



HANDY: Novel Hand Exoskeleton for Personalized Rehabilitation

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Abstract. Worldwide, stroke is the third cause of disability. The majority of people affected by this disease cannot perform activities of daily living. Bringing the therapy to the patients' home is complex, and in literature, there are still open challenges to face. Starting from therapists' and patients' needs, this paper describes a possible solution: HANDY, a rehabilitative active hand exoskeleton for post-stroke patients. With a desktop application, they perform three different types of exercises: passive, active and based on activities of daily living. They can also control the exoskeleton themselves in a serious-game approach with a leap motion controller. We evaluated our method with patients at the Villa Beretta rehabilitative center. Preliminary results from the session about comfort, usability and willingness to utilize the system are promising.

Keywords: hand exoskeleton, additive manufacturing, stroke, CAD modeling, interactive applications

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1 INTRODUCTION

According to the United Nations, we are experiencing a social transformation: the world population is ageing [49]. A longer life brings new opportunities, but it can cause an increased incidence of diseases, such as stroke. According to the Global Burden Disease study, stroke is the third cause of disability [51].

Based on the medical definition [40], we can identify two principal types of stroke: ischemic and haemorrhagic. An ischemic stroke occurs when a clot or a foreign mass obstructs a blood vessel, reducing the bloodstream to brain cells. A haemorrhagic stroke occurs when a damaged blood vessel breaks and bleeds into the surrounding brain area.

Stroke symptoms depend on the type, the severity and the location of the affected area of the brain. However, there are some similarities [2]. One of the most common consequences is contralateral hemiparesis. It involves weakness on the side of the body opposite to the harmed brain hemisphere. The most affected parts of the body are limbs, particularly hands. During the acute phase, the muscles of the limbs are flaccid (lose their tone). After a few days or a few weeks, the muscular activity evolves. Some temporarily altered nerve fibres recover their functions, and the

paralysis stabilizes only in the affected body parts. At the same time, the muscles move from flaccidity to spasticity. Twitchell [45] demonstrated that motor recovery starts immediately after the stroke and follows a foreseeable pattern. These stages have been empirically described by Brunnstrom [15]. As shown in Figure 1, a post-stroke patient can progress from flaccidity to full recovery moving through different levels of spasticity. However, not the totality of patients reaches the full-recovery stage. Many of them stop in the previous ones and remain permanently disable [45, 15].

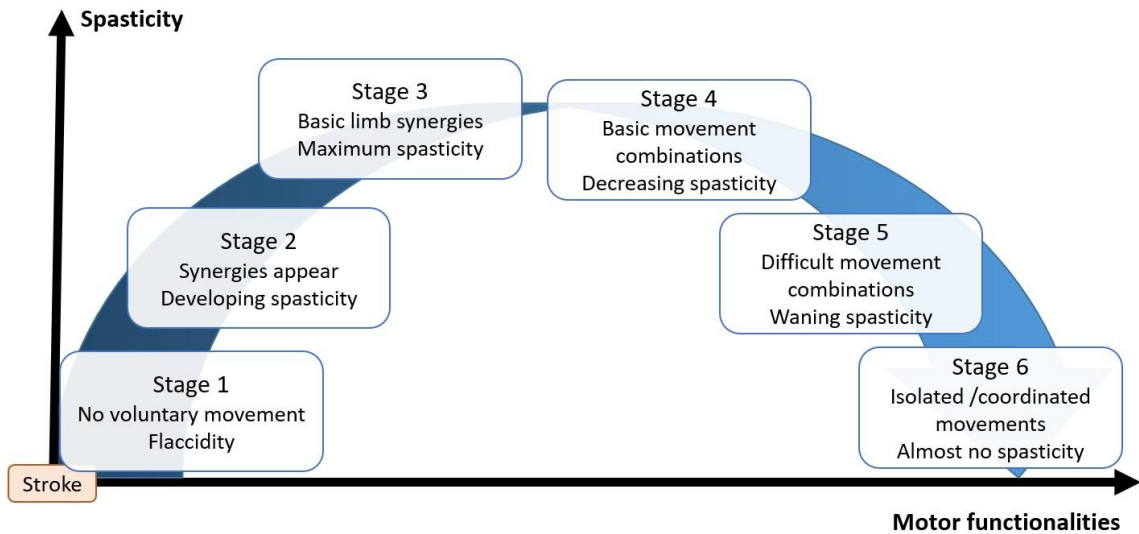


Figure 1: Graph that encapsulates Brunnstrom's phases of stroke motor recovery.

To regain dexterity, post-stroke patients must undertake as soon as their conditions have been stabilized a rehabilitative therapy. It can be a long process that usually requires the patient to periodically and frequently perform exercises in the rehabilitative clinic. It has a high social and economic impact on the patient and their family. In the long-term, it can lead to the abandonment of the therapy. Moving the rehabilitation to the patient's home, when possible, could allow greater flexibility and increase the patient's sense of autonomy.

In recent years, this aspect has induced a rapid expansion of mechatronic devices for hand rehabilitation (also called hand orthosis), as seen in recent research studies and reviews [11, 34, 41, 1]. However, the number of commercial robotic devices is limited [31] with respect to the number of prototypes developed in recent decades. Hand orthosis can be categorized according to numerous parameters, such as application field, mechanical mechanism and transmission, actuation, control strategy. [11]. This work considers only robotic devices for medical purposes, discarding the ones used for military [30] or industrial applications [19].

Regarding the mechanical design of hand orthosis, they are usually differentiated in end-effector and exoskeleton devices. End-effector devices are connected to the patient hand only in its most terminal part [31]. They are typically coupled to or grasped by the patient's hand, such as the AMADEO® [46] and the InMotionARM/HAND™ [9], respectively. The principal advantage of an end-effector is its structure. It is mainly independent of the size and the proportions of a patient's hand. In the beginning, it allows a faster design process and set up in a clinical environment. However, the control of the position of the user's joints can be puzzling. All the other joints of the upper limb are moved indirectly by the device. Therefore, the device does not directly control the force applied to them. One advantage of end-effector devices compared with exoskeletons is that they can fit different hand sizes and are usually ambidextrous. On the other hand, proximal joints training seems

to transfer limited benefits to distal parts highlighting new opportunities for exoskeletons [1]. Exoskeletons overlay the patient's hand. Examples of commercial exoskeletons are the Hand of Hope [39], the ExoHand [22], the CyberGrasp [18], and the Gloreha [28]. Due to their direct coupling with the hand, exoskeletons need to be designed keeping in mind some anatomical aspects of the upper limb, more than required for end-effector. One concern is the coincidence of the centre of rotation of the device with the fingers' joints [24]. A subclass of hand exoskeletons derives from soft robotics. It is a section of robotics that deals with soft materials [41]. Examples of soft hand exoskeleton are the Harvard Glove 2.0 [37] and the NUS Glove [52]. One of the main advantages of soft robots is their ability to adapt their shape to complex bodies. Furthermore, compared with exoskeletons based on rigid linkages, they seem more lightweight and compact [41]. However, many of them use pneumatic actuators, which require an external pressure reservoir that generates force by inflating air in the flexible bodies.

Several mechatronic devices for rehabilitation have been developed. They show that hand training seems beneficial for the rehabilitative process of the upper limb damaged by a brain injury. However, in literature emerge also open challenges. We decided to summarise them here.

- **Comfort.** A painful or annoying device will be unlikely used with perseverance and desire. Especially for rehabilitation, a hand exoskeleton should be comfortable for the user [20]. These devices have to be worn for long periods. One cause of discomfort is the misalignment between the orthosis and the human hand. It can damage skin and tissue [11].

- **Lightness.** Even though there are examples in the literature of lightweight devices [38, 25], they are still a limited number. According to Heo et al., lightness must be considered a high priority [24].

