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A soft wearable exoglove for rehabilitation assistance: a novel application of knitted shape-memory alloy as a flexible actuator



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Abstract

We developed the knitted shape-memory alloy (SMA) as a flexible actuator and applied it to a soft wearable exoglove for rehabilitation assistance. Based on user needs and anthropometric data, we custom-designed the exoglove for three hemiplegic patients using the knitted-SMA actuator and evaluated its bending performance, gripping force and wearability under the four simulation conditions (S1–S4). To address the specific needs, both SMA plain- and double-knit modules were applied to the exoglove based on the patients' finger joint range of motion (ROMs). The joint ROMs of all fingers increased by 13.71% and the skin temperature increased by 2.21 °C after actuating the glove (p=0.006). The gripping force increased as much as 55.01%, when compared to the baseline. All patients were able to don and doff the developed glove independently, and positively evaluated their subjective satisfaction and thermal perception. The findings suggested the potential of the knitted SMA for the future development of soft wearable robots.

Keywords: Knitted shape memory alloy, Soft wearable exoglove, Ergonomic design, Rehabilitation assist device, Wearability

Introduction

Along with the global increase in the number of older people, the aging of the disabled population is emerging as an important issue in modern society. As of 2024, more than 46% of the global population aged 60 years or older have at least one disability, and this trend is predicted to increase (United Nations, 2022). Furthermore, approximately 16% of the global population currently suffers from severe disabilities that affect their daily lives (World Health Organization, 2023). In particular, hemiplegia caused by brain lesions results in abnormal muscle activity, skin reflexes, and spasticity owing to muscle paralysis, which makes it challenging to control voluntary movements (Cauraugh et al., 2000). The hands of hemiplegic patients, which have the most complex anatomical structure in the human body, can experience difficulties during daily activities such as grabbing objects, writing, and button fastening because their function is weakened (Nasir & Troynikov, 2019). Functional impairment in the hands of hemiplegic patients is caused by decreased activity of the extensor muscles of the fingers and the inappropriate



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simultaneous activation of the flexor muscles, and more motor defects appear in the extension function than the flexion function (Cauraugh et al., 2000).

Most treatment strategies for hemiplegic disorders begin by reducing spasticity (Ji et al., 2013). Thermal stimulation in localized parts of the body can diminish pain in paralyzed areas by increasing the blood circulation in the body's internal tissues to relieve muscle stiffness (Kim et al., 2005). In addition, repetitive hand flexion and extension exercises can improve hand function by improving limb sensation and reducing muscle tension in hemiplegic patients (Kawahira et al., 2010). Thus, continuous and steady exercise with thermal stimulation is effective in increasing the joint range of motion (ROM) (Matsumoto et al., 2010). Furthermore, people with disabilities who use rehabilitation devices tend to have higher functional-recovery efficiency than those who only receive physical therapy (Yoon et al., 2018).

Recently, research has been conducted on assistive devices that are necessary to improve the life quality of people with disabilities. However, actual user satisfaction and usability of assistive devices are low, owing to the high cost of rehabilitation treatment and low wearability of the devices (Yeung et al., 2016). In particular, robotic assistive devices such as exoskeletons cause discomfort because of their large size and low flex-ibility, and they tend to focus only on the function of assisting daily activities rather than relieving the stiffness that is typically experienced by hemiplegic patients (Cappello et al., 2018; Kang et al., 2019). Furthermore, if people with physical disabilities wear ill-fitting assistive devices, they may stop using them, thereby furthering functional loss and mental-health problems (Yeung et al., 2016). Wearable assistive devices go beyond the concept of attaching assistive devices to the human body; in other words, they are worn on the body and can interact with each other. To increase user satisfaction, it is necessary to design assistive devices that are lightweight and flexible, have good wearability, and minimize the burden on the human body when applied to a body part (Walsh, 2018).

Toward this end, researchers have adopted shape-memory alloys (SMAs) as a flexible smart material, for its unique characteristic of returning to a memorized shape (Granberry et al., 2019). When the SMA wire is structured in a knit form, it can be applied to the body curvature at synovial joints as it can provide not only one-dimensional contraction deformation but also bending and contraction changes; further, it can provide a higher driving force when using a shorter wire (Han & Ahn, 2017). Lightweight and flexible actuators can be made without additional materials through the inherent flexibility of weft knit with continuity of loops and shape-transformation characteristics of SMA, making the smart material suitable for human-oriented assistive devices that can be applied to various body motions.

