UNIVERSITÀ
DEGLI STUDI
DI PADOVA

DIPARTIMENTO
DI INGEGNERIA
DELL'INFORMAZIONE

**DEPARTMENT OF INFORMATION ENGINEERING**

**MASTER'S DEGREE IN**
**BIOENGINEERING**

# "Feasibility Study and Development of Wearable Upper Limb Orthoses Using Shape Memory Alloy Actuators"


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**ACADEMIC YEAR 2024 – 2025.**

**Graduation date 26/11/2025**

SUMMARY

# ABSTRACT

Nowadays, one of the main challenges in the development of upper limb orthoses is to create devices that are lightweight, user-friendly, and functional for patients during their daily routines.

The principal aim of this project is to carry out a feasibility study and then design a hand orthosis that combines specific technical fabrics and shape memory alloy (SMA) actuators.

This idea is part of a larger project carried out in collaboration with Moveo, an Italian start-up that developed Exoband, a passive exoskeleton for lower limb, and SMArtEST, a company specializing in SMA actuators.

After the realization of the prototype, this work focuses on a test methodology to evaluate the main characteristics of the device, analyze the data, and compare them with other studies to establish the quality of this device and the possibilities for improvement.

The second part of this work concerns a prototype of a shoulder orthosis. In this case, my work focuses on two aspects: the integration of technical fabric into an already designed prototype and the draft of a method to test its comfort.

The final part of this work consists of the analysis of the data and the conclusions about these two prototypes.

# ABSTRACT

Al giorno d'oggi una delle sfide più importanti nello sviluppo di ortesi per arto superiore è quella di creare dispositivi che siano leggeri, intuitivi e funzionali per i pazienti, sia durante il processo riabilitativo sia nelle attività quotidiane.

L'obiettivo principale di questo progetto è studiare la fattibilità e successivamente progettare un'ortesi per mano che combini tessuti altamente specifici ad attuatori in lega a memoria di forma (SMA).

L'idea è parte di un progetto più ampio ed è stata sviluppata in collaborazione con Moveo, una startup italiana che ha sviluppato ExoBand, un esoscheletro per arti inferiori passivo, e un'altra azienda, SMArtEST, specializzata nella progettazione e produzione degli attuatori in SMA.

Dopo aver progettato e realizzato il prototipo, il lavoro si è concentrato sulla concretizzazione di una metodologia di test con lo scopo di valutare le caratteristiche del dispositivo e, analizzando i dati e comparandoli con altri studi, stabilire la qualità del dispositivo realizzato e i suoi sviluppi futuri.

La seconda parte di questo lavoro, si riferisce alla prototipazione di un'ortesi per spalla.

In questo caso ci si è concentrati su due aspetti: l'integrazione di tessuti tecnici su un prototipo già progettato e la successiva valutazione dei suoi aspetti di indossabilità e comfort.

La parte finale di tale progetto consiste nell'analisi dei dati ottenuti dai test ed espone le conclusioni raggiunte al termine di questi processi di sviluppo di ortesi, oltre che valutare aspetti futuri migliorativi.

# LIST of ABBREVATIONS

WHO= World Health Organization

SMA= Shape Memory Alloy

CMC=Carpometacarpal joint

MCP = Metacarpophalangeal joint

PIP = Proximal interphalangeal joint

DIP =Distal interphalangeal joint

CRS= Comfort Rating Scales

UEQ=User Experience Questionnaire

VAS=Visual Analogue Scale

T= Torque

F= Force

D= Distance

$T_a$= Torque Active

$T_r$ = Torque resistive.

# CHAPTER 1
# INTRODUCTION and AIM OF THE THESIS

## Project context

The thesis project presented here is part of a broader research project, entitled: "SMART materials-based solutions for Soft Wearable robots", included within the "AGE_IT" project, specifically within spoke 9 "Advanced gerontechnologies for active and healthy ageing".
AGE-IT is a national-level research programme that aims to make Italy a scientific hub for ageing studies, as well as an empirical laboratory for studying population ageing [1]. Age-IT involves universities, research bodies, and businesses to develop this topic across 10 different areas, known as spokes.

