Wearable Thimble-like Device for the Objective Follow-up and Therapy of Multiple Sclerosis

Elif Hocaoglu

Abstract—**Multiple sclerosis (MS) is an autoimmune disease that affects more than 1 million people worldwide. Since there is no definitive treatment for the disease, the treatment plan for each patient should be updated regularly according to the current level of the disease. There are standard clinical tests, each with its own scoring scale, used to monitor the deterioration of upper and lower extremity functions of MS patients under the supervision of a neurologist and physiotherapist. However, non-objective scoring based on the opinion of the physiotherapist is open to erroneous assessments and may vary from person to person. In addition, clinical tests do not provide detailed information about the functional impairment of the patient. Unfortunately, an objective evaluation system has not yet been implemented all over the world, and the treatment plan is still determined according to the disease in neurological-based disabilities, such as MS, which is of vital importance. personal assessment. To address the aforementioned problem, the design and experimental evaluation of a wearable thimble-like device that can be substituted for the standard clinical tests to assess the follow-up of MS are presented. The device provides the measurement of high sensitivity and opportunity for objective assessment and allows patients of all ages to use it in any desired place during their treatment phase.**

Index Terms—**Multiple sclerosis, wearable device, sensor fusion, objective assessment, rehabilitation.**

I. INTRODUCTION

MULTIPLE Sclerosis (MS) is a complex, progressive, immune-mediated disease and is the third most common disease-causing neurological disability, occurring in approximately 400,000 people in the United States and approximately 2.3 million worldwide [1]. MS disease, which is mostly diagnosed between the ages of 20-50, brings with it emotional and economic problems as well as physical limitations [2]. It is among the basic needs of MS patients to develop effective solutions for this disease, which is frequently encountered in the world and includes financial and moral difficulties, and to be able to follow the patient with high sensitivity.

As well as the treatment process of MS disease, the follow-up of the disease is of great importance in terms of observing the effect of the methods applied for treatment and the instantaneous condition of the physical functions of the patient. With the help of various clinical tests, (the 9-hole peg test [3], the expanded disability status scale [4], The Jebsen-Taylor hand function test (JTHFT) [5]) performed under the supervision of physiotherapists, the regression or improvement in the physical functions (hand functions) of MS patients can be observed. The general approach in the evaluation of sensory-motor control is that physiotherapists, using the measurement values of the specified standard clinical tests, evaluate and score the patient's movements according to the defined tasks. Besides, the expanded disability status scale (EDSS) is still actively used for various reasons such as determining the medical treatment method and deciding on the rehabilitation process and the tools to be used in this process. The disadvantage of this measurement method is that it only evaluates the patient's gait disturbance and ignores the problems in the upper extremity [6]. Because these methods also depend on the personal perspective of the physiotherapist, assessments are inaccurate and cannot provide sufficient detail about the patient's disability level. However, objective, accurate and precise assessments provide valuable information in the evaluation of the sensory-motor abilities of the patient and allow for accurate treatment planning.

Considering the need for objective and instantaneous assessment of MS patients, accurate diagnostic techniques based on sensor data have been recommended by some research groups instead of individual evaluations [7]. An isometric force/torque measurement, in which subjects interact with a sensing system that measures the force/torque was proposed as an objective method applied in the static condition of the patients. In such studies, The expectation from the individual during the experiment is applying force to the experimental setup fixed to the planar surface by using their hands, and the normal and tangential force coordination of the individual was investigated based on the force sensor placed on the device [8]–[10]. In particular, the isometric strength of the patients was also evaluated utilizing a simple isometric setup considering the six different directions of exerted force/torque [11]. However, studies so far have been limited in terms of the analysis of the force exerted by the patient only, the grabbed object endowed with load cells fixed on a plane. In addition, the weight of the employed object during the experiment is always constant and the task assigned to the individual throughout the experiment is the same [8]–[10], [12], [13].

Recent studies show that various functional attributes of hand function can be evaluated through kinetic analysis. In particular, the manipulation of stationary and moving objects requires a proper contribution of two particular force components, grip force and load force which are perpendicular and parallel to the surface of the grabbed object, respectively. The findings in the literature validate the importance of the coordination between grip and load force applied to the object without any time delay between them. Moreover, the high coordination between these particular forces takes