Therefore, we aimed to develop a rehabilitation-assistive exoglove for hemiplegic patients with the use of a knitted SMA. To achieve this goal, we took the ergonomic wearable design approach, which was characterized by a two-way interaction between the human body and wearable device, with an ultimate intention to optimize the desired functionality and positive user experience. As the first step, we identified specific user needs using the FEA Consumer Needs Model (Lamb & Kallal, 1992), and brainstormed a glove design solution based on the identified user needs. Next, we analyzed the changes in joint ROMs in the recruited hemiplegic patients to gauge the required mobility range for the rehabilitation-assistive exoglove, which also informed the bending

and contraction span of the knitted SMA module. Once the exoglove prototype was developed, we evaluated the glove's and assessed its wearability with the actual human subjects.

Literature Review

Soft wearable robotics

Soft wearable robotics is an emerging field that can solve the limitations of heavy and rigid materials, which can burden the human body when using exoskeleton robots. These robots were developed to enhance the performance of physical activities, such as helping healthy people lift heavy loads, reducing energy consumption during running, and assisting in movements for patients with reduced muscle strength (Walsh, 2018). Quinlivan et. al. (2017) developed a fabric-based multi-jointed soft exosuit that reduced the metabolic rate by approximately 20% by assisting the ankle joint during walking. Kim et. al. (2022) developed an exosuit that was capable of assisting hip flexion and reducing energy consumption during walking by approximately 15%. In et. al. (2015) developed a wearable robot for the hand that could help grasp various objects using a soft tendon routing system. In addition, tendon-driven soft wearable gloves were developed to assist finger movements using SMA wire (Hadi et al., 2018; Wang et al., 2021). Recently, soft wearables have been developed in a form similar to clothing, and interest in their functionality and wearability is increasing (Walsh, 2018). A soft exoskeleton provides the advantages of being supported by the wearer's skeletal structure and conforming to the user's body better than a rigid exoskeleton can.

Rehabilitation-assistive technology

A key component of assistive technology for people with disabilities is rehabilitation, which is a comprehensive concept that includes rehabilitation products and related services covering all types of disabilities (De Witte et al., 2018). These rehabilitation-assistive technologies, particularly those for hands, primarily enable motion in stiff fingers to improve the quality of daily living. Recent attempts have been made to develop assistive devices using lightweight and flexible textile materials with good wearability. Zhang et. al. (2017) developed a ring-type assistive device using a pneumatic-based actuator composed of ultralight silicon. Kang et. al. (2019) proposed a lightweight hand-assistive device made of only polymer materials to assist the tendon drive. These technologies have been developed for people with disabilities who can grasp objects with their hands without completely bending their fingers. Moreover, Wang et. al. (2017) designed a rehabilitation exercise glove that repeats finger flexion and extension motions using a lightweight bidirectional pneumatic actuator. Cappello et. al. (2018) developed a fabric-based finger-muscle strength-assisting glove that is inserted using a pneumatic method, and they succeeded in manipulating light objects with a force that was approximately 30% of the maximum gripping power of adults. Ge et. al. (2020) developed rehabilitationexercise gloves by designing a pneumatic actuator based on knitted textiles and fabrics. Thus, rehabilitation-assistive technology increases the usability of assistive devices by minimizing the burden on the human body through textile-based designs.

Shape-memory alloy and its applications

Among SMAs, Nitinol (Ni–Ti), an alloy of nickel and titanium, is the most used alloy that exhibits a shape-memory effect, and it can exhibit a contraction of up to 8% under thermal stimulation (Eschen et al., 2020). SMAs with these shape-transforming properties have been used in various fields such as mechanical engineering, aviation, and protective clothing. Holschuh and Newman (2014) designed a spiral SMA wire in tiny microunits for potential applicability in the aerospace field. Wang et. al. (2020) demonstrated that the air gap between the fabric layers created by an SMA spring can be applied to temperature-sensitive protective clothing. Ozbulut et. al. (2016) designed an SMA cable composed of multiple layers of wire and demonstrated that a high driving speed can be achieved with less energy. Furthermore, some attempts have been made to maximize the transformation of SMA materials by designing new structures, such as cables or spiral shapes. Nonetheless, such efforts have a limited impact on wearable devices owing to the reduced flexibility resulting from the structures added to the actuator.

As an alternative solution to the soft wearable researcher's dilemma between maximizing the SMA actuation performance and improving wearability, some researchers suggested SMA wires in a knit structure as it provided flexibility as well as a greater actuation force relative to the amount of material used. For example, Han and Ahn (2017) presented various 4D deformations through the knitted SMA, and compared the loads according to each pattern. Kim and Kim (2022) compared and analyzed the actuating force of a manufactured knitted SMA module through simulation using finite element analysis. Furthermore, knitted SMA can potentially be applied to soft wearable products because it exhibits more than 40% improvement in contractile force, higher energy density, and improved mechanical performance compared to those of SMA wires, which present the unique flexible characteristics of knitted textiles (e.g., Eschen et al., 2020). Granberry et. al. (2019) developed a knitted SMA actuator for a calf-swelling preventive compression product that fits along the curve of the human body. Lee et. al. (2022a) suggested the possibility of an exoglove application by comparing and analyzing the joint finger ROMs of older adults and applying the bending motion of the knitted SMA.