- **Validation.** Several studies demonstrate the devices only in a laboratory setting. Usually, not all components are developed enough and packed to be easily transported and used in clinics or daily life situations. Challenges also involve reliable power sources and wireless technologies [24].

- **Cost.** Maciejasz et al. state that, even though numerous devices are technically advanced, there is still the need to reduce the cost of home-based devices that allow therapy based on daily living activities [31]. The economic aspect is a big issue by McConnell et al., as stated in their review. They suggest that 3D printing technology could be a possible solution to build customized devices [34].

- **Appearance.** McConnell et al. state that: "if a machine appears intimidating, it may affect the patient's progress or desire to use the device". It is usually an underestimated concept. A solution to prevent this negative consequence is to include therapists and patients in the design process [34].

- **Portability.** One further big open challenge highlighted in numerous reviews is that many exoskeletons in literature lack portability, while they should be portable to allow home and personal use [1].

- **User involvement.** In literature, there are pieces of evidence that the development of a medical device requires considering the needs and capabilities of its users. For rehabilitative exoskeleton, we consider as users both patients and healthcare professionals [26]. Despite this, only a limited number of researches involve users during the whole development process. This process appears difficult because it inevitably requires time and financial resources for the development team, patients and therapists [33].

This research aims to develop a portable hand exoskeleton for post-stroke patients. This solution meets the users' needs and addresses the current open challenges in the literature. A further objective consists of coupling the prototype with engaging exercises to reduce the high therapy abandonment rate. We propose two significant elements to address this question:

- a) HANDY, the rehabilitative hand exoskeleton that could be used in clinics and at patient's home with the help of their family.

- b) The desktop application for both therapists and patients with several rehabilitative exercises.

2 HANDY

User involvement has been a paramount aspect of the development process. Since the initial phases of the research, we collaborated with Villa Beretta. It is a praesidium of the Valduce Hospital in Costa Masnaga specialized in the rehabilitative treatment of congenital or acquired diseases. Bioengineers and medical professionals have been involved with meetings, interviews, focus groups, and testing. It allows having feedbacks from the viewpoint of a possible final user. These are the initial requirements and suggestions from them:

- placement: the device should be placed on the dorsal side of the hand to permit interaction with the environment
- weight: do not overpass approximately 250g on the hand. It is a rehabilitative device. The patient (usually elder with motor impairments) should undertake repetitive exercises for several minutes without feeling pain or fatigue.
- movement: the fingers extension is an essential movement to prevent the occurrence or aggravation of spasticity. It is also important to avoid hyper-extension of the phalanges.
- cost: the device should be affordable to let the patient buy it or lease it from the rehabilitation centre, allowing the home-therapy.

Regarding post-stroke patients, they have been involved at the beginning to understand their needs. They stated that the aspect of the device should be smooth and not bulky. It must be lightweight to enable rehabilitative sessions lasting several minutes. Furthermore, they emphasize the desire to be able to perform the exercises. In the advanced phases of the development, three patients tested the device and provided us with their opinions and their willingness to use it in a clinic and at home. We decided to include them for testing only with the latest prototypes because we wanted that the device was secure and comfortable enough to use.

2.1 Physiology of Hand

We believe that a prerequisite for developing a safe and effective upper-limb exoskeleton is the knowledge of the biomechanics and anatomy of the human hand. The human hands are extremely complex and adaptable body parts. They allow performing complex manipulations with various degrees of precision and force [17]. They are also a meaningful sensory organ and have many receptors, especially on the fingertips. Without these pieces of information, we could not perceive several qualities of an object, and it would be more complex to understand and interact with our surroundings.

Behind the capability to perform a vast number of movements and activities, there is a complex structure of rigid and soft tissue. Figure 2 summarises the bones and joints of a hand, while Figure 3 the main movements of fingers. The skeleton consists of 27 small bones: 8 in the carpus, 5 metacarpals bones and 14 phalanges in fingers (5 proximal, 4 middle and 5 distal). Five carpometacarpal (CMC) joints connect carpus and metacarpus. The joints that connect metacarpals to proximal phalanges are called metacarpophalangeal (MCP). They are usually classified as ellipsoids. Both CMC and MCP have two degrees of freedom: flexion/extension and adduction/abduction movements. The interphalangeal joints (IP) can be divided into proximal interphalangeal (PIP) and distal interphalangeal (DIP). PIP is between the proximal and middle phalanges. DIP is between the middle and distal phalanges. They are both hinge joints and allow only one degree of freedom, the flexion/extension movement [29].

2.2 CAD and Additive Manufacturing of the Exoskeleton

Based on the users' needs, HANDY has a deformable element connected to the dorsal side of each finger. It guides a cable to assist the flexion/extension movement avoiding hyperextension. Considering the limited space on the hand and the amount of supported weight, it has a remote actuation system. It inheres in placing the actuators in an external structure with Bowden cables. They are flexible cables that transmit mechanical force by the relative movement of an inner one to

a hollow outer cover. With a few changes, HANDY can work in two different configurations: push-pull, for both flexion and extension movements, and pull-only, which controls the only extension but does not obstruct voluntary movement of the patient. This paper describes the second one.

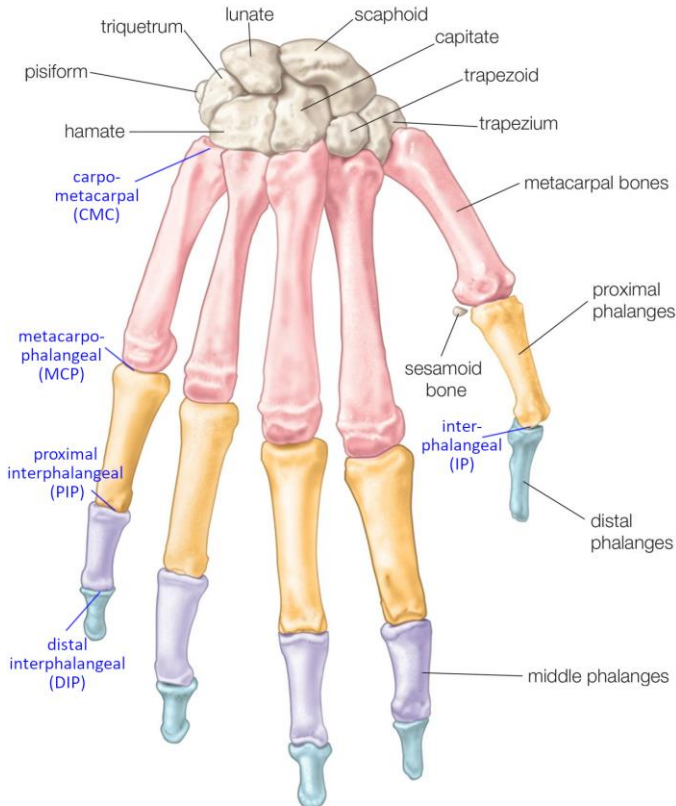


Figure 2: Names of the bones (black) and joints (blue) of a hand. Figure elaborated from [21].

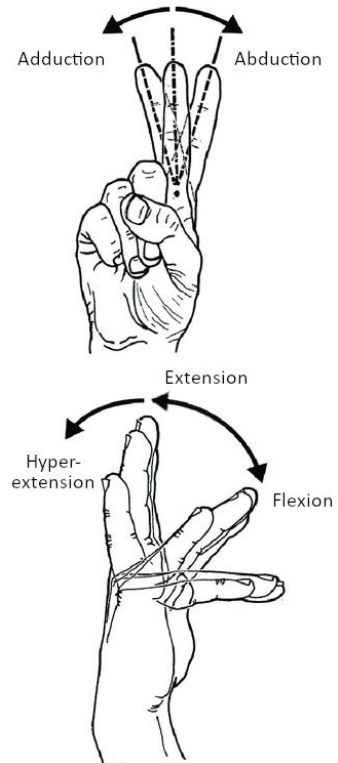


Figure 3: Main movements of fingers. Figure elaborated from [29].