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place based on the anticipatory neural control mechanism of humans [14], [15]. In other words, disharmony between such forces results in the slippage of the object. However, although the detection of incipient slippage time of an object is an important indication of the moment when the exerted improper force, these studies did not consider the force level that causes the slippage. In the study of Krishnan's group, static and dynamic tasks were defined for the individual by using two plates fixed on the table where the force sensor was placed, and the ratio of normal and tangential forces applied to the plate by the individual compared to a healthy individual was compared [16], [17]. They argued that the tasks in dynamic conditions contribute to alleviating the problems of patients with MS by reconstructing the nerve connection corrupted by the degenerated nerve. Different from the study above, a cylindrical assessment device endowed with an accelerometer and load cell was proposed to compare the amount of force applied by the patients to move the object from one point to another [12]. The device provides an advantage in terms of testing the coordination of force components applied by the patient under dynamic conditions. On the other hand, there are a number of restrictions on performing tests of different difficulties. For example, holding an object with different weights, and needing more manipulation skills to successfully grasp different thicknesses of objects were not involved in the study. In other words, the study was limited by the single configuration of the fingers/ hand to hold a single object with the same load and geometry. Given the sensorimotor ability of the patients was evaluated based on the isometric strength in literature, the assessment of the patients was not properly performed as the assigned tasks and the used devices do not allow to reveal the important features of their movement. Thus, the clinical evaluation of the aforementioned studies does not allow the individual to fully express his/her daily life functions usually carried out under dynamic conditions. Furthermore, the determined metrics are insufficient to evaluate the success of the individual in performing such activities.

In this study, the proposed wearable robotic device addresses all the limitations mentioned earlier and facilitates patients to perform assigned tasks similar to daily activities. In such a way, these tasks require MS patients to use their upper extremities under both dynamic and static conditions. Furthermore, this device allows for objective assessments of patients through various performance metrics, such as comparing the force applied to an object against the required force (such as the force component ratios of a healthy individual) based on the ability to hold or release an object without slipping. This device endeavours not only to monitor and track the progress of patients but also to augment their performance through the utilization of tactile stimulations facilitated by the device. The proposed system for rehabilitation and clinical evaluation presents an electromechanical design that enables objective assessments, detached from subjective viewpoints. The efficacy of the proposed device was assessed through the involvement of two distinct cohorts of healthy participants. The control group, characterized by its normative status, actively engaged in the experimental procedures, while the other group experienced a significant symptom of MS by means of a specialized glove. Accordingly, the aforementioned performance metrics indicate two separate performance characteristics of each group. Thus, the aforementioned performance metrics delineate distinct performance attributes exhibited by each group.

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A. Materials and Methods

This section presents the design objectives for the thimble-like sensor fusion system, data gathering from the device and implementation of the proposed objectives.

1) Design Objectives: The proposed methodology in this study enables the wearable device to provide individuals with the autonomy to manoeuvre their hands in 3-D coordinate space and actively participate in dynamic activities that closely resemble those encountered in their daily routines. The performance of the device is evaluated based on the introduced terminology in the literature [18]. Accordingly, the imperative design requirement of the wearable sensor fusion system is the system's capability to perform realistic daily activities by hand.

Manipulating different thicknesses and weights of objects is an optimal design requirement in terms of the activities requiring various difficulty levels of manipulation skills. The findings in the literature also support the importance of objective assessment therapy evaluating the progression or regression of patients' hand response after completing a task of placing a cylindrical object from one place to another [12]. Such a therapy provides advantages in terms of testing the force coordination applied under dynamic load. However, the aforementioned therapy does not allow to change in the difficulty level of the tasks as the employed object has a single geometric shape and a constant load. Enhancing such tasks applied in dynamic conditions with various difficulty levels provides more efficacy to patients during their therapy. Accordingly, the optimal design requirement of the thimble-like wearable device allows the grabbing of objects with different thicknesses requiring more manipulation difficulties based on the real-time performance assessment of the patients.

The primary design requirement is the ability to detect the applied force, the incipient slippage time, the duration to hold the object stable, and also to observe the force coordination applied by the fingers of the patient to the object at such critical moments. That being said, although an object can be held without slippage, MS patients may apply more force than required, or sometimes cause it to slip due to the lack of exerted force. Such possibilities are frequently encountered in daily activities and can only be observed in experiments where realistic conditions are mimicked with a special device containing the above-mentioned features.

The secondary requirement of the device is that the wearable device is lightweight and adaptable to any size of the user. Accordingly, the lightweight design allows the patients to concentrate their focus only on manipulation. Besides, the wearable structure can be adjustable considering the ergonomics of the user. By following these criteria, the biomechatronic design is