Methods

Participants

Adopting the multiple-case study approach, we recruited the three hemiplegic patients from a local community rehabilitation center, located in a metropolitan area, as the three individual use cases. According to Yin (1981, 2002), the multiple-case study approach, which is suitable to apply for hard-to-reach participants (e.g., hemiplegic patients), offers an effective venue to collect sufficient information from several different sources (or individuals), enabling to reach a sound conclusion. As summarized in Table 2, the three hemiplegic patients recruited for this study showed different demographic, anthropometric and clinical profiles (see Table 1), yet they all satisfied the following criteria: (a) they were aged 60 years or older; (b) had a disability grade of 1+ or lower on the Modified Ashworth Scale (MAS); (c) could bend their finger within less than half of their finger joint ROM without resistance; and (d) had experienced limited physical abilities in daily activities. Patients diagnosed

ID	Hemiplegic participants (N=3)							
	P1	P2	P3					
Sex (F/M)	F	M	M					
Age (years)	73	72	74					
Hemiplegic side	Right	Right	Left					
Onset period (years)	9	14	11					
Hand size (cm, mean (SD))								
Hand length	16.80 (0.09)	18.25 (0.18)	18.10 (0.39)					
Hand width	8.96 (0.11)	9.39 (0.26)	10.38 (0.23)					
Wrist width	8.43 (0.47)	7.59 (0.28)	7.70 (0.08)					
Joint ROM (°, mean (SD))								
DIP	9.04 (7.89)	2.85 (2.68)	2.98 (3.30)					
PIP	20.82 (15.89)	3.58 (3.49)	11.62 (1.13)					
MCP	22.29 (4.49)	27.79 (1.58)	14.71 (3.80)					
3D scan image	Hand length Width	PIP PIP WCP Hand width	Hand PIP MCP Wrist width					

Table 1 Hemiplegic participants' demographic and physical profiles

DIP distal interphalangeal joint, PIP proximal interphalangeal joint, MCP metacarpal phalangeal joint

Table 2 Interview questionnaire for user needs

For hemiplegic patients	For a physical therapist		
General behaviors for rehabilitation	Symptoms and rehabilitation methods for hemiplegia		
 How old are you? What is the diagnosis name? When was the onset? Where did the hemiplegia develop? Do you have a guardian? When did you first visit the welfare center? How often do you visit the welfare center? What type and frequency of rehabilitation are you receiving at the welfare center? What is your daily routine? 	 What are the symptoms of hand parts of hemiplegic patients, and which should be alleviated first during rehabilitation exercises? What rehabilitation treatment is being applied to alleviate the symptoms of hand parts of hemiplegic patients? How long does it take on average for rehabilitation treatment for hemiplegic patients? What temperature is appropriate for applying heat to the hemiplegic hand? 		
Previous use experience with hand assistive devices	Functional requirements for assistive devices		
 Is there any hand assistive device that you currently use? If not, have you had any experience using it in the past? If yes, what kind? if not, why? Are you thinking about using an assistive device? If not, why? 	 Is there any treatment that uses a hand assist device during rehabilitation treatment for hemiplegic patients? If yes, what is it and if not, why? What kind of functions do you think are needed for rehabilitation exercises using hand assist devices for 		
Personal preferences for the devices	hemiplegic patients? What do you think is the need for improvement in		
 What are your thoughts on hand assistive devices? What color assistive devices do you want? If you were to use the device, what features would you like it to have? Do you think the ability to put on/off the device yourself is necessary if you use it? What type of device would you like to use? 	 Are there any nerves that I need to pay special attention to when wearing assistive devices? In relation to the direction of the arms and hands during rehabilitation, what posture would not put a strain on the body? 		

with language, intellectual, or mental disorders were excluded from this study. We also recruited a physical therapist with 15 years of experience in rehabilitation therapy who served as a senior physical therapist at the center. The physical therapist provided expert opinions on the rehabilitation needs of hemiplegic patients. All participants signed the written informed consent before participating in the study. This study was approved by the Institutional Review Board Committee of the participating university (IRB No. 2112/002-019).

Procedures

User needs identification

We conducted semi-structured interviews with participants to identify specific user needs. The interview questions for the hemiplegic patients consisted of 18 items in total (Table 2). The questions inquired about the patients' general behaviors for rehabilitation (nine items), previous use experience with wearable assistive devices (four items), and personal preferences for the devices (five items). The interview questions for the physical therapist included nine questions concerning medical symptoms and rehabilitation methods for hemiplegic patients (four items) and functional requirements for new wearable assistive devices (five items). Following Lamb and Kallal's (1992) FEA consumer needs model, interview data were analyzed for functional, expressive, and aesthetic needs (refer to Table 4 for results).

