

# Development of A Wrist and Hand Stretching Device for Managing Spasticity in Stroke Patients: A Pilot Study

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Spasticity is a common problem of central nervous system damage leaving functional impairment and problems related to the hygiene. We developed a straightforward stretching device for the wrist and hand. The device, primarily constructed from plastic, comprises a forearm support module, a wrist module, and a finger module. To assess the device's effectiveness in managing spasticity among chronic stroke patients, twenty stroke patients used the device four times daily, 7 days a week, for 1 month. Spasticity severity was measured using the modified Ashworth scale (MAS) for the wrist, thumb, and index fingers. A questionnaire evaluated the device's feasibility and areas for improvement. Before treatment, the mean MAS scores for the wrist, thumb, and index finger flexors were  $1.50 \pm 0.36$ ,  $1.52 \pm 0.34$ , and  $1.50 \pm 0.30$ , respectively, compared with  $1.25 \pm 0.26$ ,  $1.27 \pm 0.30$ , and  $1.32 \pm 0.33$  post-intervention. Patients and occupational therapists expressed satisfaction with the device, citing its ease of use, effectiveness in stretching the wrist and fingers, and overall ease of manipulation. Half of the patients reported that all fingers were easily extended. The rigid plastic finger module was subsequently replaced with an inflatable, flexible rubber ball, providing a more comfortable contour for the stretched fingers, which increased user satisfaction. The stretching device effectively reduced spasticity in the wrist and hand, and the upgraded device enhanced patient satisfaction.

**Keywords:** Spasticity, stretching device, stroke, user feedback, pilot study

## Introduction

Spasticity is a form of hypertonus characterized by increased muscle tension in response to stimuli, which intensifies with the velocity of joint movement<sup>1,2</sup>. It is a common sequela of central nervous system disorders, including stroke, traumatic brain injury, spinal cord injury, multiple sclerosis, and cerebral palsy. After a stroke, approximately 65% of patients experience spasticity<sup>3</sup>. This condition can lead to muscle tightness and joint stiffness in the affected extremity, resulting in functional disability<sup>4,5</sup>. Therefore, effective management of spasticity is crucial for stroke patients.

Several methods are currently employed to manage spasticity in stroke patients, including oral medications, botulinum toxin or alcohol injections, bracing, serial casting, and stretching exercises<sup>6-10</sup>. Among these therapeutic options, stretching exercises, which involve moving joints through their full range of motion via an external force, are one of the most fundamental approaches<sup>11,12</sup>. However, stretching exercises are typically performed manually, requiring a therapist to administer repetitive exercises regularly<sup>11,13</sup>. This manual approach is time-consuming, and outcomes can vary depending on the therapist's experience. To address these limitations, various stretching devices have been developed, demonstrating positive effects in reducing spasticity<sup>14-17</sup>. If patients could independently wear

and use these stretching devices without the assistance of therapists, or with minimal help, it would save therapists' time and enhance the effectiveness of spasticity management.

We developed a wrist and hand stretching device designed for patients to use conveniently. We evaluated its effectiveness and assessed feasibility through patient feedback, leading to subsequent device upgrades based on this feedback.

## Results

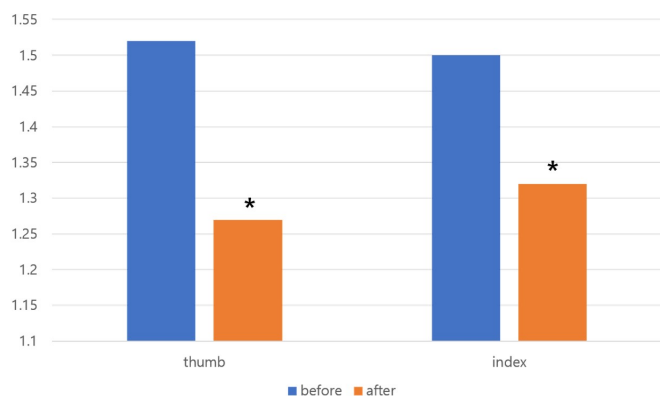
The mean MAS scores at pre-treatment were  $1.50 \pm 0.36$  for the wrist flexor,  $1.52 \pm 0.34$  for the thumb flexor, and  $1.50 \pm 0.30$  for the index finger flexor. After treatment, the mean MAS scores were significantly reduced to  $1.25 \pm 0.26$ ,  $1.27 \pm 0.30$ , and  $1.32 \pm 0.33$ , respectively. Statistical analysis confirmed that the reductions in MAS scores for the wrist flexor, thumb flexor, and index finger flexor were significant when compared to pre-treatment values (wrist flexor,  $p=0.002$ ,  $Z=-3.162$ ; thumb flexor,  $p=0.002$ ,  $Z=-3.162$ ; index finger flexor,  $p=0.020$ ,  $Z=-2.333$ ) in Figure 1.