We designed all CAD components using Autodesk Inventor® Professional 2018 [5]. HANDY is composed of several elements obtained by additive manufacturing (AM). The flexible ones lead and accompany movements of the human hand and must adapt to its deformation. Others require more strength, for example, to fix the actuators, and are rigid.

In Figure 4, it is possible to notice that the core element of the assembly is the flexible Body (item 2.1). It is connected by the Thimble (item 2.2) to the patient's distal phalanx and the proximal and middle phalanges (excluding the thumb) by two strips of Velcro (items 2.12). Initially, we inserted the strips directly inside the Body's cavities above the phalanges. However, during the flexion movement, they rotated, prejudicing both the pulling force and comfort. For this reason, we 3D printed two rigid partial Rings (items 2.5 and 2.6) with different diameters, sewed the Velcro strips to them and fixed them to the Body with a removable rigid RingLock each (items 2.7). At the extremity of the Finger, a screw fixes the pulling wire. The head is totally inside the Body to avoid contact with the user's nail. To cover its extremity and prevent unintentional wounds, we made the flexible Stop (item 2.3). It has an M3 brass insert (item 2.9) that allows tightening the screw. The rigid FingerLock (item 2.4) attaches the Body to the Glove thanks to a small piece of Velcro sewed below its base. Using Velcro, the Finger can be detached, worn by the patient and reattached based on his/her hand size. The FingerLock also permits fixing the Bowden tube's extremity using a push-

in fitting (item 2.8) and an M6 nut (item 2.10). The two through holes on the side of both Body and FingerLock permit to block the two parts and group all fingers to keep them in order and not lose them by using a strand (Figure 5).

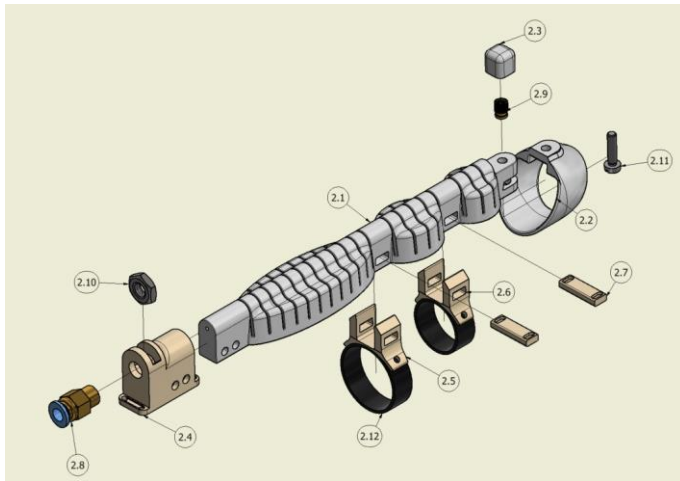


Figure 4: Exploded view of the Index Finger.



Figure 5: Dorsal view of the Glove.

The length and width of the oval cavities above the knuckles in the Body and the Thimble's diameter define the size of a Finger. Even though it is moderately adaptable, people's hands can differ a lot. Considering the reasonable time and cost to build customized Fingers, we exploit the power of parametric CAD. We design a tool that automatically generates the parameters needed by Inventor from a few measurements of the patient's hand. Changing the values, the CAD software automatically modifies the Finger's parts that only need to be exported as Standard Tessellation Language (STL) files and 3D printed.

We use Microsoft Office Excel to define parameters because it is widely known and compatible with Autodesk Inventor. Figure 6 shows the input window. While the joints' width needs to be measured by therapists, we used a different approach for the length. Buryanov et al. in their study [16] report the ratio between phalanges' dimensions of the same finger. On the other hand, Aydinlioğlu et al. [6] state the proportions of the proximal, middle, and distal phalangeal lengths compared to each other. Combining the results of the two studies, starting from a single measure (in the example in Figure 6, the middle phalanx of the index finger) the tool suggests the lengths of all other phalanges. However, a therapist can set the other measures manually if they prefer. The 'Automatic output' values are equal to the manual input if defined or computed automatically if the input is left empty. The CAD parameters derive the width from the 'Manual input' table and the length from the 'Automatic output' table.

For both flexible and rigid components that have been created using AM, the process is based on the Fused Deposition Modeling (FDM) technology [4, 23]. However, they followed two distinct configurations.

All flexible parts use the thermoplastic polyurethane (TPU) NinjaFlex filament with a diameter of 1.75mm. It is a non-toxic material that combines elevate strength (ultimate tensile strength 26MPa tested with ASTM D638 method), hardness (85 Shore A tested with the ASTM D2240 method) and elongation (65% elongation at yield and 660% at break tested with ASTM D638 method) [35]. We used the BQ Witbox 3D printer [12] and Ultimaker Cura [47]. It is a slicing software that, as the name suggests, slices an STL 3D model in vertical layers and establishes the best path that the print head must follow to obtain the desired object.

Manual input					
Lenght	1	2	3	4	5
Proximal					
Middle	x	26			
Distal					
Width	1	2	3	4	5
IP	x	20	20	20	17
DIP	23	17	18	16	14
Automatic output					
Lenght	1	2	3	4	5
Proximal	20.89	46.43	54.08	45.91	30.81
Middle		26.00	32.59	30.92	16.75
Distal	22.66	18.57	19.50	19.69	17.64



Figure 6: Part of the tool to generate Fingers' parameters based on few measurements (highlighted in yellow) and a combination of Buryanov [16] and Aydinlioğlu [6] results about phalanges proportions.

Defining the correct orientation of the flexible models (especially for the Fingers) has been particularly challenging. Removing TPU support from the part is not as simple as with rigid polymers due to its flexibility. It is difficult to break and tends to leave some residues. Moreover, we need to consider that this component is on the hand of a patient. If the inner surface is not smooth, due to the support leftover, it can cause discomfort during the usage. The orientation showed in Figure 7 is the one that, according to our tests, minimizes the support and produces the best results in terms of surface finishing, resistance and printing time.

Approximately it takes 14 hours and 20 minutes to produce all the models. Considering the weight and length of the filament used (almost 96g and 31.13m) and the current average price of the NinjaFlex with a diameter of 1.75mm of 39.90 €/kg, it results in a material cost of €3.83. We need to consider that the resulting time is less than the real one due to the calibration and setup time for the process and the machine. Also, the amount of money is not the global cost of the process. However, these figures highlight the capabilities of the process for a fully customized product.

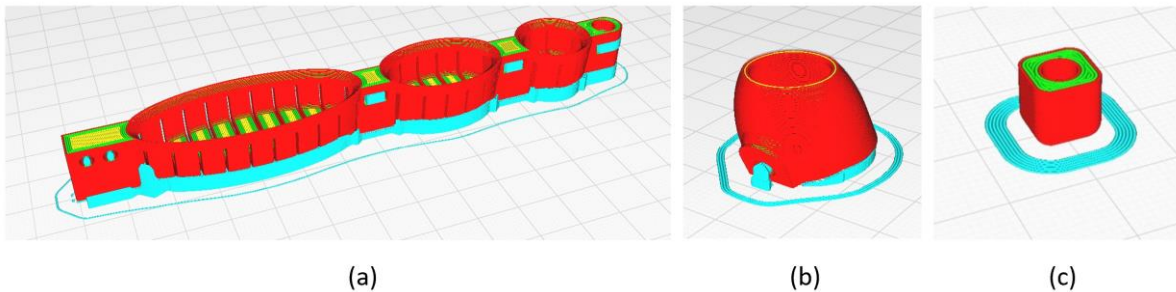


Figure 7: Preview of FDM result for the index finger (a), thimble (b) and lock (c) using Ultimaker Cura. The color scheme represents the support material (blue), the shell (red), the top/bottom lines (yellow), and the inner walls (green).