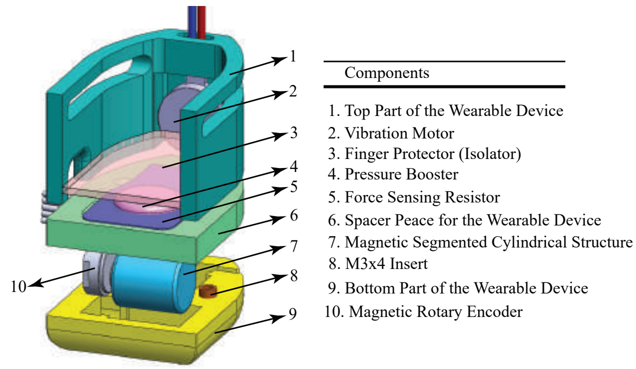

Fig. 1. Exploded view of the solid model of the thimble-like device

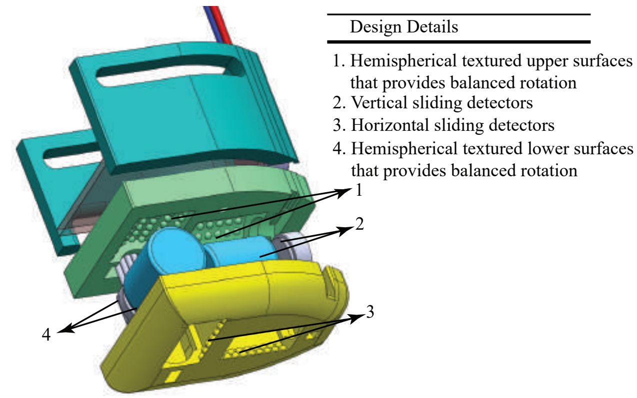

Fig. 2. Housing of the sensors detecting incipient slippage

determined to be a solution to all the aforementioned needs. In light of the required design criteria, a wearable fingertip tactile sensor design capable of detecting the incipient slippage time and force variation while manipulating the objects is proposed.

The tertiary design requirement for the device is the capability of giving biofeedback to the user when the tasks are carried out with low performance. With the integration of such property into the device, the thimble-like device warns the patients via tactile feedback and forces them to regulate their motor control and accordingly improve the success rate of the task.

2) Electromechanical Design: The sensor fusion design is aimed to be wearable by fingertip and allows freedom to perform some of the activities of daily living as a means of pinch grasp. The device is basically composed of three segments, and the exploded view of the device's solid model is presented in Figure 1. The distal phalanx of the finger is placed into the allotted nest, enumerated by 1 and fixed by an adjustable tie. Thus, the finger is only responsible for carrying the rather light design it wears. Moreover, the wireless communication of the thimble-like device enables the patient to manipulate the fingers. Since the device is not fixed to a stationary place via wires, the use of the device does not compel the patient to stay nearby the device during the therapy. In both thin and lightweight thimble design and wireless communication, patients can perform realistic activities realized by pinch grasping anywhere they live, as targeted by the imperative design criterion.

With the objective of meeting the optimal design criterion, the dimensions of the sensor housings are determined considering the maximum size of a person's distal phalanx, as illustrated in Figure 2. Accordingly, minimizing the base of the device provides the patient with the ability to grasp objects of varying thicknesses and allows for spatial manipulation tailored to the specific requirements of different tasks.

Designing a highly responsive device to detect incipient slippage in both vertical and horizontal directions is one of the primary design criteria of the device. This crucial design aspect is accomplished by incorporating a high-resolution magnetic encoder, which empowers the device with exceptional accuracy and sensitivity in detecting even the slightest signs of slippage. In order to bring this feature to the system, two magnetic rotary encoders integrated into the system detect the angular movement occurring in the mechanical system and provide the necessary data about the slip moment. As detailed in Figure 3(a), the magnetic encoder enumerated by (1) detects the vertical sliding by sensing the rotation of the vertical cylinder embedded with a tiny magnet (2). Similarly, the horizontal sliding is sensed by the other pair of the magnetic encoder (4). The employed 12-bit non-contact magnetic encoders (RLS®Miniature Rotary Magnetic Encoder) are sensitive enough to detect nearly stationary motion (1 count equals 0.09° revolutions)). The nests of the cylindrical elements and the sensors are placed on part (3). The other half of the nests are also represented in Figure 3(b). The small hemispheres covered the nests to decrease the contact friction between the cylinders and their nests as much as possible. Accordingly, once the shear force is exerted by the object on the cylindrical elements, thanks to the negligibly small contact friction, the required slip moment as an indication of the slippage of the object is easily generated.

As for the measurement of the force exerted by the patient on the thimble-like device, a force-sensing resistor is placed on the protruding surface to be able to collect the force acting on this area efficiently. The system performs the necessary measurement during the follow-up of the patients based on the cooperation of the two sensors. The force sensing resistor (FSR), which is used to measure the force applied by the finger, has been selected in such a way that it can accurately detect the maximum force value [19] that men and women can apply in the pinch grasp category. The FSR is placed in its slot in the mechanical design of the wearable device, enumerated by 5 in Figure 1, to sense the force in the stressed direction. The FSR sensors (Tekscan®), which can detect a maximum force of 44N, can also measure the upper limit of the force of 12N exerted by a fingertip. The sensing diameter of the selected FSR is 3.8mm and thus does not exceed the dimensions of the device worn by the fingertip. That being said, the evaluation of data gathered from both types of sensors allows us to detect the amount of force exerted by the patient to grip the object while it tends to slip. Accordingly, the primary design criterion is satisfied by the collaborative work of slippage and FSR sensors by determining the moment/force to initiate the sliding of the object.