## User Feasibility Test

Overall, patient feedback was positive (see Table 1 for detailed data).

Category	Easy	Moderate	Difficult
<b>Donning and Doffing</b>			
Easy to don and doff	18 (90%)	2 (10%)	0 (0%)
Duration (minutes)	<3 (15,75%)	3–5 (4,20%)	>5 (1,5%)
Optimal positioning	Yes (18,90%)	Moderate (2,10%)	No (0,0%)
How many helpers?	0 (18,90%)	1 (2,10%)	2 (0,0%)
<b>Wrist Extension</b>			
Easy to operate?	20 (100%)	0 (0%)	0 (0%)
Stretch to wanted angle?	19 (95%)	1 (5%)	0 (0%)
Sustain the extended posture?	20 (100%)	0 (0%)	0 (0%)
<b>Finger Extension</b>			
Easy to operate?	20 (100%)	0 (0%)	0 (0%)
Stretch to wanted angle?	20 (100%)	0 (0%)	0 (0%)
Sustain the extended posture?	20 (100%)	0 (0%)	0 (0%)
All fingers extended equally?	10 (50%)	5 (25%)	5 (25%)
<b>General Point</b>			
Too heavy?	No (20,100%)	A bit (0,0%)	Heavy (0,0%)
Firm support?	Yes (20,100%)	A bit (0,0%)	No (0,0%)
Any trouble?	No (18,90%)	A bit (2,10%)	Yes (0,0%)
Willing to use?	Yes (20,100%)	A bit (0,0%)	No (0,0%)

**Table 1** User feasibility test results.

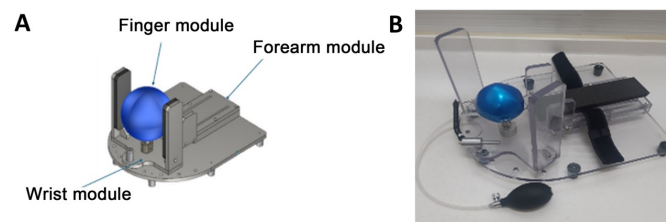


**Fig. 1** The comparison of the grade of spasticity, according to the modified Ashworth scale, in the MP joint of the thumb and index finger before and after using the device (\* $p < 0.05$ ).

The numbers in parentheses indicate the tallies of patients who responded and percentage.

However, when assessing finger extension, only 10 patients (50%) reported that all fingers were easily extended, suggesting that the finger module required improvement to ensure equal extension of all fingers. Based on this feedback, we focused on

enhancing the finger module by incorporating a ballooning ball mechanism in Figure 2.

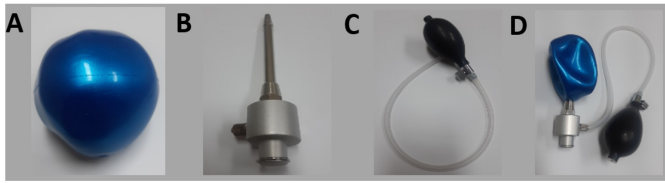


**Fig. 2** (A) 2D schematics and (B) photograph of the newly developed device.

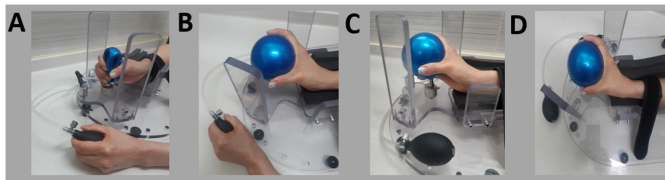
This design features a flexible and resilient rubber ball, a metal upright pole, and an air pump connected to a manually operated cuff in Figure 3.

In its resting state, the ball remains deflated, allowing the metal upright pole to support the spastic hand as it fits into the finger module. When the cuff is used to inflate the ball, the expanding ball stretches the spastic hand and fingers in Figure 4.

We applied the upgraded device to all 20 patients and re-assessed the user feasibility, specifically focusing on finger extension (see Table 2 for detailed data). Following the upgrade,



**Fig. 3** Components of the newly developed device: (A) inflatable rubber ball, (B) upright pole, (C) air pump, (D) fully assembled device.



**Fig. 4** Steps for using the newly developed device: (A) Initial setup: Position the patient's hand in the device and secure the forearm with Velcro tape. (B) Stretch the wrist by rotating the wrist module and locking it in place. (C) Stretch the fingers by inflating the ball using the cuff. (D) Final target position with extended fingers and wrist.

all patients reported that all fingers were equally and easily extended. Additionally, all patients indicated that they could easily operate the device, achieve the desired angle of extension, and maintain the extended posture. During the stretching program, the occupational therapists were monitoring adverse events.