For building the rigid components, we used Acrylonitrile butadiene styrene (ABS). It is a thermoplastic polymer commonly used in AM for creating rigid parts. However, ABS demands particular care during the FDM process. It requires a heated and closed chamber to avoid part shrinking and, because it produces fumes and odour while printing, an air-filtration system or a well-ventilated area is needed. For these reasons, we prefer not to use the Witbox to print this material. Indeed, we used a Stratasys uPrint SE Plus [43], with its ABSplus™ [42]. Its datasheet reports a tensile strength at yield of 31MPa and a tensile elongation at break of 6% (tested with the ASTM D638 method).

The uPrint SE Plus was able to print all the rigid components in one step. It works coupled with Catalyst Ex software that slices the models, defines supports and controls the process. In Catalyst Ex it is not possible to set the infill percentage. But there are only three options with an increasing amount of material: low-density, high-density, solid. We opted for "solid": it results in a long process but a more resistant output. A further advantage of this machine regards the support. As emphasized previously, the post-processing of AM about removing support material needs time. The uPrint SE Plus uses the SR-30 as support material, which is water-soluble. After the process was over, we left the new components in a circulation tank full of support-removal solution for a few hours to remove all the excess material.

2.3 Final Assembly

HANDY is the union of multiple components. Figure 9 is a photograph of the device. To better examine it, Figure 8 shows a drawing of the system with balloon annotations. It includes the hand exoskeleton, electronic elements, structural parts, actuators, and safety components.

Items 1-5 are the assemblies of the exoskeleton's Fingers. They are the core of the system and need to be worn by a patient. Each Finger has different sizes, but the same parts constitute it.

The Glove (item 6) is a hand tutor that fixes the Fingers on the dorsal side of the patient's hand and keeps them in place (Figure 5). We sewed it by combining three layers of different materials: Velcro (beige), cotton (white) and Plastazote® (blue). Velcro is the most external element. It allows closing the tutor and attaching the Fingers allowing different placements for different hands' sizes. The most internal one is in Plastazote®. It is an orthopaedic thermoplastic material widely used in healthcare [54]. We inserted this layer to obtain a non-toxic, breathable and lightweight element to reduce skin irritations. However, it is not very stretch-resistant. To prevent it from breaking, we used a cotton layer between Velcro and Plastazote®. It is not as rigid as Velcro, allowing the Glove to adapt to the hand shape; it is more durable than Plastazote®, allowing the user to wear the tutor without destroying it.

Five linear actuators (item 21) pull a wire through the Body and tied it to each Finger's Thimble, moving a prismatic element (item 20). The wire runs into a Bowden tube (item 22) and allows a remote actuation. It reduces the weight on the patient's hand, notably increasing the comfort of the device.

For the pull wire, initially, we tested a nylon (PA) monofilament line. However, it presented undesired plastic deformation and a discrete elongation. So, we moved to a braided line: the Spectra® Extreme Braid with a diameter of 0.44mm. It allows pulling till 70lb (approximately 30kg) and, compared to nylon monofilament, has 24% less stretch, is four times stronger, and is five times smaller for the load [27].

BaseA and BaseB (item 18 and 19) fix the actuators to the Structure and avoid collisions between their pieces. For all mechanical connections that involve 3D printed parts and screws, we insert a threatened brass into the component to tighten the screw. It ensures a more reliable connection.

To control the linear actuators, we associated an Arduino Mega 2560 Rev3 with a custom printed circuit board with five h-bridges and an Ethernet module (items 12 and 13). The actuators demand 12V and 5A as power input. To satisfy this requirement, we used a LiPo battery (item 10). It also powers the router (item 14) through a DC-converter (item 11). Between the battery and all other

electrical elements, there is a mushroom push-button (item 15). It is used as a security element to stop the device in case of an emergency or malfunctioning.

Considering that each human hand is different, the wire pulled by an actuator is also connected to a guitar tuning peg (item 9) used to customize the wire tension to each patient. To prevent the wire from unwinding and getting out from the guide while the actuator returns in a more relaxed position for the patient, we added a flexible cap (item 8) at the upper extremity of the tuning peg. Finally, to keep the Bowden tubes tidy, we produced two elastic Bands. They also allow for fastening the tubes to the user's arm, improving the device's comfort.

Finally, HANDY needs to be portable to be easily carried or allows a patient to perform rehabilitation exercises while s/he is moving. To achieve this result, it is fixed to the internal frame of a small backpack.

Considering all components, the base Structure's size (item 23) is 210x297mm (equal to A4 paper size) and HANDY's global weight is about 3.7kg. However, only 190g are on the patient's hand, value notably below the threshold of 250g suggested by therapists and less than numerous prototypes proposed by the literature.

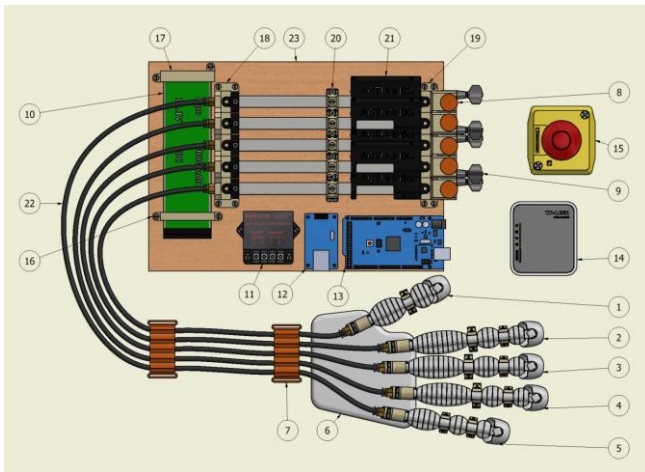


Figure 8: Top view of all components of HANDY.

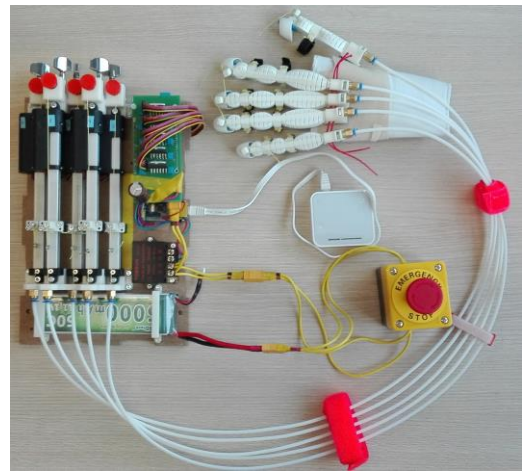


Figure 9: HANDY assembled.

2.4 Actuation and Control

HANDY and a personal computer with a dedicated desktop application need to send data to each other. As control strategy, we use a closed-loop proportional control on position. Figure 10 shows a schematic diagram of this approach.

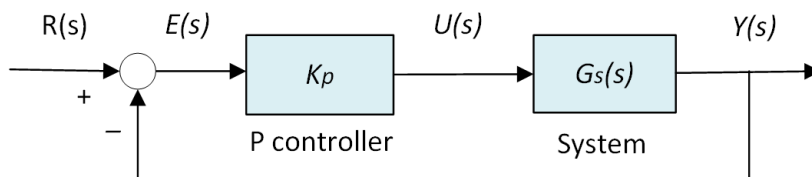


Figure 10: Schematic representation of the closed-loop proportional control.

Initially, the controller (P) receives as input the desired position of the moving block of the actuator ($R(s)$) and its actual position as feedback from the internal potentiometer ($Y(s)$). Based on these two values, it computes the error ($E(s)$) and sends to the system the direction and speed needed to reduce the error. However, the error could never reach the zero value. It can result in unexpected behaviour or noise of the actuator. To avoid this, we set a small error interval instead of an absolute number.