Fabrication of a knitted SMA actuator

By adopting Han and Ahn (2017)'s approach, we fabricated an actuator using an SMA wire wrapped in a thread (100% polyester), which was originally coined to prevent shortcircuit leakage between loops and increase the friction coefficient during the deformation phase of the SMA wire (Table 3). We used a plain knit having unique bending characteristics in that the needle loops in each loop are bent toward the leg loop (Lee et al., 2022a). We also used double modules in which a plain-knit and rib-knit overlapped because they contract in the course direction during actuation (Jung et al., 2022). Additionally, we measured the forces and bending angles of the plain-knit and double-knit modules to analyze the performance of the knitted SMA (Fig. 1). The actuation force was measured using a multiaxis force sensor (F/T Sensor-Nano 17, ATI Industrial Automation, USA), and the bending angle was measured over time using an online protractor on the knit-module side (Iconico Inc., USA) from the start point to the end point of the deformation. The knit module was divided into three parts—top, middle, and bottom, and the angle at each of these three points was defined as the bending angle.

SMA wires	Diameter (µm)	Actuation temperature (°C)	Composition	
Dynalloy Corp. (USA)	200	70	55 wt% Ni, 45 wt% Ti	
Kellogg's Research Labs (USA)	150	45	55.74 wt% Ni, 44.26 wt% Ti	

 Table 3
 Material properties of SMA wires



Fig. 1 Knitted SMA's actuating motion

Table 4	Identified	user	needs and	suggested	design	solutions

Attribute	te Target Problems		Needs	Design solutions
Functional	Patient	Difficulty in wearing gloves on fingers Uncomfortable when worn for a long time Hand stiffness is worse on waking up/in low temperature Difficulty understand- ing how to use assistive devices Rehabilitation treat- ment only possible with the help of experts	Ease of donning/doff- ing Comfortable to wear Ease of movement Warmth/heating func- tion Ease of operation Available home care	Opening of palm part Fastening position of the hand on the contralateral side of the hemiplegia Ease between each finger Elastic material for joints On/off driving method Using Joule heat Insulation Slow actuation speed Wrist size adjustable Double neoprene mate- rial for wrist area
	Physical therapist	 Muscle contraction before rehabilitation Speed of rehabilitation exercise Nerve compression when wearing an assis- tive device Wrist drop 	 Heating function Adjustable actuating speed Safety for users 	
Expressive	Patient	 Appearing disabled when wearing assistive devices 	· Confidence · Activity	 Fabric-type actuating unit Hidden driving part Glove-type
	Physical therapist	· Reluctance to use new rehabilitation equipment	· Familiarity	
Aesthetic	Patient	 Inconvenient design Standing out design 	 Soft touch and light materials Minimization of details Inconspicuous color 	· Elastic material for joint area · Achromatic color · Hidden driving parts and
	Physical therapist	· Machine-like design	 Minimization of expo- sure to driving parts 	wires

Exoglove design and prototyping

We referred to the specific user needs identified in the previous stage, and decided on the overall structure and design details to meet the users' functional, expressive and aesthetic needs. Additionally, we determine a specific body part to attach an SMA actuator on the exoglove based on the user's hand dimensions and joint movement. We obtained the 3D shapes of the hemiplegic patients' hands in a relaxed posture using a 3D body scanner (Artec Eva, Artec 3D, Luxembourg) and used the 3D data to draft the glove patterns (Lee et al., 2022b). We first 3D-scanned the hemiplegic patients' hands, filled the missing holes on the 3D hand scan, flattened the surface of the 3D hand scan into 2D patterns in reverse engineering software (Geomagic Design X, 3D Systems, USA) (refer to Table 1), and finally customized the glove patterns to fit the hand of the individual patient. We also optimized the driving force of the knitted SMA actuator in the joint areas through an iterative prototyping process. The knitted SMA modules were then attached to the developed glove and positioned at each finger joint to assist with force when performing the hand extension exercise.

Evaluation

For evaluation of the prototyped exoglove, we carried out tests to gauge the functional performance of the knitted SMA and wearability of the exoglove. For testing of functional performance, we measured the joint ROM changes before and after glove actuation using a digital goniometer (EasyAngle, Meloq, Sweden). Subsequently, we analyzed the differences in the joint ROM and grip force before and after the four stimuli using a hand dynamometer (FBA_EH101, Camry, USA) to confirm the multiple effects of thermal stimulation and exercise assistance using the developed glove. The four stimuli were as follows: (a) finger extension exercise for 20 times (S1); (b) thermal stimulation using SMA actuation for 60 s (S2); (c) S1 and S2 simultaneously (S3); and (d) S3 and prototyped glove actuation simultaneously (S4). A baseline with no stimulus was denoted as S0. All evaluations were performed in triplicate.

