together [3,7,11]. Although previous robotics or devices have great potential for applying beneficial rehabilitation modalities, the actual use in clinical practice is still lacking due to several disadvantages. For example, exoskeleton robotics are bulky and show reduced motion in unactuated directions or misalignment with the finger's anatomic axis during motion. Soft robotics also have disadvantages, such as discomfort of wearing a glove, loud noise due to compressed air, lack of power to flex or extend spastic fingers, and complicated mechanisms [7].

To overcome these points, we introduced the use of magnetic force. Due to simple mechanisms, a device using magnetic force has advantages in easier development and less cost than those of other robotics using electric motors or pneumatic systems. In addition, rehabilitation devices based on magnetic forces can be developed as end effector types using magnets, not a glove form that impedes the patient's compliance, and implement a variety of movements depending on the direction of the magnetic field. Therefore, we developed a new hand rehabilitation device based on magnetic force and investigated the feasibility and therapeutic effects for subacute stroke patients with hand motor impairment.

MATERIALS AND METHODS

Development of device

We proposed a one-dimensional hand rehabilitation device using an electromagnetic control system (Fig. 1). When an electric current is applied to a coil in an electromagnetic control system, a magnetic field is generated in the coil. This magnetic field is called the gradient magnetic field because the shape of the generated magnetic field becomes weaker as it moves away from the coil. Between this magnetic field and the magnet, the attractive force or repulsive force acts by electromagnetic phenomena. Flexing or extending motions of fingers were induced by these forces. The permanent magnets fabricated using a 3D printer were adjunctively devised to reinforce the magnetic forces. For example, magnets were attached to the palm so that the magnets could be attracted to each other and the fingers could flex more effectively when flexing the fingers. The magnetic forces required to move the fingers as much as desired can be controlled by the amount of current flowing through the coil.

Patients' selection

Subacute stroke patients within three months of the occurrence were recruited. The patients with grade 3 or less when evaluated finger flexion or extension by manual motor test were

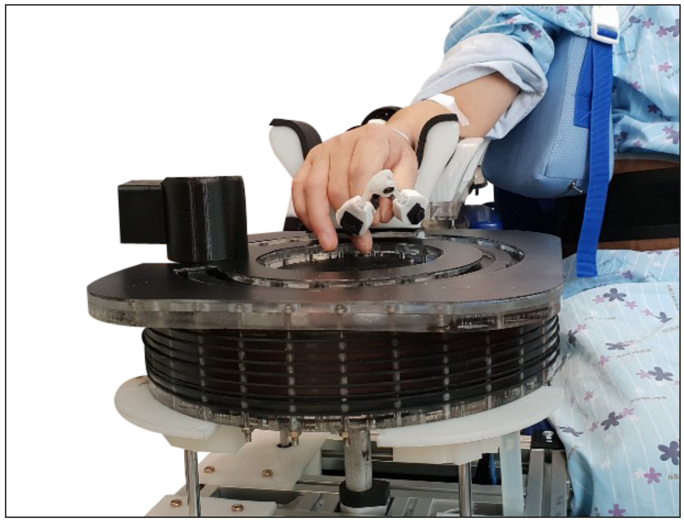

Fig. 1. Magnetic-based hand rehabilitation therapy. The patient's finger movements are induced by the interaction between a permanent magnet placed on the patient's fingers and the electromagnetic force generated at the top of the machine. Permanent magnets have a constant magnetic direction, but the electromagnetic forces generated from the coil can generate the manpower and repulsive force in accordance with the current direction.

included among them. Patients with severe cognitive impairments, poor sitting balance, and serious medical comorbidities were excluded. This study was approved by the Institutional Review Board of the hospital (WKUH 2017-07-023-003), and written informed consent to the details of the experiment was received from all participants.