More in detail, for each actuator, Arduino reads its actual position (P_c) and the amount of current absorbed (C). It checks the thermal state of the h-bridge and saves it into a boolean variable (T), which can only be 1 in normal conditions or 0 when it exceeds the thermal limit. It also computes the cumulative error (E_c) between P_c and P_d . Then stores all these values plus the last desired position (P_d) of the actuator into an array called "big buffer" (BB). A checksum variable (B_Cks) is put at the end of BB . The application uses it to verify the correctness of a message.

On the other hand, the application sends Arduino the desired position of each actuator (P_d) and its speed (Pwm) with another buffer called "small buffer" (SB). Also, in this case, a checksum is computed and added (S_Cks). The application analyses the content of BB to verify that HANDY is working properly. In case of malfunctioning, it stops the actuators. If BB is damaged, re-ask the last one. Furthermore, when there is no new instruction for the exoskeleton, the application sends a beat (a brief message) to Arduino. It allows the latter to understand that the application is still connected.

We adopt the User Datagram Protocol (UDP) and a dedicated router to obtain fast, wireless and reliable communication. Sending data in a loop and using a network protocol analysers software (Wireshark version 3.0.1), we established that the fastest transmission rate without generating errors for the application messages sent among PC and Arduino was 40 Hz.

Figure 11 displays two examples of output data received from an actuator while trying to reach the desired position in two different situations: when no load (a) and a high load (b) is applied. All data is saved at 40Hz. The graphs in the first row highlight the trend of P_d and P_c . Values range from 0 to 1023: 0 corresponds to the actuator's position of the maximum pulling while 1023 corresponds to the resting position. The following rows report the cumulative error E_c , the electrical current index C , and the thermal state T of the h-bridge.

In the first case (column a), the actuator, indicatively at frame 40, moves from a pulling situation (position 430) to a more resting one (600). Only five frames are needed to reach its destination. The value of E_c increases only because of the calculation method and return equal to 0 in a few frames, indicating that the actuator reached its destination. C rises during the motion transient and reaches almost 80. T is always equal to 1, meaning that the integrated circuit works correctly.

In the second column (b), at frame 40, the actuator moves from 800 to 1000. The trend is similar to the one examined in situation (a). Approximately at frame 85, the actuator pulls from position 1000 to 100 an excessive load. It can reach a position around 300 but more slowly than the case (a). The absolute value of the slope of P_c is notably less than the first case. From frame 100 to 130, the actuator cannot surpass the resistant force. The current index C increases and reaches about 200. E_c cannot reach 0. At approximately frame 130, for security reasons, the actuator moves back slowly to position 750, and both C and E_c return to their normal conditions. T is always equal to 1.

3 APPLICATION

The following step was creating a global desktop application. It allows patients performing rehabilitative passive and active exercises with HANDY, and therapists to define the therapy and monitor their results. The application has been developed using Unity 3D software [50]. We also decided to supplement standard input devices with a more natural one: the Ultraleap Leap Motion Controller (LMC) [48].

The LMC is a small device that enables hand tracking and gesture recognition. It combines two CCD cameras that detect light emitted by three infrared LEDs with an internal human hand model.

To use the device, it must be connected to the PC via USB cable and place a hand over the controller. It detects the hand with a tracking speed up to 200Hz in a 150° field of view [7] and generates its virtual representation on the screen.

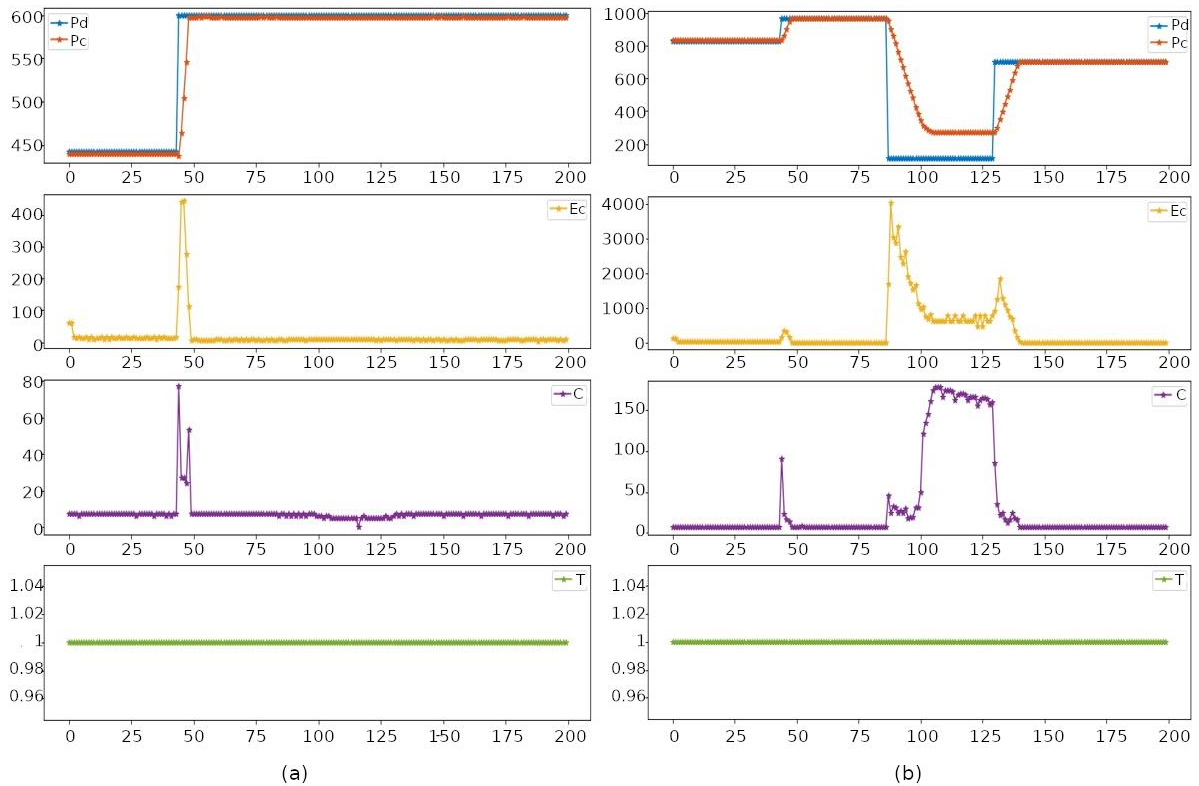


Figure 11: HANDY's controller output for one linear actuator, in two different resistance conditions: low (a) and high (b) load. Pd (blue) identifies the desired position of the actuator while Pc (red) its real current position. Ec (yellow) identifies the cumulative error in time between Pd and Pc. C (purple) gives an idea about the amount of current drained from the actuator. T (green) is used to flag if the board's temperature is reaching the maximum threshold: if equal to 1, it means that the circuit is in its normal condition.

In literature, there are pieces of evidence that applications designed for LMC show a high usability rating. The sensor also has some limitations, such as influences of bright light conditions [7]. However, it provides patients with a different way of interaction with the application and therapists an instrument to obtain visual and quantitative feedback of the patient's range of movement during rehabilitative exercises. One advantage of LMC is that it is a non-contact measurement device. It brings a notable benefit for therapists compared to the traditional rehabilitative process. Currently, therapists assess patients' conditions, such as range of motion (ROM) and spasticity, at the beginning of the therapy and periodically. The application exploits the LMC to continuously measure and store flexion/extension ROM of the fingers. Particularly, the angular position of MPC, PIP and DIP joint of each finger through time is recorded and saved in textual files that can be easily analysed to reconstruct the motion of the hand during the whole exercise. Furthermore, the app continuously records and saves all the data from HANDY described in Section 2.4 (desired and current position of actuators, cumulative error on their stroke, current drain, temperature flag of the control board, and motors' speed). These, combined with the setting of each exercise, increase the pieces of information therapists could use to evaluate the patients' signs of progress.