To explain the rationale behind this project, it is useful to provide some contextual data.
According to European studies, it is estimated that the portion of the population over 65 years of age will increase from 17.1% in 2008 to 30% in 2060, and that the portion of people over 80 years of age will increase from 4.4% to 12.1% in the same period (EUROSTAT demographic projections).
Neurological conditions, as we will see in Chapter 2, especially stroke, are the main cause of disability among the elderly. The incidence of a first stroke in Europe is approximately 1.1 million, and the prevalence is approximately 6 million. Currently, about 75% of stroke-affected subjects recover within one year; about 40% of stroke patients with neurological conditions are unable to perform daily activities.

By 2060, the number of elderly people will equal that of workers, which shows that the demand for caregivers, as currently projected by healthcare strategies, cannot be met in the future. Furthermore, the "Rehabilitation 2030" initiative, promoted by the WHO, draws attention to the importance of strengthening national health systems to provide rehabilitation services [2].
In this context, the need to develop tools that can ensure a good quality of life for the elderly and their autonomy in their own social environments, while simultaneously providing the necessary medical assistance without a human presence, becomes evident. In other words, it is essential to make the rehabilitation process as simple and convenient as possible to reduce the intervention of clinical staff, who will no longer be sufficient to cover all demands.

The focus of this project is to guarantee, in addition to the aforementioned, assurances of personalization, comfort, and lightness.
A device of this type will therefore be usable by a wide range of patients and will be perceived as safe, comfortable, and adaptable to different levels of assistance.

## 1.2 Companies involved

The research project, carried out by two companies, 2SMArtEST and MOVEO, therefore aims to design and create wearable and flexible devices for the upper and lower limbs. These devices will be produced using highly technical materials integrated with actuation systems and sensors.
These exoskeletons, compared to traditional ones already on the market, must also ensure greater lightness, comfort, and adaptability. To pursue this goal, the devices will be made active through actuators composed of Shape Memory Alloys (SMAs). These materials, in fact, allow for continuous and distributed actuation, induced by temperature variation.
The work presented in this paper specifically concerns the conception and creation of prototypes of orthoses for the upper limb, for the hand and shoulder, and was carried out during an internship at MOVEO, a Padua-based startup that we will mention below.
As mentioned, two companies are involved: 2SMArtEST and Moveo.
The company 2SMArtEST, a spin-off startup from the University of Calabria, was founded in 2019. Its main activity consists of developing solutions that use shape memory alloy technology in various industrial sectors [3]. In this project, it is responsible for the conception, creation, and validation of the actuation systems for the designed orthoses.
A more in-depth focus is dedicated in the next section to Moveo, the company where I had the opportunity to work during my internship and which I was able to get to know in greater detail.


**Figure 1 Moveo and 2SMArtEST logo**

## 1.3 MOVEO srl

Moveo srl is an innovative startup founded in 2019 by a former researcher at the Biodesign Lab of Harvard University.

Moveo's main activity consists of the development and sale of wearable medical devices that increase the autonomy, independence, and quality of life of children and adults with walking difficulties. The first device developed by Moveo Srl is ExoBand: a passive, lightweight, and adjustable exoskeleton. The device uses an elastomeric material that "stores" the energy generated by the hip extensor muscles during ambulation and uses it to assist movement, allowing the user to walk further, faster, and more comfortably. This translates into greater trunk stability, a lower risk of falls, improved balance, and increased distance covered. Other noted improvements include enhancement of pendulum-like upper limb movements, posture, and a reduction in foot slippage during ambulation.

The technology is patent-protected, certified as a Class I medical device by the Italian Ministry of Health, and approved for reimbursement in Italy as a rehabilitation product. In 2024, ExoBand received FDA approval for commercialization in the USA [4].

**Figure 2 ExoBand**

## 1.4 Structure of the thesis

The structure of this thesis follows the work process used for the development project of the upper limb orthoses and develops in a parallel manner.

Chapters 2, 3, and 4 will delve into the conception and development of the device for the hand. Starting from an initial analysis of the state of the art and clinical needs, the section concerning the design and implementation of the prototype will then be addressed, and it will conclude with an in-depth analysis of the tests performed and the results obtained.

