Abstract—A dynamic splint is superior to traditional static splint, offering more benefits such as reduced spasticity, allowing comfortable stretch, repositioning fingers in extension positions, and increasing hand performance. This paper suggested the development of a dynamic splint based on a pulley rotation with a locking system as a home rehabilitation device to reduce hand spasticity in stroke patients. Moreover, this study consisted of two main activities: simulation using finite element analysis and clinical experimental trials. Eight stroke patients participated in 4 weeks of intervention using the proposed dynamic splint for a combined total of at least 3 hours per day at home. Outcome measures included Fugl-Meyer Assessment (FMA) and Modified Modified Ashworth Scale (MMAS) at baseline, 2 weeks, and 4 weeks. After 4 weeks of wearing, participants were also asked to fill out a satisfaction questionnaire. The results showed that wearing this proposed dynamic splint over 4 weeks, the hand function of participants increased significantly (p < 0.05), and the spasticity of the hand muscles decreased significantly (p < 0.05). With an overall rating of 8 out of 10 points, stroke participants had a high level of satisfaction with this home-use dynamic splint. The findings indicated that stroke patients who used this proposed splint showed substantial changes in hand function and reduced hand spasticity.

Index Terms—Dynamic splint, pulley rotation, hand spasticity, stroke.

I. INTRODUCTION

HANDS are one of the most important parts of the human body, particularly in activities of daily living such as reaching, grasping, and lifting objects. However, function can be lost due to accidents or diseases such as strokes. Strokes are the third most dangerous disease that can cause death after coronary heart disease and cancer. In the United States, 795,000 people continue to experience a new or recurring stroke every year [1]. Meanwhile in Taiwan, the number of stroke patients who required hospitalization reached 30,599 between 2006 and 2008, according to the Taiwan Department of Health [2]. Stroke is the most common disabling condition, with 30% to 66% of individuals losing functional ability in their more affected arm and hand [3]. Although this motor dysfunction is improved to some extent after rehabilitation training, a large proportion of patients are left with persistent impairment of upper-extremity movement [4]. Only 5%–20% of stroke patients can completely regain upper limb function after stroke [5], [6].

The reported prevalence of spasticity in the patients’ upper limb 6–12 months after stroke ranges from 23% to 46% [7]–[9]. Upper limb spasticity has been found to affect the functional abilities of the upper limbs [10]. Therefore, appropriate treatment of upper limb spasticity is required. Hand splint intervention, either static or dynamic splint (e.g., SaeboFlex), had been used as an efficient approach to the prevention of spasticity by keeping the more severely impaired upper limb in a preferred position for rehabilitation and also by inhibiting reflexive muscle contractions [11]. Although both types of splints serve similar functions, a dynamic splint is superior, offering more benefits such as reducing spasticity, allowing comfortable stretch, repositioning fingers in extension positions, and increasing hand performance [12], [13].

Over the last decade, several rehabilitation training devices have also been developed to help stroke patients overcome hand impairment. Generally, therapeutic devices are divided into two types: soft robotic gloves [14], [15] and robotic hand exoskeleton [16], [17]. Soft robotic gloves contain several kinds of actuators, such as pneumatic [18], fiber-reinforced [19], spring [20], or motor actuators [21]. Some researchers have also developed hand rehabilitation models integrated with virtual displays [22], [23]. These robotic devices are promising because they have the potential to fine-tune the levels of assistance for each digit during task practice [24]. However, these robots are complex, massive, difficult to install, and only for clinical use [25], [26]. Furthermore, glove devices that require a virtual reality system or computer graph are passive devices and cannot generate
assistive external force on the finger [27], [28]. They are also expensive and not affordable to all patients. In order to be affordable, it is necessary for such devices to have a moderate price that can be achieved by using low-cost materials that are easy to manufacture.

The goal of this study was to propose and develop a new dynamic splint that could reduce hand spasticity in chronic stroke patients. This dynamic splint was expected to manage the spasticity stage of motor recovery through prolonged stretching. This splint was also intended to be light, easy to fabricate, convenient to operate, and inexpensive. Poststroke users can use the sound side to wear themselves up at home as a supplementary training program in addition to hospital-based rehabilitation.

II. METHODS

There were four key steps in this research. First of all, the model started with the process of designing dynamic splint parts, followed by the assembly of the entire model. The model was designed using Autodesk Inventor and Solidworks to be used by all circles. This design took into account the shape and ergonomics of the hand. The second step was to simulate the model using the Ansys Workbench 18 software and to analyze the maximum stress, strain, and deformation.