## Discussion

In this study, we examined the effects of a simple stretching device for the wrist and hand, developed specifically to manage spasticity in chronic stroke patients. After using the device for 1 month, patients exhibited significant reductions in spasticity, as measured by the MAS, in the wrist flexor, thumb flexor, and index finger flexor muscles. Additionally, patient feedback revealed a key limitation of the initial device: not all fingers were easily extended. In response to this feedback, we modified the device by incorporating an inflatable balloon mechanism, which effectively allowed for the equal extension of all fingers. All participants reported satisfaction with the modified device. In addition, we confirmed that the compliance and safety of this stretching device were good because all subjects completed the stretching program without any problems.

Previous efforts to develop stretching devices for managing hand spasticity have been made<sup>14–17</sup>. However, these devices were limited in their ability to control spasticity in the fingers without addressing wrist spasticity. Additionally, earlier devices often required assistance for donning and operation, limiting their practicality for independent use. In contrast, our device addresses spasticity in both the fingers and wrist and is designed

for independent use by the patient. This independence allows patients to use the device as frequently as needed, facilitating more consistent management of spasticity. Feedback from our patient survey further highlighted the device's ease of use, including its straightforward donning and doffing process, user-friendly module manipulation, and portability.

Another critical advantage of our device is its ability to maintain the forearm in a neutral position. Previous devices often positioned the forearm in a prone position, complicating the fitting process and causing discomfort in the spastic upper limb. When the wrist and fingers are flexed due to spasticity, a prone forearm position hinders proper accommodation of the flexed joints, potentially leading to additional strain on the wrist during stretching. Our device avoids these issues by supporting the forearm in a neutral position, making it easier and more comfortable to fit the spastic limb into the device. Moreover, the device applies stretching forces that are evenly aligned with the wrist and finger joints, preventing undue stress on the joints and ensuring a more effective treatment process.

Our study was conducted without a control group. However, we specifically recruited patients who were at least 12 months post-stroke. Given this timeframe, it is unlikely that the observed reductions in spasticity were due to natural recovery. Therefore, although we did not compare the therapeutic outcomes of our stretching device with a control group, our results suggest that the device is effective in managing spasticity in the wrists and hands of chronic stroke patients.

The user survey revealed that patients had some issues with the original finger module, particularly with uneven stretching of the fingers. The rigid plastic module was not well-suited to accommodate spastic fingers, especially at the interphalangeal joints. In response to this feedback, we redesigned the finger module, incorporating an inflatable ball with an upright bar and an air nozzle to serve as a guide pole. This design made it easier for spastic hands to fit into the module. We integrated a puffing device from a sphygmomanometer into the air infusion system, allowing the ballooning ball to provide a flexible and comfortable contour for the fingers, both at rest and during stretching. With the initial device, some severely spastic fingers could escape during stretching, exacerbating the spastic posture. The redesigned module, with its ballooning ball concept, applied fluid pressure evenly across the fingers, ensuring uniform stretching.

In conclusion, our stretching device effectively alleviated wrist and hand spasticity in chronic hemiparetic stroke patients, and its feasibility was confirmed through user feedback. Moreover, by incorporating the insights from the user survey, we upgraded the device, leading to enhanced patient satisfaction. However, our study has limitations. It was conducted without a control group, and we did not evaluate the therapeutic outcomes of the modified device. Additionally, we did not monitor serial changes in MAS scores during the 1-month treatment

Finger Extension Task	Easy	Moderate	Difficult
Easy to operate?	20 (100%)	0 (0%)	0 (0%)
Stretch to wanted angle?	20 (100%)	0 (0%)	0 (0%)
Sustain the extended posture?	20 (100%)	0 (0%)	0 (0%)
All fingers extended equally?	20 (100%)	0 (0%)	0 (0%)

**Table 2** User feasibility test results with the newly developed device. The numbers in parentheses indicate the tallies of patients who responded.

period, nor did we investigate the long-term effects of the treatment. Therefore, further studies are warranted to address these limitations.