To evaluate the wearability of the exoglove, we asked the hemiplegic patients to perform donning and doffing of the prototyped glove three times each and complete the Quebec user evaluation of satisfaction with assistive technology (QUEST 2.0) on a five-point Likert scale (Demers et al., 2002). Of the 12 items in QUEST 2.0, we retrieved the eight items concerning assistive devices and used them for subjective evaluation. Furthermore, to ensure user safety from the Joule heat from the SMA actuation, we analyzed changes in the skin temperature of the patients' hands, using the data measured for 1 min using the iButton (DS1923, Dallas Instruments, USA), and assessed the patients' subjective thermal perception and comfort following the ISO standard (ISO 10551, 2019). Thermal perception, which is perceived thermal sensation, was measured on a 9-point Likert scale (-4 = very cold; 0 = neutral; 4 = very hot), and thermal comfort, the pleasantness of thermal sensation, was assessed using a 7-point Likert scale (-3 = very unpleasant; 0 = neutral; 3 = very comfortable).

Data analysis

We used SPSS ver. 26.0 (IBM SPSS Statistics 26, USA) to analyze the joint ROM, grip force, and evaluation data. Because of the small sample size, the normality of the data was not obtained based on the Shapiro–Wilk test results (p > 0.050). Therefore, we performed nonparametric statistical analyses, i.e., the Kruskal–Wallis *H* tests, for the mean comparison in the joint ROMs; and Mann–Whitney *U* tests for the differences between knitted SMA modules. Additionally, we conducted one-way ANOVA and post-hoc tests to determine the mean differences in joint ROMs and grip forces across the four stimuli conditions (S0–S4). Statistical significance was set at a 95% confidence level for all analyses.

Results and Discussion

Identified user needs

Table 4 summarizes the user needs identified from the interviews with the participating hemiplegic patients and a physical therapist. As for the *functional* needs, the patients indicated difficulties in wearing gloves due to stiffness, understanding the use of new devices, and problems with low skin temperature on the hemiplegic side. There were needs for ease of donning/doffing, comfort, ease of movement during wearing gloves, and a heating function for the hemiplegic side and home care. A physical therapist pointed out muscle contraction, nerve compression, and wrist drop of the patients' hands as the functional considerations. The patients' need for safety while using such wearable devices was also noted. Regarding the *expressive* needs, the patients had been reluctant to be seen as disabled or patients by wearing assistive devices, and there was a need to be seen as an active and confident person. Similarly, the physical therapist indicated a need for familiarity as patients had problems with reluctance to use new rehabilitation equipment. As for the *aesthetic* needs, the patients were hesitant to use inconvenient and standing out designs. Thus, details should be minimized, and an inconspicuous color needs to be used. A physical therapist raised a problem with the machine-like design of existing assistive devices; therefore, there was a need to minimize the exposure of driving parts. Although alleviating the symptoms of hemiplegic patients was an essential factor, other unsatisfactory factors could cause low usability (Bettoni et al., 2016). In other words, from the FEA analysis, we noted key user needs for aesthetic and expressive design as well as functional elements in developing exogloves. This supports the results of previous studies (Nasir & Troynikov, 2019).

Knitted SMA actuator

To select the knitted SMA modules suitable for each finger joint and apply them as an actuator, the characteristics of SMA plain- and double-knit modules were identified. In the plain- and double-knit modules, the actuation force increased until approximately 10 s after the start of actuation, and it was then maintained at a constant (Fig. 2a). The phase changes of the plain-knit and double-knit modules started after 10 s and before 10 s and ended after 20 s and 25 s, respectively. The double-knit module had a longer phase-change time because the two modules were driven. In addition, the bending angle of the plain-knit module increased until 10 s, but became constant after 14 s, and the bending transformation no longer occurred (Fig. 2b). The angle of the double-knit



Fig. 2 Actuation characteristics of knitted SMA: a actuation force and b bending angle

Knit structure (diameter)/ actuation characteristics (mean (SD))	Plain knit (200 μm)	Double knit: plain \times rib knits (200 $\mu m \times 150 \mu m)$	Z	p
Actuation force (N)	0.94 (0.33)	0.75 (0.05)	- 1.964	0.050
Bending angle (°)	157.90 (12.87)	95.57 (6.17)	- 1.964	0.050
Electrical power (Wh)	0.18 (0.01)	0.29 (0.02)	- 0.655	0.513

Table 5	Differences	of actuating	characteristics	between th	ne knitted SMA	modules
	Differences	oractaating				(introduce.