After fabrication, the proposed splint was tested on one subject to get a response and feedback from the patient. If there was no need to modify the design of the splint model then, the next step could be taken. The fourth step was recruiting stroke patients to participate in the clinical trial, who were then asked to wear this proposed splint for 4 weeks. The flowchart of the study can be seen in Fig. 1.

![Flowchart of the method](image)

**TABLE I**

| Characteristic  | Value | Unit |
|----------------|-------|------|
| Density        | 1.04  | g/cm³|
| Young’s modulus| 2400  | MPa  |
| Poisson’s ratio | 0.37  |      |
| Yield strength | 28.5  | MPa  |

A. Design Development Process of the Dynamic Splint

The idea for designing a dynamic splint was to use a pulley as a movement actuator and a fishing line as a link between the static bases with the movable parts. This concept was inspired by a fishing mechanism that enables the fishing reel to rotate in a line. Fig. 2 shows the final design of the main splint, while Fig. 3 shows the final design of the finger cap. In order to produce custom parts, including the width of the splint and the length of the finger cap, the diameters of the forearm and the wrist of the participants and the length of their fingers were measured, respectively. These dimension parameters were then used to edit the STL files in Solidworks. Afterwards, the splint was manufactured using fused deposition modeling 3D printing.

There are several types of 3D printing filaments available with different properties. In this model, ABS material was chosen for the parts due to its high tensile strength and ductility over polylactic acid. Although thermoplastic polyurethane (TPU) can produce elastic, durable parts that can be easily bent or compressed, the main objective of the designed parts is to counteract hypertonic forces. High tensile strength is the first priority choice of 3D printing materials. The mechanical properties of the ABS 3D printing material are shown in Table I [29]–[31].

B. Simulation Setting

In order to ensure good meshing quality, it was based on the skewness scale and was manually set between 3 mm and 5 mm since, at this rate, the stress results were reasonable, as shown in Fig. 4. The results of the manual meshing showed that the node numbers were 43,396 and the element numbers were 23,745. The average element metric was 0.47. Thus, the meshing quality of the model was strong on a
C. Clinical Experiment Process

Ten chronic stroke patients signed informed consent in compliance with procedures approved by the Kaohsiung Medical University Hospital Institutional Review Board (KMUH-IRB-20180253) prior to participation in the study. However, two of them were excluded from this study due to recurrent strokes. As a result, the remaining eight patients had completed the study. The average age of the subjects and years post onset were 48.88 ± 14.27 years old and 30.5 ± 15.68 months, respectively. The patient information is displayed in Table II.

All subjects were provided with a customized dynamic splint and were asked to wear this splint, accumulating at least 3 hours per day for 4 weeks (Fig. 6). During the experiment, three assessments were carried out. The first assessment (baseline) was performed before the dynamic splint was worn. The second and third assessments were conducted at 2 weeks (posttest 2) and 4 weeks (posttest 4), respectively, after the dynamic splint was worn. A senior therapist with at least 10 years of clinical experience in stroke rehabilitation evaluated the hand function of the participants using Fugl-Meyer Assessment (FMA) [32], and Modified Modified Ashworth Scale (MMAS) [33] before and after wearing the dynamic splint. The test-retest reliability and inter-rater reliability of MMAS were 0.86 and 0.81, respectively [34], [35]. Furthermore, the FMA and MMAS scores were compared and analyzed to determine if there was a substantial improvement in the use of this proposed splint.

D. User Satisfaction Questionnaire

After finishing 4 weeks of intervention, participants were asked to rate their satisfaction with this dynamic splint, ranging from 0 (very unsatisfied) to 10 (very satisfied) on a 10cm visual analog scale. Participants were asked to place an “X” on the scale to show their level of satisfaction. The specific questions were as follows: On this scale of 0 to 10, how would you rate the performance of reducing muscle tone from this dynamic splint? On this scale of 0 to 10, how would you rate the comfort level when you wore dynamic splint? On this scale of 0 to 10, how would you rate the easy self-wear when you put on this dynamic splint?.

E. Statistical Analysis

Descriptive statistics were used to define the means and standard deviations of the dependent variables and satisfaction scales. The Friedman test (nonparametric alternative to the one-way analysis of variance with repeated measures) was used.
Dunn-Bonferroni post-hoc tests were used to compare the FMA and MMAS score before and after wearing the splint. Statistical analysis was performed using IBM SPSS Statistics software version 22 (IBM Corp, Armonk, NY). The level of significance for all tests was set at $p = 0.05$.

### III. RESULTS

#### A. Simulation Results

The results of the deformation showed that the pulley had the highest deformation distribution at 0.368 mm. However, it was not included in the count because it was a rotating component. The important parts were the lock mechanism and lock housing, which were slightly bent. Based on the color indicator, the deflection was approximately 0.1–0.15 mm in range as depicted in Fig.7(a). As for the deformation transformation, every moment is shown in Fig.8(a). The graph shows a linear escalation; as the moment increases, the displacement also increases.