Intervention

The patients were randomly divided into two groups: the intervention group and the control group. Conventional physical therapy directed at both improving upper extremity mechanics through passive range of motion exercises and reducing neurologic injury based on the Bobath approach was performed twice per day in both groups. Other occupational, language, and cognitive therapies commonly performed in stroke rehabilitation settings were carried out in both groups during the study period. In the intervention group, additional therapy using a magnetic-based hand rehabilitation device was administered. Three therapeutic techniques focused on the active assistant training modality were performed: gross flexion and extension, opposition, and metacarpal (MCP) joint deviation. The specific training protocol was as follows. Gross flexion/extension except for the thumb was performed for 10 minutes. Opposition movements were conducted by touching the patients' thumb to each finger, making an “okay” sign. At the same time, the patients tried to keep other fingers straight and pointing upward as much as they could. Twisted stretching exercise of the MCP joints of each finger was performed in a half-supinated arm position. One session of the treatment took approximately 30 minutes and was administered for four weeks once per day. Adverse effects, such as pain, swelling, or abnormal movements, were closely monitored while performing magnet-based rehabilitation therapy.

Outcome measures

Both primary and secondary outcome measures were evaluated twice, before and after the intervention. The Manual Function Test (MFT) to determine the recovery of hand function was used as the primary outcome measure. The MFT was developed as a measure to assess the functions of the paralyzed upper limb in hemiplegic patients after stroke [12], and

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normative values based on age, sex, and hand dominance are available [13]. The MFT score can even be calculated for patients with severe hemiplegia and shows high reliability and validity in stroke patients [12]. The MFT score can range from 0 to 100 points, and a higher score indicates better hand function.

Secondary outcome measures included upper limb motor score of the Fugl-Meyer Assessment (FMA), the Wolf Motor Function Test (WMFT), and the motor Functional Independence Measure (FIM). The FMA is used to assess sensorimotor impairment in individuals who have had a stroke [14]. The FMA scale is an ordinal scale that has 3 points for each item, and the maximal score in the upper limb is 66 [14]. The WMFT tests a broad range of upper extremity functions through two strength measurements and a series of 15 functional tasks that progress from simple movements in proximal joint areas to complex movements in distal joint areas [15]. Each of the 15 tasks is timed to completion, up to a maximum of 120 seconds. Functional ability subscores represent the quality of the movement during the performance of these functional tasks [16]. The WMFT is a valid and reliable measure of upper extremity function even in severely impaired subjects with high test-retest and interrater reliability [16]. WMFT scores are distributed from 0 to 75 points, and higher scores indicate good performance. The motor FIM consists of 13 items that evaluate independence in ADL. The scoring of each item ranges from 1 to 7 points depending on the level of independent performance, and the maximum score is 91 points [17].

Age, gender, stroke type, dominant hand side, stroke side, period after stroke onset, spasticity, initial National Institutes of Health Stroke Scale (NIHSS), the Korean version of the mini mental status examination (K-MMSE), and the Korean version of the modified Barthel Index total (K-MBI) were investigated as baseline information.

Statistics

To determine differences in the baseline parameters between the two groups, the Mann-Whitney U test for continuous variable and Fisher's exact test for categorical variables were used. Changes in each variable from before to after the intervention were analyzed within groups by the Wilcoxon signed rank test. The Mann-Whitney U test was performed to compare the therapeutic effects between groups. A p value below 0.05 was defined as statistically significant, and all statistical analyses were performed using SPSS 22.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

A total of 10 patients were assigned to the intervention group (n = 5) or the control group (n = 5). No adverse effects, such as pain, overstretching, and subluxation of the joints, were reported, and there were no dropped patients during the study period. The mean poststroke period of the participating patients before starting the intervention was 29.2 ± 5.9 days, and the mean age was 64.1 ± 5.0 years. The baseline characteristics are summarized in Table 1. The demographic, clinical, and radiological factors were similar between the groups. In addition, there were no significant differences between the groups in the NIHSS, K-MBI, K-MMSE, or the degree of spasticity in the upper limbs.

The primary outcome MFT score significantly increased from 21.8 ± 2.8 to 38.1 ± 3.0 in the intervention group after 4 weeks of treatment ($p = 0.039$) (Fig. 2). MFT in the control

Table 1. Baseline characteristics

Factors	Intervention group (n = 5)	Control group (n = 5)	p value
Age (yr)	63.8 ± 5.8	64.4 ± 4.4	0.832
Sex			1.000
Male	3 (60)	3 (60)	
Female	2 (40)	2 (40)	
Stroke type			1.000
Ischemic	4 (80)	4 (80)	
Hemorrhagic	1 (20)	1 (20)	
Dominant hand			1.000
Right	5 (100)	5 (100)	
Left	0 (0)	0 (0)	
Affected side			1.000
Right	3 (60)	3 (60)	
Left	2 (40)	2 (40)	
Period after onset (day)	28.8 ± 6.2	29.6 ± 6.3	0.611
NIHSS	9.8 ± 2.1	9.6 ± 3.6	0.892
K-MBI	38.6 ± 8.8	36.3 ± 5.3	0.733
Spasticity*			1.000
MAS ≥ 1	2 (40)	2 (40)	
MAS < 1	3 (60)	3 (60)	