Fig. 3 Application method of knitted SMA modules on the glove

module exhibited a rapidly increasing trend until approximately 7 s and then became constant after 16 s.

According to the Mann–Whitney U test, the actuation force and bending angle tended to be higher in the plain-knit than in the double knit; however, the difference was not statistically significant (all p = 0.050) (Table 5). The electrical power values applied during actuation were 0.18 (0.01) and 0.29 (0.02) Wh for the plain- and double-knit modules, respectively. Although the difference in electrical power between the two modules was not significant (p = 0.513), less power tended to be consumed during the plain-knit operation. Based on these results, plain-knit modules with higher bending angles and actuation forces were applied to the distal interphalangeal (DIP) and proximal interphalangeal (PIP) joints, where the joint ROM of the patients tended to be smaller than those of other joints. In contrast, double-knit modules with a relatively small actuation force and bending angle were applied to the metacarpal phalangeal (MCP) joint, which showed a greater joint ROM than those of the other joints (Fig. 3). These findings corresponded to the results of a previous study (Lee et al., 2023) that proposed design guidelines for the knitted SMA for assistive wearable applications based on human data from hemiplegic patients.

Exoglove design and prototyping

As specific design solutions to satisfy the *functional* needs, we included the open-type enclosure system in the exoglove for ease donning and doffing. For the comfort and ease of movement, elastic materials were used for the joints and between the fingers with a

large ROM. We attempted to provide thermal stimulation using the Joule heat generated when operating the SMA to relax stiff muscles. For ease of operation, the power controller was designed using an on/off actuating method that operated with a single button. A 2.50-mm-thick double-sided neoprene material was used in the wrist area to minimize the wrist-drop phenomenon. To respond to the *expressive* needs, we tried to show the wearers as confident and active human-beings and did not emphasize their disabilities. To minimize the fear of using new devices and familiarizing the users, the device was designed in the same shape as regular thermal gloves. This design minimizes the gaze of others. In addition, the operating part of the glove was fabricated using a knitted SMA and covered with fabric to make it discrete. For the *aesthetic* needs, light, soft-touch, and stretchable materials mixed with polyurethane fibers were used, except at the wrist area. Additionally, lightweight and flexible nylon materials were primarily used for the joints. For an inconspicuous design, achromatic colors such as gray and black were used in keeping with patients' comments.

We developed a soft wearable exoglove through the iterative prototyping process. To draft the ergonomic patterns of the designed exoglove, the glove pattern of each patient was designed by referring to the glove-pattern design method (Lee et al., 2022b). The developed exoglove comprised the four layers, as seen in Fig. 4. The innermost part that encountered the skin was designed with an insulation fabric for safety against the Joule heat generated during the actuation of the SMA modules. In the second layer, an elastic material was used for the joint area as the base fabric to which the actuator was attached to provide comfort during hand movement. For the wrist area, double neoprene material was used to minimize wrist drops on the hemiplegic side. Fourteen knitted SMA modules were attached to the base fabric. A porous material was used on the outer part of the glove to cover the SMA modules so that they were not visible from the outside and to dissipate heat. In addition, an Arduino AT mega 2560 R3 microcontroller-compatible board and a power supply were used to operate the SMA module.



Fig. 4 Developed exoglove: a glove layer and b final prototype

	Joints	S0	S1	S2	S3	S4	F	p
ROM (°,	DIP	5.50 (2.60) ^{d,e}	6.22 (2.03) ^{d,e}	16.61 (3.68) ^c	22.06 (6.61) ^b	25.92 (1.31) ^a	125.105	0.000
mean (SD))	PIP	12.01 (7.04) ^e	13.69 (6.09) ^d	26.14 (4.53) ^c	36.51 (14.16) ^b	45.20 (9.90) ^a	114.041	0.000
	MCP	21.60 (5.36) ^{d,e}	22.71 (3.70) ^{d,e}	27.44 (3.98) ^c	30.84 (9.489) ^b	33.78 (2.79) ^a	62.375	0.000
	Total	13.57 (11.98) ^e	14.78 (10.90) ^d	23.88 (11.68) ^c	30.36 (12.17) ^b	35.61 (15.88) ^a	290.106	0.000
Grip force (kg, mean (<i>SD</i>))		4.49 (2.92) ^c	5.25 (3.35) ^c	5.78 (3.73) ^b	6.32 (3.98) ^b	6.96 (4.20) ^a	31.119	0.000