The maximum strain energy appeared at the same location uniformly with the maximum stress corresponding to a maximum moment of 10 Nm. These energies concentrated at the border and spread to the nearest area of the lock mechanism. In addition, the maximum strain energy was approximately 0.2856 mJ and was indicated on the label as shown in Fig.7(b). The lock mechanism was able to withstand the force. In addition, Fig.8(b) illustrates the relationship between the strain energy and the moment of the dynamic splint, which was also linear.

The biggest von Mises stress result occurred in the lock mechanism, particularly in the area between the tube and the cone shape near the tip. Fig. 7(c) depicts the maximum stress on the label of 25.0786 MPa. The graphic of the stress correlation with a moment from 1 Nm to 10 Nm was linear, as shown in Fig.8(c).

#### B. Clinical Assessment Results

FMA measures four sections (upper extremity motor function, wrist motor function, hand motor function, and coordination/speed), and the maximum score was 66. Table III indicated the cumulative FMA score of eight patients for baseline, 2 weeks, and 4 weeks of intervention. Four participants (S01, S03, S04, and S05) showed significant improvements after 2 weeks, while S02 and S03 showed an increase after 4 weeks. Thus, the FMA scores for all patients generally increased, and only S07 remained constant. In addition, the post-hoc analysis indicated that there was a significant difference ($p < 0.01$) in the FMA scores between baseline and posttest 4. No statistically significant differences were observed between baseline and posttest 2 ($p = 0.40$) and posttest 2 and posttest 4 ($p = 0.18$).

Four hand joints (elbow flexors, wrist flexors, finger flexors, and thumb flexors) were evaluated using the MMAS. Further, the MMAS is an ordinal level measure of spasticity, which rates the intensity of spasticity from 0 to 4. A smaller score indicated better improvement of spasticity release. The average MMAS scores of the eight subjects from baseline, 2-week wearing, and 4-week wearing were listed in Table IV. Fig.10 showed the graph of the average MMAS score of the four sections. Moreover, the overall results decreased, indicating that there was good progress.

In generally, elbow flexors ($p < 0.01$), wrist flexors ($p < 0.01$), and finger flexors ($p = 0.01$) demonstrated statistically significant improvements in the muscle tone from baseline over 4 weeks. But the thumb flexors did not display a statistically significant change. The average MMAS score only decreased by a small amount ($p = 0.06$). This result occurred because the spasticity level of the thumb was already low at the baseline, so there was only a slight improvement after the intervention. Post-hoc analysis also revealed that the significant muscle tone decreases in elbow flexors ($p = 0.04$), wrist flexors ($p = 0.02$), and finger flexors ($p = 0.02$) occurred only between baseline and posttest 4, not posttest 2. This meant that this dynamic splint could dramatically reduce muscle spasticity by prolonged muscle
stretched over 4 weeks. Moreover, although this splint was used to keep the wrist in extension position to reduce the wrist and finger flexor tone, a surprising finding was that elbow flexors also seemed to reduce spasticity. Prolonged positioning of the wrist in extension position could break down the flexor synergy patterns, characterized by simultaneous shoulder abduction, elbow flexion, and wrist flexion. As a result, the elbow flexor tone was reduced as well as wrist flexor tone.

C. User Satisfaction Questionnaire Results

The performance satisfaction of reducing muscle tone was 8.6±1.2, the comfort level score was 8.3±1.9, and the easy self-wear score was 8.9±1.6.

IV. DISCUSSION

In this experiment, all fingers could be exercised because the model also provided a place for the ring finger and small finger. It was therefore possible for the patient to handle all the fingers. However, this dynamic splint was focused on stretching three fingers (the thumb, index finger, and middle finger). These three fingers are known as the “three-prong chuck,” and their function is most frequently used in everyday activities. Three common finger prehension patterns described by Schlesinger [36] were used: (a) the lateral style, (b) the tip style, and (c) the three-prong chuck style [37]. A comparison of the three styles of grasping revealed that the frequency of the three-prong chuck style in holding a small object was approximately 88% of the total, followed by the lateral style at 10% and the tip style at 2% [38]. Also, the three-prong...
chuck is a common prehension pattern used to pick up small objects. Furthermore, three-finger caps are much easier self-wear design than five-finger caps. Thus, this dynamic splint was designed to stretch these three fingers.