The lightweight and ergonomic design criteria are met

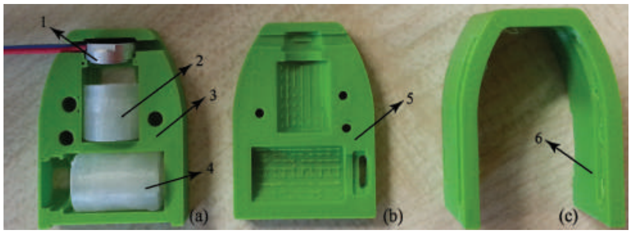

Fig. 3. Fabrication of the lower part (a), spacer (b) and the finger nest (c) of the thimble-like device (a) The lower part of the wearable device also consists of two parts. The lower part houses the rotary encoder and the cylindrical parts in which the magnetic part is embedded. (b) The spacer of the wearable device incorporates the necessary spaces for mounting rotary encoders and force sensors. (c) The lateral sides of the top part are designed to accommodate the finger, which is designed according to the finger anthropomorphic model.

by avoiding more than the required size for the fingertips (18x27x11mm), choosing a flexible resin material with a density of 1.1 g/cm3, and designing the overall platform as durable yet thin enough. The criterion is satisfied as a means of UV LCD 3d printer manufacturing technique, which allows adjusting the size of the wearable device for any finger. From the ergonomic point of view, keeping the volume of the device as small as possible enables a wider workspace for the manipulation of the fingertips.

Lastly, the tertiary design criterion is addressed by adding a shaftless mini-vibration motor at the tip of the device (in Figure 1, enumerated by 2) whose vibration is sensed by the finger directly. For example, when the patient slides the object that is wanted to be held, the patient is expected to successfully perform the holding task by giving a vibration at the first moment of the incipient slippage. It is hypothesized that such simulations based on the performance of the patient help alleviate the patient's complaints as a means of recovery of the damaged nerve area in the long term.

II. Results

The aim of the experimental procedure is to reveal the efficacy of the thimble-like wearable device for MS symptomatic patients when performing dynamic tasks that simulate activities of daily living (ADL). While our future endeavours include conducting experiments specifically with MS patients, it is of great importance that the experiments with healthy individuals can provide a preliminary assessment of the hand functions of MS patients in terms of shedding light on our future studies. Consequently, having a comprehensive understanding of the symptoms associated with MS is instrumental in shaping the experimental procedures. Additionally, to simulate the diminished sensory perception encountered by MS patients, the research group employs a strategy wherein a powder-free nitrile glove is worn by volunteers prior to using the robotic device. This approach intentionally restricts the sensory feedback experienced by the volunteers, aiming to replicate the limitations reported by individuals with MS.

A. Experimental Procedure

Somatosensory complaints are encountered in %70 of MS patients. These include symptoms such as decreased sensation, numbness, and tingling. In this study, two groups of healthy volunteers contributed to the study. The first group who wears the latex glove represents the conditions in which MS patients live; whereas the second group is the control group responsible for unveiling the performance of the device considering the different grasping capacities of people. As indicated in Figure 6, the first group of volunteers represents healthy people and they wear the device directly on their bare fingers. Thus, the volunteer's perception of feeling the environment becomes clear to a large extent. This experimental group was named the control group.

The performance evaluation of the volunteers during the experiments is carried out based on their upper extremity (hand-arm) coordination and accordingly grasping ability. The performance evaluation is mainly concentrated on task-based force control and reaction time [20] against slippage. The experiments are performed based on conducting two different tasks. In the first task, as presented in Figure 7, it is expected for the subjects to grasp the object whose weight is gradually increased without slippage. In the second task as shown in Figure 8, the subjects need to achieve the grasping of the object while orienting their arm/ hand in the 3D space.

The salient aspects pertaining to the performance exhibited by the participants encompass the following key attributes:

- The time until successful grasp of the object whose weight is predicted.
- The dynamic nature of the applied force exerted in order to accomplish successful object grasping, considering the predicted weight of the object.
- The duration until the prevention of object slippage is achieved in response to the applied force exerted on the object.
- The duration necessary to avert slipping when administering vibrational stimulation to the subject in instances where their grip is deemed insufficient (also referred to as the reaction time)

B. Experimental Evaluations

Four healthy volunteers aged between 26 and 39 participated in the experiments performed in the study. The volunteers read and approved the informed consent form, which was approved by the Istanbul Medipol University Ethics Committee.

In the first experiment, volunteers are required to carry out the task of lifting objects with increasing weight until the last object does not touch the surface. The main concerns of the experiment are both the maximum displacement to shift the object and the dynamic behaviour of the force exerted on the grasped object. When the maximum sliding distance of the object was assessed based on the first performance metric in the initial experiment, it was observed that healthy volunteers demonstrated a more proficient performance by sliding the object at a lower rate compared to MS symptomatic volunteers, as depicted in Figure 9.