Continuous values are presented as mean ± standard deviation and categorical values as number (%).
NIHSS, National Institutes of Health Stroke Scale; K-MBI, Korean version of the modified Barthel Index; MAS, modified Ashworth Scale.
*Elbow, wrist, and finger flexor muscles of affected side were evaluated. If even one muscle showed spasticity, it was determined positive.

group was also significantly improved from 23.1 ± 3.3 to 31.9 ± 3.1 ($p = 0.041$). There was a significant difference in the degree of improvement between the two groups ($p = 0.016$).

The results of the secondary outcome measures are summarized in Table 2. The upper limb motor score of the FMA significantly increased from 21.2 ± 2.5 to 31.2 ± 3.0 in the intervention group ($p = 0.039$) and from 20.8 ± 2.3 to 25.6 ± 2.6 in the control group ($p = 0.042$). A significant difference in the FMA improvement was found between the two groups ($p = 0.034$). The WMFT rating also significantly increased from 12.0 ± 2.8 to 20.2 ± 3.1 in the intervention group ($p = 0.034$) and from 11.8 ± 2.5 to 14.6 ± 2.5 in the control group ($p = 0.041$) after the treatment period. In addition, the WMFT time significantly decreased from 89 ± 11 to 68 ±

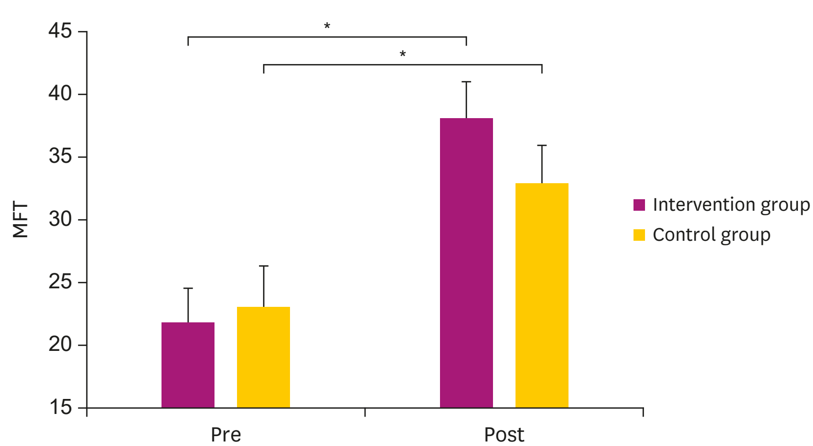

Fig. 2. Change in score of the MFT after 4 weeks of intervention. The score increased in both groups, but the degree of improvement was significantly greater in the intervention group than in the control group.
MFT, Manual Function Test.
*$p < 0.05$.

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Table 2. Comparison of the secondary outcome measures between two groups

Indicators	Intervention group		Control group		p value†
	Pre	Post*	Pre	Post*	
FMA (upper limb)	21.2 ± 2.5	31.2 ± 3.0‡	20.8 ± 2.3	25.6 ± 2.6‡	0.034‡
WMFT					
Rate	12.0 ± 2.8	20.2 ± 3.1	11.8 ± 2.5	14.6 ± 2.5	0.038‡
Time (sec)	89 ± 11	68 ± 12	92 ± 13	72 ± 13	0.594
Motor FIM	30.8 ± 4.5	44.2 ± 6.9	31.6 ± 3.9	38.6 ± 4.8	0.038‡

Values are presented as mean ± standard deviation.
FMA, Fugl-Meyer Assessment; WMFT, Wolf Motor Function Test; FIM, Functional Independence Measure.
*Analyzed by Wilcoxon signed rank test; †Analyzed by Mann Whitney U test; ‡p < 0.05.