During the experiment, one participant with high muscle spasticity broke the device in the middle of a cone shape near the tip of the lock mechanism. The same result occurred during the simulation, indicating that this area had the maximum stress point. Thus, when applying the dynamic splint, there was a correlation between the simulation and the experimental results. However, the above problem could be solved by replacing the damaged section with a new component or by changing the infill type in the print settings. The infill is the internal density of the printing part. It was originally set at 13% or 15% but could be changed to 20% or more (65% and 90%) as a solution; however, this would take additional time.

Overall, the findings revealed a decrease in the wrist and hand MMAS and an increase in FMA over 4 weeks. Since MMAS and FMA mean the degree of spasticity and functional state, respectively, therefore, by using this dynamic splint for 4 weeks, hemiparetic stroke patients achieved spasticity relief and functional recovery of the wrist and hand. It is worth noting that one participant (S03) showed significant improvement in the FMA score at posttest 2 and posttest 4. It was recommended that all participants in this study wear this splint for at least 3 hours per day to reduce spasticity. When the splint was removed, they were encouraged to practice hand grasp activities (e.g., hand gripper exercises) on their affected side. Since the log of daily activities was not documented in this study, it could not be verified whether some wore the splints for a shorter/longer period of time. This participant (S03) reported that he wore this splint more than 3 hours a day for 4 weeks after some improvements were observed. Another explanation for this improvement could be that active finger extension was elicited as a result of decreasing finger flexors spasticity. The prolonged muscle stretch has been proven to be an effective approach to reduce excessive muscle tone. Therefore, improvement in finger extensor function could be caused by decreased antagonist inhibition of the extensor or diminished passive resistance to lengthening of the flexors. Active extension of fingers is a critical element to establish prognosis of motor recovery, and knowledge of this capacity can be harnessed to direct the therapy to those who will benefit the most from it [39], [40]. Thus, wearing this dynamic splint is almost certain to result in some improvement or reduction in impairment; e.g., patients will improve their FMA scores. However, a small number of participants may limit the generality of the results obtained in this study. Further research with a larger sample size is warranted. Nevertheless, this proposed dynamic splint is easy self-wear and is the perfect aid for a home exercise program with an efficient everyday stretching method.

Many devices for reducing hand spasticity have been developed (such as SaeboFlex or SaeboGlove); however, most of these devices were too complicated to wear with a glove or hook-and-loop fasteners strapping each finger firmly. It has become technically difficult for a stroke patient with spasticity to wear it alone at home. Moreover, despite widespread use of static hand splints in adult stroke patients, dynamic splints may have a more beneficial effect than static splints in reducing spasticity [13]. The dynamic splint presented in this study maintains simple device configuration and low-cost fabrication. The finger cap has a similar design as the finger sleeve for easy and quickly self-wears or take off. It provides firm support and stability to digits. Even though their hands clenched into a fist, and the fingers curl into themselves due to spasticity, users still can slide the finger caps over digits to stretch the fingers. Afterwards, users can gradually stretch their fingers and open their hands using pulley rotation design operated by one hand (unaffected side). Users might use one at home or at work. Further, this stretching device is effective not only in reducing spasticity and improving functional recovery but also in shifting therapy from the hospital setting to the on-patient ecosystem.

In this study, participants reported satisfaction with three aspects: muscle tone reduction, comfort, and ease of use. All participants gave very good satisfaction about the performance of this dynamic splint. With an average rating of 8 out of 10 points, stroke participants had a high level of satisfaction with this home-use dynamic splint.

There were some limitations to this study. The first was the usage time of this dynamic splint. It was recommended that the device should be worn for at least 3 hours a day, but due to the lack of time records, it could not be verified whether some of the subjects wore it for a shorter period of time. Stretching for longer periods of time could reduce the spasticity; however, it depended on the cooperation of patients and caregivers. As a result, some subjects did not show a drastic increase in our findings. The second limitation was that we did not schedule a follow-up after 4 weeks; long-term outcomes were also not discussed. The third was lack of control group. It cannot be assured that these improvements were not due to factors other than intervention. However, the majority of participants in this study have late chronic stroke (>18 mo). Besides wearing this dynamic splint at home, they only underwent routine rehabilitation programs (including physiotherapy and occupational therapy) for 4 weeks. Hence, this proposed dynamic splint may be used as an integrative treatment for poststroke upperlimb spasticity. It can be used safely at home in selected patients with high muscle tone.

In order to enhance future studies, this paper provided a range of suggestions. In this study, some patients complained about the compression of the finger caps and pressure in the wrist joint. To improve the quality of the design, smooth surfaces should be optimized to match the shape of the hand. The simulation in this study focused only on the lock mechanism; therefore, future studies should investigate more complex mechanisms such as finger cap pressure, line friction, and line connections between the finger cap and the pulley. Further, more additional patients could be recruited as a control group to reinforce the results.

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