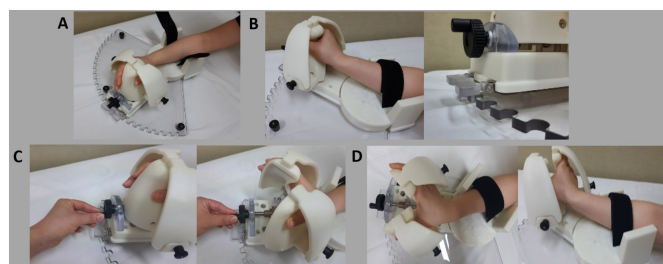
## 1 Methods

We prospectively recruited 20 consecutive stroke patients (M:F=9:11, age=68.7±4.4, cerebral infarct:cerebral hemorrhage=7:13, right hemiplegia:left hemiplegia=11:9, time between onset and start of clinical trial=13.4±1.1) based on the following inclusion criteria: 1) ≥12 months after stroke onset; 2) hemiparesis or hemiplegia due to stroke; 3) sufficient cognitive ability to understand the clinical trial process and respond to our questionnaire; 4) spasticity in the wrist flexor, thumb flexor, and index finger flexor with a modified Ashworth scale (MAS) score between 1 and 2; 5) no history of musculoskeletal disease (e.g., arthritis, musculotendinous injury, or bone fracture) or peripheral nerve injury in the affected upper extremity. The Ethics Committee of the Korea National Institute for Bioethics Policy approved this protocol(P01-202410-01-012), and all patients provided written informed consent before participating in the study.

### 1.1 Stretching device and intervention

The device comprises a forearm support module, a wrist module, and a finger module. Most components were fabricated from plastic using 3D printing techniques. The device lacks electronic controls or a motorized system, ensuring ease of use and safety for users. The primary function of the device is to stretch and extend the spastic wrist and fingers, allowing individuals to operate it independently without assistance. The forearm support module stabilizes the patient's forearm during stretching in Figure 5, providing a base upon which the wrist module can rotate to achieve dorsal wrist extension. A rotational axis between the hand and forearm modules allows for easy wrist stretching, and the wrist can be securely fixed at any point using a locking system. The finger module, designed ergonomically for spastic hands and fingers, comfortably and securely holds the patient's fingers. It stretches the fingers by widening the gap between the thumb and the other fingers, controlled by rotating a wheel. The module can also be fixed at any desired position. Parti-

cipants used the device independently, four times daily, 7 days a week, for 1 month. Each stretching session was maintained for a minimum of 15 minutes and a maximum of 20 minutes. All the participants received conventional rehabilitation during the intervention period. No medications or procedures influencing spasticity were changed during the study period.



**Fig. 5** Illustration of device usage. (A) Initial setup: Place the patient's wrist and hand into the device and secure the forearm with Velcro tape. (B) Stretch the wrist by rotating the wrist module and locking it in place. (C) Stretch the fingers by rotating the wheel. (D) Final target position: Fully extended wrist and fingers.

### 1.2 Assessment of spasticity

The degree of spasticity was evaluated using the MAS for the wrist flexor, thumb flexor, and index finger flexor<sup>17</sup>. MAS assessments were performed by blinded assessor. MAS assessments were conducted immediately before the first therapeutic session with the device (pre-treatment) and again 1 day after the final session (post-treatment). The MAS scores were defined as follows: 1—slight increase in muscle tone, indicated by a catch and release or minimal resistance at the end of the range of motion (ROM) during flexion or extension; 1+—slight increase in muscle tone, indicated by a catch followed by minimal resistance throughout less than half of the ROM; 2—more marked increase in muscle tone through most of the ROM, although the affected part(s) could still be moved easily. For statistical analysis, scores of 1, 1+, and 2 were assigned values of 1, 1.5, and 2, respectively.

### 1.3 User feasibility assessment

A questionnaire was administered to the participants to identify the device's potential shortcomings and assess its convenience. The questionnaire included the following items:

#### A. Donning and doffing

- Is it easy to don and doff?
- How long does it take to don and doff?
- Does the device provide optimal positioning for the wrist and fingers?
- How many helpers are required to don and doff?

#### B. Wrist extension

- Is the wrist module easy to operate?
- Can the wrist be stretched to the desired angle?
- Can the extended posture and angle be easily maintained?

#### C. Finger extension

- Is the finger module easy to operate?
- Can the fingers be stretched to the desired angle?
- Can the extended posture and angle be easily maintained?
- Are all the fingers equally extended and stretched?

#### D. General points

- Is the device too heavy to carry?
- Does the baseplate provide firm support?
- Are there any inconveniences during use?
- Would you be willing to use the device daily to manage hand spasticity?

### 1.4 Statistical analysis

Data were analyzed using SPSS Statistics for Windows, version 27.0 (IBM Corp., Armonk, NY, USA). To verify normal data distributions, Kolmogorov–Smirnov tests were performed prior to each analysis. As the data were not normally distributed, we compared pre-treatment and post-treatment MAS scores using the Wilcoxon signed-rank test. Statistical significance was set at  $p < 0.05$ .

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