12 seconds in the intervention group (p = 0.042) and from 92 ± 13 to 72 ± 13 seconds in the control group (p = 0.042). The WMFT score showed a significant difference between groups (p = 0.038), but there was no significant difference in the WMFT time (p = 0.594). Finally, the motor FIM score significantly increased from 21.2 ± 4.5 to 31.2 ± 6.9 in the intervention group (p = 0.042) and from 20.8 ± 3.9 to 25.6 ± 4.8 in the control group (p = 0.042). The patients in the intervention group showed a better improvement of motor FIM than did those in the control group (p = 0.038).

DISCUSSION

The patients treated with a new hand rehabilitation device using magnetic force showed better hand functional recovery than the patients receiving only conventional rehabilitation therapy did after a four-week intervention. In addition, the improvement in the affected hand function contributed the ability of patients to perform ADL more independently. This study suggests that magnetic-based hand rehabilitation is a safe and effective therapeutic modality that can be used in combination with conventional physical or occupational therapy in stroke patients.

This device performs rehabilitation therapy by inducing various finger movements according to the magnitude and direction of magnetic force between the electromagnetic field generated by the driving coil and permanent magnets installed on the finger without using mechanical components. When an electric current is applied to a coil in an electromagnetic control system, a magnetic field is generated. Between this magnetic field and the magnet, the attractive force or repulsive force acts by electromagnetic phenomena. A method of flexing or extending fingers using the magnetic force between the magnetic field and the permanent magnet was devised. The magnetic force according to the field distribution required for proper hand rehabilitation was operated by control programs according to the patient's hand motor function using previous experimental study data from normal control participants [18].

Hand rehabilitation robotics classified end effector and exoskeleton by structural arrangements, and linkage and cable type according transmission [3,7]. Regardless of stroke type, these robotics show beneficial effects for hand motor improvements in patients with stroke, as confirmed by the results of this study. Novel magnetic-based hand rehabilitation equipment has several advantages compared to previous soft or hard robotics. Because the current device can induce hemiparetic hand movements only with coils and permanent magnets, the mechanisms are relatively simple, and the size of the device is small. In contrast to the inconvenience of conventional soft robotics, this device is simple enough to wear only permanent magnets. Because it is not a glove form, it is more hygienic and can be easily produced according to personal finger size. This comfortable device can contribute to improving patient compliance. Finally, this magnetic device can implement various finger motions that other hand rehabilitation robotics cannot achieve. The previous robotics focused on the gross grasp and often exercised this motion repeatedly. However, the current device can induce various hand movement patterns, such as abduction, lateral deviation, opposition, and flexion/extension, by rotating the arm according to the directions of the magnetic force.

A four-week magnetic-based hand rehabilitation therapy regimen effectively improved motor function and ADL to a greater degree in the intervention group than in the control group. These results are concordant with the previous studies that showed benefits of robot-assisted rehabilitation administered in conjunction with physical and occupational therapies [19,20]. Robotic training combined with the repetitive training of isolated movements showed a greater positive effect on stroke-related motor recovery than increasing the therapy time alone [20]. These results confirm previous findings that robot-assisted hand rehabilitation in stroke patients can provide more intensive treatment and ensure correct movement patterns, yielding a superior outcome compared to that with conventional treatment only [21]. Robotic devices assist movement, achieving more consistent, measurable repetition than can be achieved with conventional therapy [22]. Therefore, a magnetic hand rehabilitation device allowed a therapy paradigm that is intensive, frequent, repetitive and follows to the principles of motor learning.

There were several limitations in this study. We analyzed the therapeutic effect of the device before and after the intervention but did not investigate whether this therapeutic effect persisted after treatment termination. Although the training program was an important component for hand rehabilitation using this type of device, we did not investigate optimal rehabilitation strategies optimized for magnetic force-based hand rehabilitation devices. However, this study was designed to confirm the feasibility of magnetic-based hand rehabilitation devices as new rehabilitation equipment and should take into consideration that this study was the preliminary research for future studies.

In summary, we developed a prototype device for hand rehabilitation based on magnetics. This device can safely perform active assisted training to the patient without side effects and can implement a variety of finger movements, such as grasp, extension, opposition, and deviated movements. A four-week adjuvant rehabilitation therapy for patients with subacute stroke using this device effectively improved hand motor function and ADL. Therefore, new rehabilitation devices or robotics using magnetic forces are expected to be useful for hand rehabilitation therapy in the future.

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