Chapters 5 and 6 follow the structure of the three preceding chapters in a parallel manner but concern the development of an orthosis for the shoulder. Chapter 5 will explore the clinical part and the design part, while the tests conducted and the results obtained are presented in Chapter 6.

Chapter 7 closes the paper by showing the conclusions reached, future developments, and lessons learnt.

## 1.5 Aims of the study

The objectives of this study can be divided according to the two different orthoses.

Regarding the hand orthosis, the objective is to study the feasibility of a device that combines highly technical fabrics with shape memory alloy actuators, while also evaluating its functionality and efficiency.

As for the shoulder orthosis, the goal is simply to study an innovative, lightweight, and compact design, and to evaluate its comfort and wearability. This is done with the aim of subsequently evaluating its efficiency and functionality by activating specific actuators designed specifically for this device.

# CHAPTER 2
# BIOMECHANICS of the HAND and STATE of ART

## 2.1 Anatomy of the hand

To be able to design a truly functional orthosis that can replicate natural movements as naturally as possible, it is important to analyse how the biomechanics of the hand and its anatomy function, which parts are involved, and what forces are at play [5].

The hand is one of the most complex structures in the human body, involving 29 bones and several joints. We can divide it into three parts:

- wrist;
- palm;
- fingers;

The wrist part involves 8 carpal bones distinct in two rows, each of 4 bones. From the radial to the ulnar side, we find the proximal row composed of scaphoid, lunate, triquetrum, and pisiform. The distal row is instead composed of trapezium, trapezoid, capitate, and hamate. These two rows form a structure that is not coplanar but forms a convex arch on the proximal side. In this position, there is a fibrous structure called the transverse carpal ligament, which transforms this area into what is called " the carpal tunnel ".

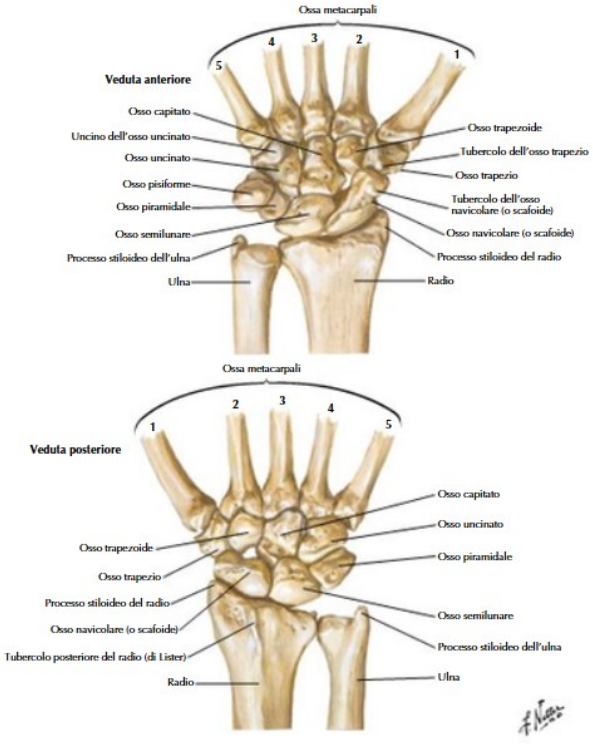


**Figure 3 details of wrist and palm**

Observing the surface of this structure, two bony tubercles can be noted: one of the scaphoid and one of the trapezium, both palpable on the radial side. On the other side, the ulnar side, the prominence of the pisiform and the hamate can be appreciated.
The transverse carpal ligament inserts onto these prominences. This ligament transforms this structure into a canal, inside which important tendinous structures pass, starting from the forearm and reaching the phalanges of the fingers.
The aforementioned tendinous structures refer to the tendons of the flexor digitorum superficialis and profundus muscles. It should be remembered that in this passage, the tendons are covered by a synovial sheath. If inflamed, this gives rise to carpal tunnel syndrome.

Moving on to analyse the palm area, here we find 5 metacarpal bones, which are long bones, each having a base, a body, and a head. On the palm side, they present a slight concavity, whilst on the dorsum (back), they are convex. At their base, they present the joints and articular facets for the carpus, whilst at the head, they present the surfaces for the joints with the proximal phalanges.