Each patient is different and requires a specific rehabilitative program. The application is designed to satisfy the needs of severe to mild conditions, starting from passive repetitive tasks to more engaging active or cognitive activities. More in detail, it provides patients with three main types of exercises:

- passive: involves repetitive specific rehabilitative hand movements performed by HANDY. Even though this type of exercise is less rousing, it is fundamental for people with severe symptoms (motor or cognitive).
- active: consists of rehabilitative movements but, unlike the previous type, the patient controls the position of each actuator in HANDY with their unaffected limb using a Leap Motion Controller.
- ADL-based: aims to involve both cognitive and motor functionalities damaged by stroke. They are task-oriented exercises inspired by activities of daily living such as cooking. This type of exercise is the most engaging of the three.

3.1 Passive Exercise

Together with medical experts from Villa Beretta rehabilitation centre, we defined four passive rehabilitative motions. According to the literature, performing these repetitive movements can prevent or reduce tendon retraction, spasticity and oedema [10].

- Grasp: from the resting position, all fingers simultaneously flex (like a fist) and then extend. It simulates the cylindrical grip.
- Pinch: all fingers are in a neutral position. Then, the thumb and index finger are extended and afterward flexed. It mimics the precision grip of a small object.
- Wave: it starts with the extension of all fingers. One finger per time is flexed and re-extended in order, from thumb to little finger and then in the other sense.
- Opposition: after extending all fingers, the movement replicates the opposition of the thumb with all other fingers. It flexes and extends the thumb and one other finger per time.

Considering that each patient is different, the caregiver can set the range of movement of each finger, the number of repetitions, and the movement's speed.

After the therapist defines the exercise from the dropdown menu, s/he can set all the other parameters: the minimum and maximum values for the actuators, the speed of the actuators expressed in seconds for one movement, and the number of repetitions. In Figure 12, for instance, the patient works on the Grasp movement. The actuators move from position 80 to position 971 in 3s. The movement is repeated ten times. To be noticed that in this case, the actuators have the same displacement, but we can also define different ranges if the users need different amplitudes for each finger. Once the therapist presses the "Start" button HANDY assists the patient in performing a grasp. The application shows an avatar of the hand on the screen. Meanwhile, the LMC measures the ROM of the fingers of the left hand. Also, it displays and saves these values in .txt files.

3.2 Active Exercise

To satisfy the patients' desire to see their hand move again and allow them to control finger extension, they can use the LMC as input device to control HANDY on the affected limb with the unaffected one. Post-stroke patients usually have contralateral hemiplegia. It means that only one side of the body is damaged, and they could use the other side to perform symmetric hands movements, exploiting the advantages of mirror therapy [44]. The exercise is active because it is the patient who decides what action to perform and when. For this reason, it is a motor and cognitive activity.

In Figure 13, a patient controls HANDY using the unaffected limb (the right hand in this case). The LMC measures the fingers' ROM. The application evaluates these new input data and estimate the desired position of each actuator so that the affected left hand of the patient can mirror the healthy one. The app sends the values of Pd to HANDY. On the top of the screen is listed the joints

ROM (from the thumb to the little finger). On the right, the five sliders show the actual position of each linear actuator. The linear actuators could not overpass the ROM limits defined by the therapist. The position sent to the actuator is an average value between MCP and PIP computed considering multiple measures of a time interval. In case of tracking loss, HANDY slowly returns in a neutral position of the hand.

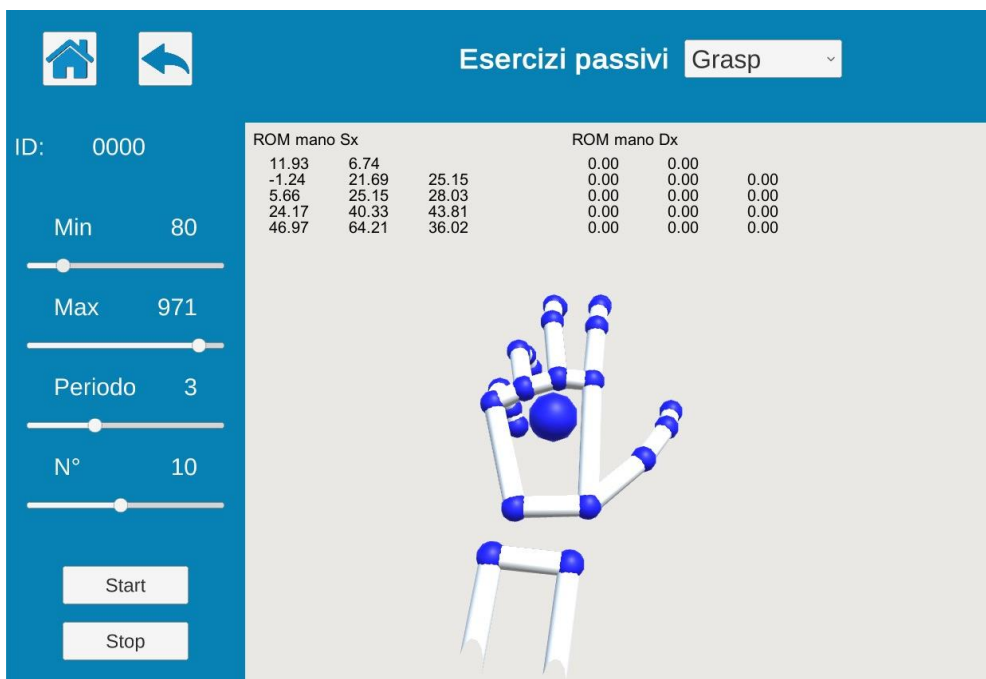


Figure 12: Passive exercise.

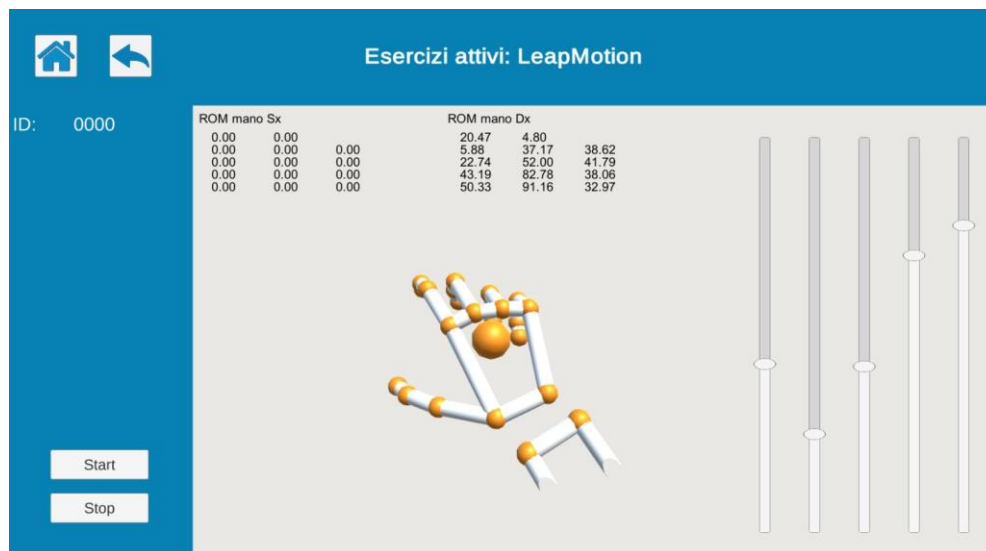


Figure 13: Active exercise.

3.3 ADL-Based Exercise

Another cause that leads to therapy abandonment is the monotony of activities. There are shreds of evidence in the literature that task-oriented exercises are more effective than repetitive passive ones to improve patients' conditions [32]. For this reason, we implemented a scene based on activities of daily living. One screenshot is visible in Figure 14.