Upon conducting a t-test statistical analysis to evaluate the accuracy of performance assessment based on the sliding distance in the first experiment, we obtained p-values of 0.014, 0.0027, 0.0107, and 0.0137, respectively, all of which were

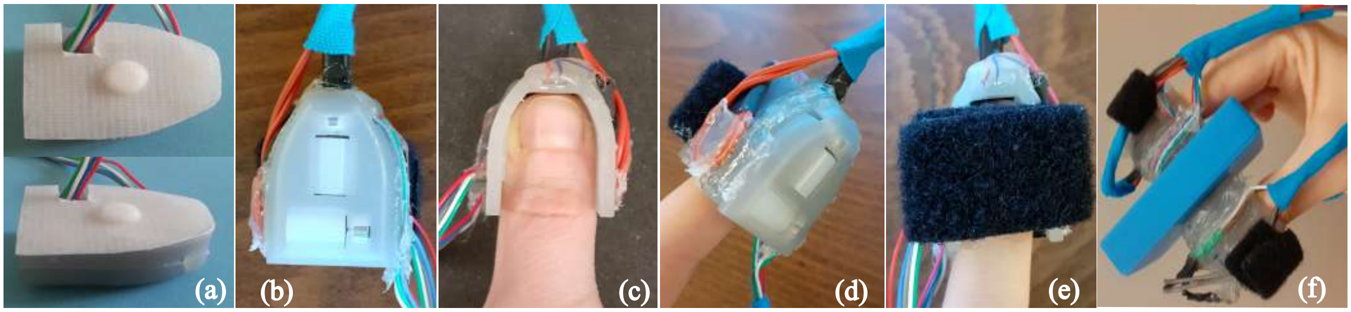

Fig. 4. Prototype of the thimble-like device (a) The protruding surface of the force-sensing sensor, which makes it possible to detect the exerted force more clearly (b) The magnetic encoder and rotary elements placed perpendicular to each other, viewed from the bottom of the device (c) The suitability of the wearable device for finger anthropomorphism (d) The ready-to-use device worn by the finger (e) A velcro tie fixes the device to the finger (e) A daily activity in the dynamic condition is performed using the device

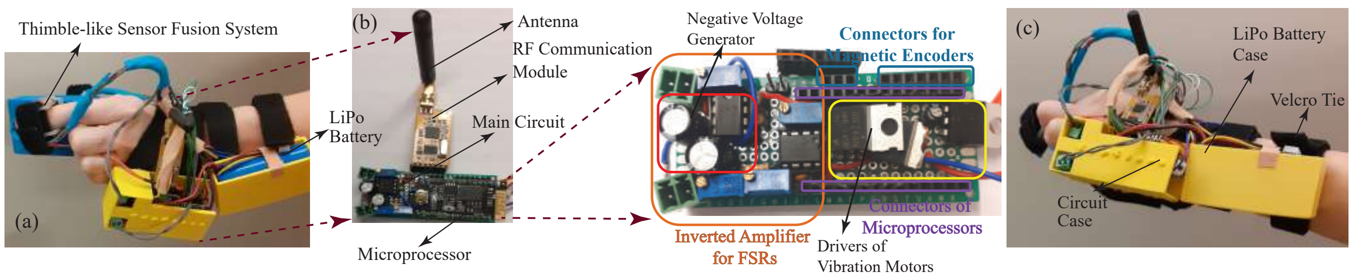

Fig. 5. Electronic unit of the thimble-like sensor fusion system

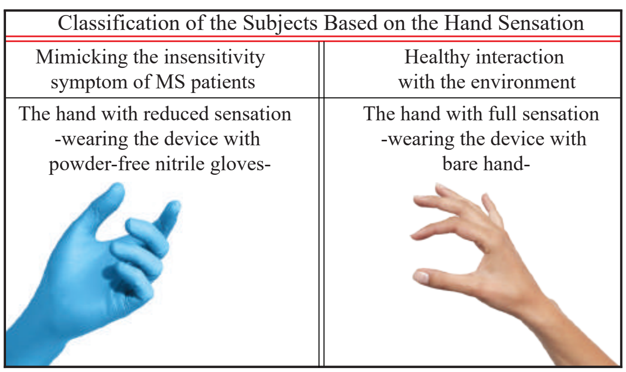

Fig. 6. Classification of the subjects based on their hand sensation capability

less than 0.05. This confirmed that the mean performances of each volunteer differed in the condition where they reduced hand sensitivity by using either bare hands or wearing nitrile gloves.