Let us now speak of the most distal part of the hand: the fingers. From the second to the fifth, they are composed of three phalanges defined as distal, middle, and proximal. The exception is represented by the thumb, which instead is composed of only two phalanges, lacking the middle one. All phalanges are composed of a base, a body, and a distal head.

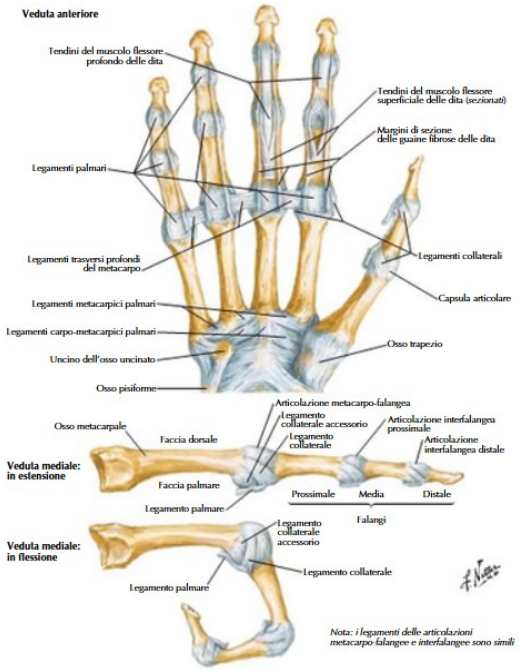


**Figure 4 details of fingers.**

Briefly mentioning the musculature, it is important to remember that the most important muscle groups for finger and wrist flexion are located in the forearm and are divided into two layers: a deep layer and a superficial layer. Here we find, for example, the flexor digitorum muscle, the flexor carpi ulnaris, and the flexor carpi radialis. We then find groups located laterally and posteriorly, also divided into deep and superficial layers, which have an extensor function. For example: extensor digitorum, extensor carpi ulnaris, and radial and carpi extensors.

In the palm and finger area, we then find several joints. In the carpus area, we find the radiocarpal joint: a joint formed by the radius and the proximal row of carpal bones. Not all bones of the row are involved. It permits wrist flexion and extension movements. Between the carpal and metacarpal bones, we find 5 joints called carpometacarpal (CMC) joints: the only one with a good range of motion is the one involving the thumb. This joint indeed allows flexion, extension, abduction, and adduction, as well as circumduction and "opposition". The other CMCs are instead much more limited.
At the base of the proximal phalanges, we find instead the metacarpophalangeal joints, which have the same range of movement as the carpometacarpal joint of the thumb. The most interesting joints for the project presented here are those between the phalanges, which take the name of interphalangeal joints: the thumb has only one, the other fingers have two: one between the proximal and middle phalanx, one between the middle and proximal one.

## 2.2 Kinetics of the hand

In kinetic terms, the hand is a chain of joints starting from the wrist and ending at the fingers. It is an open kinetic chain composed of 19 movable parts (bones) and 24 degrees of freedom represented by the joints. We can consider the joints as kinematic pairs of different classes. We recall that class III indicates 3 degrees of freedom, class IV indicates 2 degrees of freedom, and class V indicates 1 single degree of freedom [5].

Thanks to the various joints and muscles involved, as well as the size of the cerebral cortex area responsible for motor and sensory control of the hand, it is possible to perform a series of very complex movements necessary for daily activities.

Schlesinger was among the first to study and categorize the different types of grasps in 1919.

He organized the different grasps into 6 distinct types: the cylindrical grasp, the precision or tip grasp, the hook (or snap) grasp, the palmar grasp (also known as the opposition grasp), the spherical grasp, and the lateral (or key) grasp, as shown in Fig.5.

The types of grasps were later expanded and categorized differently. However, even today, the six types of grasps identified by Schlesinger remain valid for testing the efficiency and functionality of new medical devices.