The goal of the serious game is to cook a meal following a receipt. It trains the hand with the Grasp gesture. On the table, there are two plates with one ingredient each and one bowl in the middle. The user should put the correct ingredient into the bowl. It is suggested by the image on the left of the scene (some bread in this case). If the answer is correct, two new ingredients are generated. Otherwise, the user must try again with the same objects. In both cases, audio and visual feedback (different sounds and animations performed by the virtual assistant placed on the right) are played.

To put an ingredient into the bowl, the patient uses the LMC as input device. However, there are two different types of control based on two possible conditions. If the patient cannot extend the hand and is wearing HANDY, the LMC detects the palm position. When the hand stays over a plate for two seconds, HANDY flexes the fingers. When it is over the bowl, HANDY extends the fingers. To provide further visual feedback to the user about the hand position, the flat disk below dishes and bowl change their colour in fluorescent green, as in Figure 14. If the user's conditions are less severe and s/he can partially open/close the hand, s/he collects and releases the ingredient based on the LMC grabbing trigger. The device identifies a grab gesture when the distance between two or more fingertips decreases. On the contrary, opening the hand signifies the end of a grab.

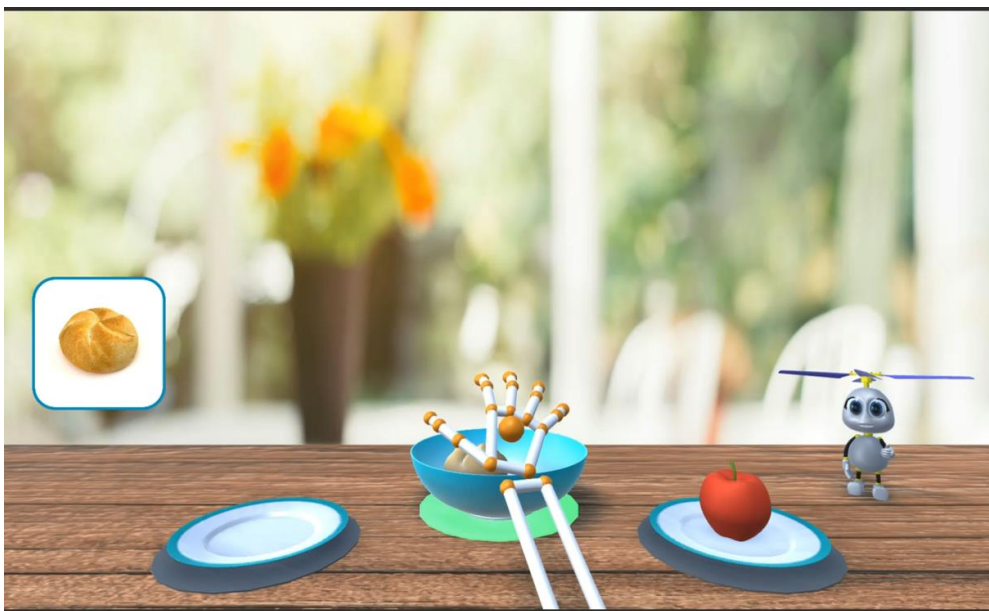


Figure 14: ADL-based exercise.

4 VALIDATION

The system was presented and tested by the bioengineers and medical professionals from Villa Beretta rehabilitation centre. They expressed a favourable opinion and defined it as safe, promising, fit for rehabilitative purposes. They willingly agreed to perform a preliminary qualitative evaluation with post-stroke patients.

The test does not aim to quantitatively measure the improvements that patients can obtain with constant use of the system. For statistically significant data, a large sample is needed. Furthermore, to observe the first results from a medical point of view, months or even years could be needed. This observational study aims to evaluate the comfort of HANDY and user's willingness to use it within their rehabilitation program. Even though a clinical trial would be necessary for the future, in our opinion, these are preliminary and fundamental requirements for a rehabilitative device.

With medical professionals, a protocol has been defined to obtain homogeneous results. Patients are recruited voluntarily by therapists based on their health conditions. Inclusion criteria are adult subjects in the post-stroke sub-acute or chronic phase with limited upper limb ROM. Exclusion criteria are disabling pain, cancer patients, severe deficiency of visual acuity, acoustic perception and communication, and Modified Ashworth scale (MAS) 3.

One therapist from Villa Beretta was always present during the evaluation. Initially, we explain to the patient the device, perform a demonstration and clarify the session's aim. Then, we help the patient wear HANDY and ask her/him to freely express any curiosity, doubt and feeling about the system. Afterwards, s/he performs ten repetitions of two passive rehabilitative movements (Grasp and Wave) assisted by HANDY. Then, s/he does the active and ADL-based exercise with the LMC. Lastly, the patient fills in one questionnaire about HANDY and the System Usability Scale (SUS) questionnaire.

The first questionnaire has nine statements specifically defined with caregivers to assess the comfort and the willingness to use HANDY. It is based on a Likert scale from 1 to 5. 1 means "strongly disagree" and 5 "strongly agree" with the statement. Similar to the SUS, this questionnaire has positive and negative (items 2, 4, 5) statements. To each item corresponds a normalised score from 0 to 4. For the positively worded items, the score contribution is the scale position minus 1. For negatively worded items, it is 5 minus the scale position. The final value is the sum of all contributions. It ranges from 0 to 36. Table 1 shows the outcome with mean and standard deviation. The statements have been here translated from the original Italian version.

SUS aims to rapidly measure people's subjective perception of the usability of a system [14]. It has ten statements based on a 5-point Likert scale. The user must assign a score to each. The score contribution of each item ranges from 0 to 4. It alternates positive and negative items to avoid response biases [14]. For the positively worded items, the score contribution is the scale position minus 1. For negatively worded items, the contribution is 5 minus the scale position. The sum of the scores is multiplied by 2.5 to obtain the overall value of SUS in a range of 0 to 100 [14].

However, in our experience, some elderly patients defined the SUS questionnaire as confusing [3]. Moreover, it gives a global index about the system's usability but does not provide specific indicators that could be used as input to improve the system further. For this reason, it has been decided to integrate it with the first questionnaire about HANDY.

Furthermore, the informal setup of the observational sessions combined with the think-aloud strategy allowed patients to express themselves freely, generating more impressions and suggestions than using just questionnaires.

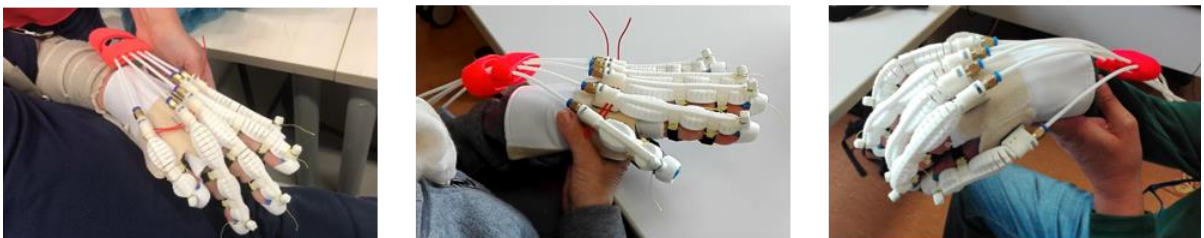


Figure 15: Photographs taken during the validation sessions with patients wearing HANDY.

5 RESULTS

Three patients (two male and one female) undergo the validation session (Figure 15). One has an ischaemic stroke in the chronic stage with left hemiplegia. Also, the second has an ischaemic stroke with left hemiplegia but in a sub-acute phase. The last had a concussion followed by a coma that caused right hemiparesis with MAS score equal to 2. It highlights that the system is not only for post-stroke. It is extensible to other diseases that involve the hand, such as concussion.