In the second experiment, volunteers are asked to place the object in slots opened in various orientations. The task of taking it from one slot and placing it in the other slot was repeated ten times. Two groups of volunteers carry out the task with bare hands and with wearing nitrile gloves. The performance metrics of this experiment are the sliding time and reaction time. The sliding time is the time spent inhibiting an object from sliding in response to the force exerted on the object; while the reaction time is the time elapsed to retain the object from slipping from the moment the subject is given vibratory stimuli.

The second experiment carried out while performing Task-

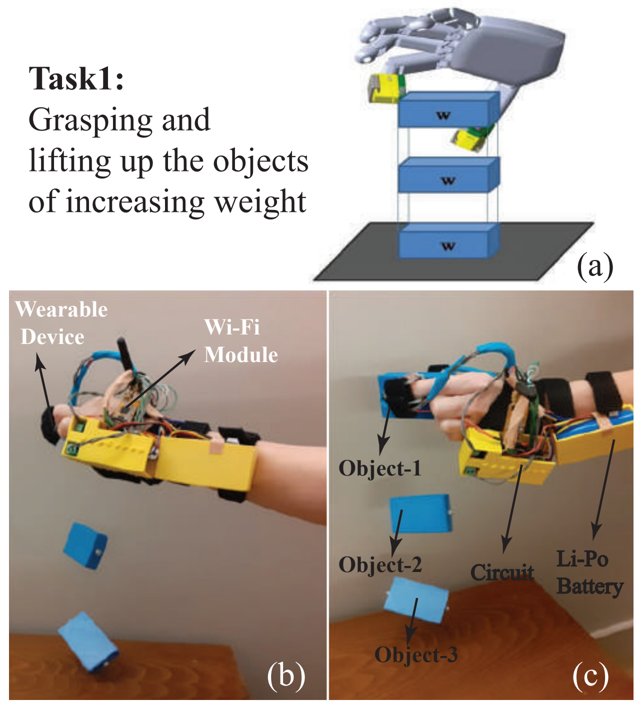

Fig. 7. The first task is evaluating the performance of the subjects while they are grasping and lifting the gradually increasing weight of the objects (a) equally separated three connected objects via wires (b-c) simultaneously grasping and lifting up the objects

2 involves measuring the duration for which the object is displaced during the course of executing the second task by the participants, using the performance metric known as "sliding

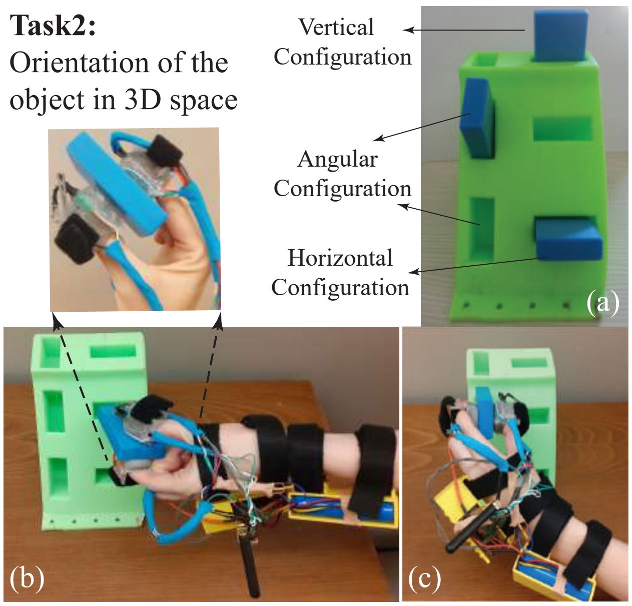

Fig. 8. The second task is evaluating the performance of the subjects while they are orienting their upper limbs in the 3D space (a) various options for different configurations of objects (b) orienting the object horizontally (c) orienting the object vertically

time". The performance of each volunteer is presented in Figure 10.

Based on the findings depicted in Figure 10 (a) and (b), the experiment involving the placement of an object from one nest to another nest with a different orientation resulted in significantly lower total displacement time for healthy individuals, as opposed to MS symptomatic volunteers. This difference was confirmed by a t-test, with the p-values obtained for each volunteer being 0.0186, 0.0113, 0.0333, and 0.0356, respectively, which are all lower than 5%.

The second experiment also sheds light on the effectiveness of vibrotactile stimulation, a form of biological feedback, in improving the performance of the volunteers during the execution of Task-2. During the object manipulation task in the final stage of the experiment, which involved picking up and placing the object from nests with varying configurations, both groups of volunteers received vibrational feedback in the event of slippage while holding the object. Accordingly, the volunteer reacts by perceiving the slipping of the object as a means of tactile stimulation and taking action to hold onto it. The time elapsed between the warning and the object stabilizing is defined as the reaction time. The reaction times of both the healthy and MS symptomatic groups are shown in Figures 11 (a) and (b), respectively. To verify this result, a t-test was conducted, which yielded p-values that are significantly greater than 0.05 for both groups (0.9374, 0.8489, 0.6653, 0.2152). This finding confirms that the data from the two groups are very similar to each other.