Table 6 Joint ROM and grip force changes across the four stimuli

DIP distal interphalangeal joint, PIP proximal interphalangeal joint, MCP metacarpal phalangeal joint, the alphabetical order is the same as the order of mean difference according to the Duncan test

ltem	Varia	ables	Mean difference	Std. error	Р	95% confidence interval	
						Lower bound	Upper bound
ROM (°)	SO	S1	- 1.20	1.61	0.943	- 5.56	3.15
		S2	- 10.31	1.61	0.000	- 14.67	— 5.95
		S3	— 16.78	1.61	0.000	-21.14	- 12.43
		S4	- 22.04	1.61	0.000	- 26.40	— 17.68
Grip force (kg)	SO	S1	- 0.76	1.73	0.109	- 1.74	0.21
		S2	— 1.29	1.73	0.024	- 2.37	-0.22
		S3	- 2.47	1.73	0.011	- 3.12	- 0.54
		S4	- 1.83	1.73	0.003	- 3.80	- 1.14

 Table 7
 Results of the post hoc test across the four stimuli at joint ROM and grip force

Evaluation on functional performance

Changes in joint ROMs

The results of Kruskal–Wallis *H* tests for differences before and after wearing exoglove and after actuating the SMA were as follows. After actuating the developed exoglove, the joint ROM of the patients' fingers increased significantly to 1.72° (13.71°) (p=0.006). The joint ROM exhibited an increasing trend at each joint, and the increase rate was the largest (18.95°) at the PIP joint (p=0.008). Although the joint ROM of the DIP and MCP joints increased by 10.56% and 11.66%, respectively, these differences were not statistically significant (p=0.170 and 0.118, respectively). Furthermore, the joint ROMs were significantly different across the stimuli at the 95% confidence level (Table 6), which were in the following order from the highest to the lowest: S4 ($35.61 \pm 15.88^{\circ}$) > S3 ($30.35 \pm 12.17^{\circ}$) > S2 ($23.88 \pm 11.68^{\circ}$) > S1 ($14.78 \pm 10.90^{\circ}$). The post hoc test result (Table 7) also showed mean comparisons between the stimuli. Specifically, the joint ROMs increased after each stimulation of S2–S4 (all p=0.000) from S0; however, they were not significant between S0 and S1 (p=0.943).

Changes in grip strength

As seen in Table 6, the result of the ANOVA test determined that the grip forces were significantly different across the stimuli (p = 0.000). In particular, the grip forces were in the following order from the highest to the lowest: S4 (6.96 ± 4.20 kg) > S3

 $(6.32 \pm 3.98 \text{ kg}) > S2 (5.78 \pm 3.73 \text{ kg}) > S1 (5.25 \pm 3.35 \text{ kg})$. Further, as seen in Table 7, the results of the post hoc test revealed that the grip forces noticeably increased after each stimulation of S2–S4 at the 95% confidence level (p = 0.024, 0.011, and 0.003, respectively), as compared to S0, but not S1 (p = 0.109), which signified that all other stimuli conditions, except S1, were effective in improving the participants' grip forces.

Wearability assessment

Donning and doffing times

The average donning and doffing times of the hemiplegic patients were 58.81 s (SD 14.70) and 8.67 s (SD 3.57), respectively; thus, more time was required for donning than for doffing (p = 0.008). The main donning and doffing processes could be divided into four tasks (Table 8). Specifically, the donning task consisted of, in order, inserting the four fingers into the glove, inserting the thumb, holding a wrist Velcro with the opposite hand on the hemiplegic side, and closing the Velcro. The most time was required to insert the thumb and four fingers into the glove (p = 0.000). The doffing task was performed as follows: gripping and removing the wrist Velcro with the opposite hand on the hemiplegic side, holding the tips of the four fingers, pulling the glove, and doffing the fingers from the gloves. A considerable amount of time was required to grip the Velcro, hold the tip of the glove, pull the fingertips, and doff the glove.

Orders	Time	Donning tasks	Orders	Time	Doffing tasks
1. Putting fingers in	21.89 (7.71) ^a	The second	1. Gripping Velcro	3.49 (2.26) ^a	
2. Putting thumb in	21.11 (4.51) ^a	Y	2. Holding the fingers	2.28 (0.55) ^{a,b}	2
3. Gripping Velcro	5.78 (1.03) ^b	Y	3. Pulling the fingers	1.87 (0.59) ^b	1
4. Closing Velcro	10.04 (1.86) ^b		4. Doffing	1.22 (0.32) ^b	

Table 8 Task processing and required time for donning and doffing

The alphabetical order is the same as the order of mean difference according to the Duncan test

Subjective satisfaction

All eight items scored higher than average. In six of the eight items, more than 4.00 points ("satisfaction") were scored on the 5-point Likert scale, and safety and durability items scored 3.67 points (between "normal" and "satisfaction"). The highest score was 4.33 for size and adjustments, and the lowest score was 3.67 for safety and durability. The weight, ease of use, comfort, and effectiveness items earned a "satisfaction" score of 4.00 points. In addition, the two items that patients considered most important were size and comfort. This is because hemiplegic patients were not typically able to use gloves owing to their rigid and bent hands as well as the related discomfort.