The second questionnaire is the SUS [13] translated in the Italian language (mother tongue of participants). Table 2 summarises the mean and standard deviation values based on the normalised scores obtained. The outcome from the SUS questionnaires was 72.50 ± 6.61 points out of 100. Using the adjective-based rating of the SUS proposed by Bangor, Kortum, and Miller in their article [8], the system obtained an overall "good" usability result.

	Statement	Likert scale (1:5)	Normal mean (0:4)	Std. Dev.
1	With the help of a caregiver, HANDY is worn quickly	4.33	3.33	0.58
2	The weight of HANDY on my hand is excessive	1.00	4.00	0.00
3	The HANDY backpack is comfortable	5.00	4.00	0.00
4	HANDY is very noisy	1.50	3.50	0.50
5	HANDY caused me discomfort or pain	1.00	4.00	0.00
6	I like the aesthetic aspect of HANDY	4.33	3.33	1.15
7	I think HANDY could help me improve	4.67	3.67	0.58
8	If I had access to the HANDY exoskeleton, I think I would use it	4.67	3.67	0.58
9	If I could use HANDY at home to do my exercises, I think I'd use it	5.00	4.00	0.00
	Sum		33.50	2.18

Table 1: HANDY's comfort and willingness to use questionnaire. Mean values ranges from 0 to 4 and negatively worded items have been normalized. HANDY obtained 33.50 / 36.

	Statement	Likert scale (1:5)	Normal mean (0:4)	Std. Dev.
1	I think that I would like to use this system frequently	4.67	3.67	0.58
2	I found the system unnecessarily complex	2.00	3.00	0.00
3	I thought the system was easy to use	4.33	3.33	0.58
4	I think that I would need the support of a technical person to be able to use this system	4.33	0.67	0.58
5	I found the various functions in this system were well integrated	4.00	3.00	0.00
6	I thought there was too much inconsistency in this system	1.00	4.00	0.00
7	I would imagine that most people would learn to use this system very quickly	4.33	3.33	0.58
8	I found the system very cumbersome to use	1.00	4.00	0.00
9	I felt very confident using the system	2.67	1.67	0.58

10	I needed to learn a lot of things before I could get going with this system	2.67	2.33	1.53
	Total = sum * 2.5		72.50	6.61

Table 2: SUS questionnaire results. Mean values range from 0 to 4, and negatively worded items have been normalized. The system obtained 72.50 / 100.

6 DISCUSSION

After the evaluation sessions, all participants assigned a high score to the comfort, lightweight of the device on the hand, and the rucksack's portability. People with a wheelchair could also use HANDY by fixing the backpack on the chair without any discomfort. They noticed the noise of actuators while moving, but it does not bother them. Two users appreciated the aspect of HANDY, while one person considers it irrelevant.

All showed interest and declared that they would use the system very willingly, both in the clinic and home. One user expected a greater ROM of the fingers. It can be understood considering the only-pull HANDY's configuration adopted during these initial tests combined with the flaccid state of the patient's hand. However, the other push-pull configuration of HANDY could overcome this aspect. None showed signs of pain or discomfort.

On the contrary, one user asked the present bioengineer if he could continue using it. Another was very surprised to see her hand move again after four months and said she didn't believe it anymore. These considerations are coherent with the results of the first questionnaire.

Analysing the SUS, we need to consider that two patients have little knowledge about interacting with computers, and none of them had ever seen the LMC before. Even though they showed enthusiasm, they agreed that the assistance of another person would be valuable. However, they also stated that the caregiver would not necessarily be a medical expert but a family member. The LMC was a complete novelty and, due to this, items 9 and 10 obtained a low rate. Nevertheless, they think that people could learn it quickly (item 6). Two of them managed to complete the ADL-based exercise. One could not finish it. The bioengineer who was present during the session explained that it was due to the patient's hemispatial neglect. It is a deficit in awareness about information perceived from one side of the field of view.

It is a preliminary qualitative evaluation of the system, and it would need a more exhaustive assessment with more participants. As future work in the short term, the follow-up will be performing a more extended and broader evaluation. Always in collaboration with the Villa Beretta rehabilitation centre, a higher number of participants will be involved to assess the system more frequently and for a longer period, at least five months.

However, the positive first outcomes obtained seem promising. According to some comments of therapists, HANDY includes several features implemented to address the users' necessities. Although still a prototype, HANDY was developed keeping security in mind. A rehabilitation device must guarantee the safety of its user. The control algorithm constantly monitors the force applied to the fingers and the electronic components at the firmware level. At the hardware level, the PCB strongly limits the presence of stray wires and improves system reliability. Besides, the emergency stop button provides a further level of protection for the patient. About the comfort, HANDY is extremely lightweight on the hand (only 190g), permitting repetitive rehabilitative exercises without fatigue. Its design avoids mechanical misalignment between the device and fingers and reduces skin abrasion, unlike some experimental and commercial devices (such as [53, 38, 36, 28]). The small backpack contains all components of HANDY, including a rechargeable power supply. It improves portability. HANDY is custom. It is composed of two subassemblies: the drive-control unit and the glove. While the former is standard for each patient, the latter can fit the individual user's hand. This solution is dictated by the fact that HANDY is designed for the home therapy of a single person. Concerning the economic aspect, it is hard to estimate the cost of a final product. However, the overall cost of the prototype was around €1000. Some comparable commercial devices significantly

exceed this amount and, if hypothetically HANDY will become a final product, costs could be further reduced compared to the single prototype.

Rehabilitative exercises are the core of the therapy. The developed application has three different levels of exercises: passive, active, and ADL-based. The integration of a rehabilitation device with this software could offer several advantages for both therapists and patients. Stroke symptoms vary among different persons, and even the same patient can move through different phases of the disease evolution, as highlighted by Brunnstrom [15]. The types and the customization of each exercise allow fitting the system with each specific requirement. Currently, most rehabilitative centres distinguish two different phases concerning the rehabilitation of patients: assessment and therapy. The first is performed at the beginning of the therapy and periodically to define and adjust the rehabilitation plan. The second includes all the activities that the patient does to improve her/his health condition. This methodology lacks in terms of treatment adaptability. The global system harvests data from the exoskeleton and the LMC. These can be used to track the patient's clinical evolution continuously during treatment. Compared to the state of the art, it can significantly improve the therapy's adaptability to the clinical evolution of the subject. If the exercises are monotonous, the user can discontinue the home therapy or even abandon it. The application endeavours to reduce this phenomenon by proposing two solutions. The use of the LMC gives the patient the possibility to control the exoskeleton naturally. It involves the patient's sense of agency and enhances the power of rehabilitation. The second is combining HANDY with serious-games based on activities of daily living. The cognitive aspects strengthen the efficacy of the activity. In the future, each rehabilitative movement could be surrounded by different environments and associated with other goals.

7 CONCLUSIONS

This work describes a rehabilitation system for the hand designed to assist post-stroke patients during their rehabilitative therapy towards regaining their autonomy. Improving hand capabilities permits performing activities of daily living and interact with the environment.

The system involves several innovative aspects designed keeping in mind the users' needs compared to the literature. Users are both patients and therapists. They have been actively consulted during the whole development process collaborating with the Villa Beretta rehabilitation centre. This collaboration allowed emphasizing some aspects overlooked in the literature during the development of a prototype.

The outcomes from the preliminary qualitative evaluation seem encouraging. Both patients and therapists showed interest and willingness to use the system. It can have multiple positive repercussions on the burden of the disease. With an active approach, the patient could be more motivated to continue the therapy compared to the traditional and passive methods currently used in clinics. It could also impact social and economic aspects, such as the cost for the patient and his/her family of healthcare and time off work, the government costs of healthcare. Finally, home-therapy allows medical professionals to address more patients' needs and monitor their progress compared to the individual patients' periodic visit.

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