III. Conclusion

This study encompasses the design of a wearable robotic device intended to serve as a substitute for conventional clinical assessments in monitoring the progression of Multiple

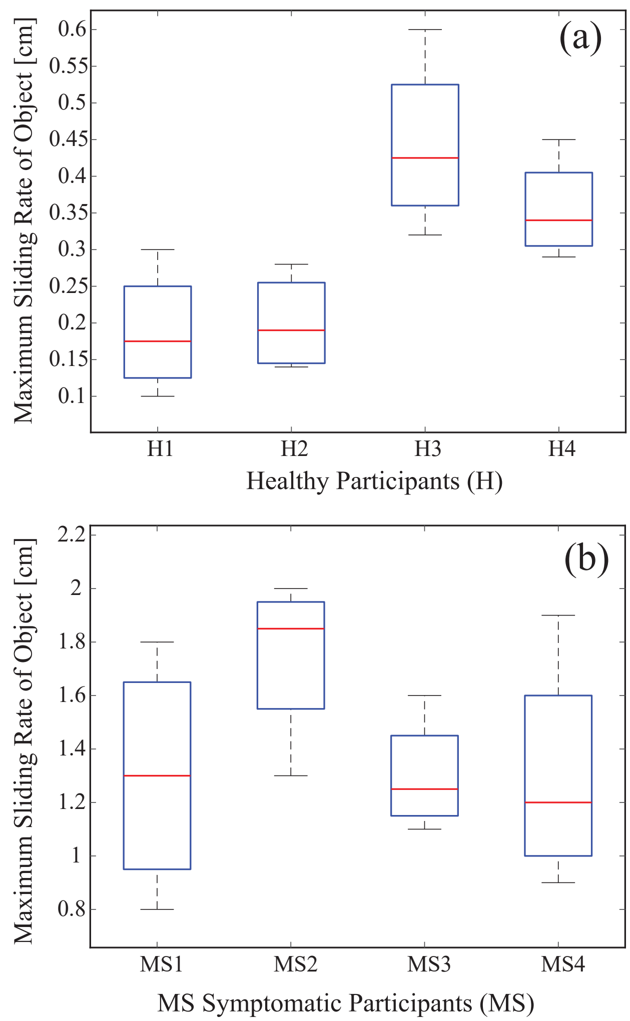

Fig. 9. The initial task involves assessing the participants' performance as they grasp and elevate the object with a gradual increase in weight a) The sliding rate of the healthy participants b) The sliding rate of the MS symptomatic participants

Sclerosis. The device offers high-sensitivity measurements, enabling objective evaluations, and allows patients of various age groups to utilize it conveniently in any desired place. Furthermore, the inclusion of an integrated vibrotactile stimulator enables patients to receive therapy concurrently in parallel with their performance evaluations. Within the scope of this study, the device undergoes experimental evaluation involving two distinct groups: healthy volunteers and individuals exhibiting artificially MS-related symptoms (MS symptomatic volunteers). While the primary focus of this study lies in substantiating the design criteria of the proposed wearable device, the current number of participants is deemed adequate.

Preliminary findings from the initial set of experiments corroborate the observation that individuals with multiple sclerosis tend to exert excessive force during object grasping, owing to diminished sensory perception. In contrast, healthy individuals demonstrate superior control modulation during activities of daily living (ADL) compared to MS-symptomatic people. Consequently, while the healthy cohort promptly rectifies any slipping occurrences by firmly gripping