Ensured thermal safety

The average skin temperature of the patients' hands when wearing the exoglove was 30.35 °C (SD 0.57). After actuating the glove, the skin temperature increased from 30.32 °C (SD 0.30) to 35.20 °C (SD 0.72) in 1 min. The average difference in skin temperature between that while wearing the glove and that after glove actuation was statistically significant (p = 0.000). Moreover, the average temperature increased by 2.21 °C for 60 s after actuation compared to that before. For the subjective thermal evaluation, the average score for thermal perception was 1.00 (SD 0.82), which was evaluated as "slightly warm." These thermal perceptions are an evaluation of the inside of the glove, that is, the part of the hand on which the glove was worn during actuation. All patients positively evaluated the increase in skin temperature on the hemiplegic side because they tended to have lower skin temperatures on the hemiplegic side than those on the opposite side (Matsumoto et al., 2010). Patients felt that the hand on the hemiplegic side warmed while performing the extension exercise, as the temperature gradually increased from the start of glove actuation. The subjective thermal perception was evaluated as "slightly warm," with a score of 1.00 (SD 0.82). This result showed that the temperature that gradually increased from the start of the glove drive warmed the hand on the hemiplegic side while performing the extension movement. Thermal comfort was positively evaluated between "comfortable" and "slightly comfortable," with a score of 0.67 (SD 0.47). The participants gave positive evaluations beyond "comfort" regarding the provision of thermal stimulation while using the developed gloves. These findings, as a psychological indicator of heat, were able to support the positive influence of the thermal stimulation of the developed gloves through the actually measured quantitative skin temperature change. Thus, these results support those of previous research that have suggested positive effects, such as increased blood circulation through local thermal stimulation (Matsumoto et al., 2010). Furthermore, these results showed that the immediate effect on joint ROMs and gripping force increase for a combined effect was greater than when only the extension exercise or thermal stimulation was applied (Wang et al., 2017; Yoon et al., 2018).

Conclusions

This study developed hand rehabilitation assistive gloves for hemiplegic patients, using the knitted SMA as a flexible actuator. To outline the outcomes of the study, we identified the patients' key problems through the systematic FEA needs analysis,

which were then applied in designing a customizable glove for an individual patient, along with the hand anthropometric information. Following, we determined the positive effects of the developed gloves on the hand ROM, bending performance, and gripping force of the patients, as well as wearability. Unlike the previous studies on the SMA that mainly focused on characterizing the actuating performance (e.g., Eschen et al., 2020; Han & Ahn, 2017), this study validated the potential of the smart material's suitability for wearable robotics that are intended to be worn on the human body, especially for rehabilitation, which offers a significance of the present study.

Nonetheless, this study had some limitations. While the multiple case study approach offers a strong advantage for an in-depth investigation (Schoch, 2020), additional empirical evidence is desirable to be generalizable in other contexts (Baxter & Jack, 2008). Although three hemiplegic patients with MAS grade 1 who exhibited different use cases showed positive results, the effectiveness of the gloves may vary when applied to those with different clinical backgrounds. In addition, because a geographical location for patient recruitment was limited to one region and country, further research is appropriate with patients with diverse geographic and cultural profiles. Moreover, the actuating force of a knitted SMA varies depending on the accompanying components used in soft wearable robotics. Thus, additional research is desirable to minimize the size and weight of the actuator to make it more compatible with soft wearable robots. Future research could be focused on long-term actuation repeatability for SMA actuators and the material durability of rehabilitation gloves in terms of usability. Besides, we used nonparametric methods for data comparison to minimize the probability of Type II errors when the data is not normalized (Qualls et al., 2010). Despite the advantage of nonparametric methods, the statistical results should be carefully interpreted, as they tend to be less sensitive to detect significant differences, as compared to parametric tests (Campbell, 2021). However, given the difficulty of obtaining immediately normal data in experimental research, we propose to accumulate and validate a larger sample set with statistical confidence. All in all, we conclude that a knitted SMA is a smart fabric-structured material promising for use as an effective actuator with shape transformation and flexibility, and our soft wearable exoglove integrated with the knitted SMA-based actuator presented positive benefits for rehabilitation assistance with good wearability.

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Author contributions

All authors collaboratively contributed to the design, planning, and execution of the research project. SL as the first authors were responsible for collecting and analysing the data and writing the first draft of the manuscript. JP supervised the overall research process and reviewed and revised the manuscript. All authors read and approved the final manuscript.

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Declarations

Competing interests

The authors declare that there is no conflict of interest.

Ethical approval and informed consent

This research was conducted under the approval and supervision of Seoul National University InstitutionalReview Board (IRB Approval No: 2112/002-019) regarding ethical issues including consent to participate.

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