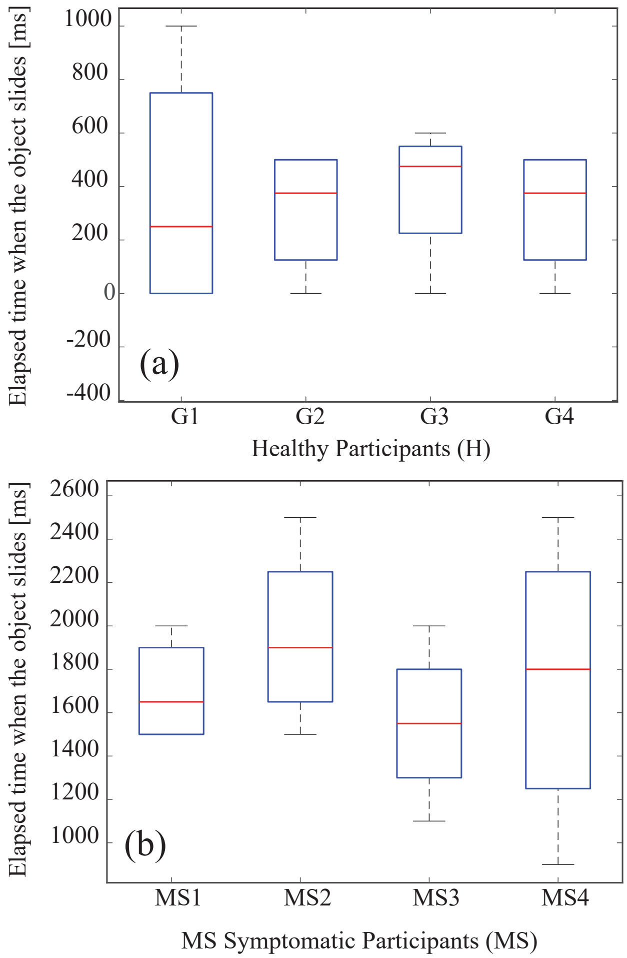

Fig. 10. In the assessment of the performance of each group of participants in the second task, the sliding rate, which denotes the time duration of the object's sliding, is the performance metric that is commonly employed. a) The sliding time of the healthy participants b) The sliding time of the MS symptomatic participants

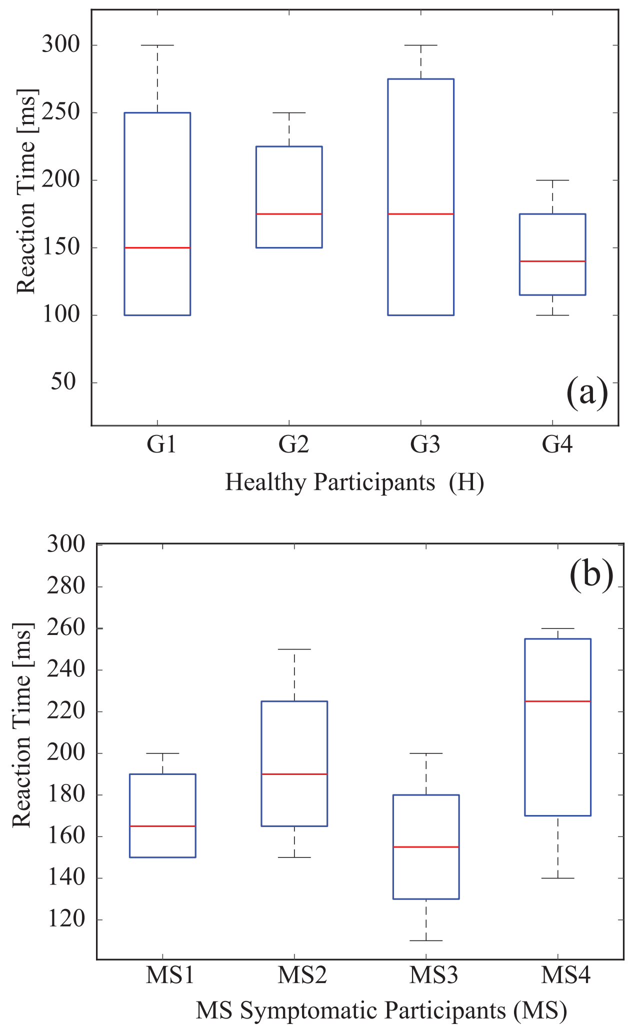

Fig. 11. In the assessment of the performance of each group of participants in the second task, the reaction time, which measures the time it takes for a participant to respond to the tactile stimulation, is used as the third performance metric. a) The reaction time of the healthy participants b) The reaction time of the MS symptomatic participants

the object, MS-symptomatic individuals experience prolonged and frequent instances of slippage.

The subsequent experiment expands the assessment scope beyond a unidirectional upward movement, as observed in the first experiment, to enclose activities involving orientation and rotational motions. Notably, the MS symptomatic group exhibited a protracted duration of shifting during the task compared to the control group. However, the final experiment yielded a surprising outcome. With the influence of the stimulant, the MS symptomatic group demonstrated enhanced reaction speed and lessened reaction time. Intriguingly, the reaction times of both groups converged, reinforcing the hypothesis that a tactile stimulus system could potentially ameliorate neural dysfunctions.

Among the future aims of this study, there also lies the inclusion of conducting the aforementioned experiments with a larger cohort, thus substantiating the veracity of the experimental outcomes. Moreover, the future objective of this study also entails the integration of the proposed wearable robotic device with an immersive virtual reality environment to provide patients with diverse tasks. The aim is to investigate the therapeutic potential of the device in facilitating the recovery process when used consistently by patients. By combining the device with a motivating virtual reality setting, the study aims to assess the impact of this combined approach on the patient's rehabilitation progress. The evaluation will focus on the extent to which the device enhances patient outcomes after regular use and contributes to their overall recovery journey. The envisioned system for rehabilitation and clinical evaluation embodies an intricate electromechanical design that facilitates unbiased and objective assessments, transcending subjective perspectives.

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