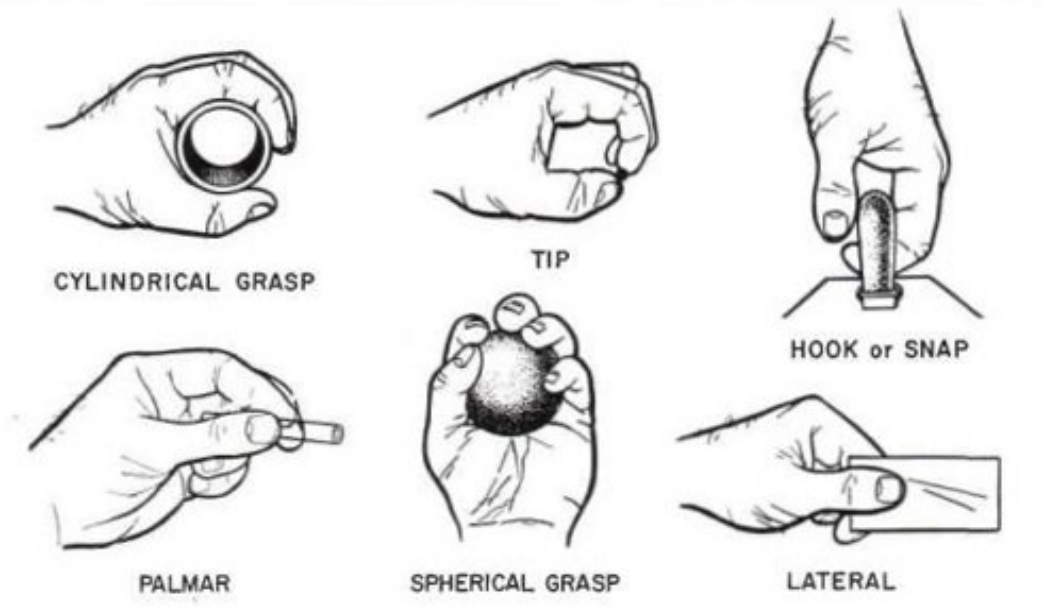


**Figure 5 Types of grasp [5].**

The various grasps and movements are possible thanks to the combinations of the various joints involved, from the carpus to the distal phalanx.

| Finger | Flexion | Extension | Abduction/adduction |
|---|---|---|---|
| **Thumb** | | | |
| Trapeziometacarpal | 50° - 90° | 15° | 45° - 60° |
| Metacarpophalangeal(MCM) | 75° - 80° | 0° | 0° |
| Interphalangeal (IP) | 75° - 80° | 5° - 10° | 0° |
| **Index** | | | |
| Carpometacarpal (CMC) | 5° | 0° | 0° |
| MCP | 90° | 30° - 40° | 60° |
| Proximal interphalangeal (PIP) | 110° | 0° | 0° |
| Distal interphalangeal (DIP) | 80° - 90° | 5° | 0° |
| **Middle** | | | |
| CMC | 5° | 0° | 0° |
| MCP | 90° | 30° - 40° | 45° |
| PIP | 110° | 0° | 0° |
| DIP | 80° - 90° | 5° | 0° |
| **Ring** | | | |
| CMC | 10° | 0° | 0° |
| MCP | 90° | 30° - 40° | 45° |
| PIP | 120° | 0° | 0° |
| DIP | 80° - 90° | 5° | 0° |
| **Little** | | | |
| CMC | 15° | 0° | 0° |
| MCP | 90° | 30° - 40° | 50° |
| PIP | 135° | 0° | 0° |
| DIP | 90° | 5° | 0° |

**Figure 6 Range of motion of finger joints ( angles express in degrees) [5].**

Figure 6 shows the summary table of the range of motion of the various joints [5].
It may be useful during the data analysis phase for the new device, as it will allow evaluation of the excursion achieved by the orthosis thanks to the actuators, compared to the maximum physiologically possible angular excursion.

## 2.3 Impairment from neuropathologies

So far, we have analyzed the anatomy and biomechanics in a physiological case. Due to accidents or pathologies, these values can undergo notable variations and compromise the mobility of the upper limb.

The independence and quality of life of people affected by upper limb dysfunctions caused by neurological diseases are compromised by episodes of motor, sensory, or functional deficit, depending on the pathology.

These problems have a significant impact on all those activities that are part of daily life (ADLs). Very often, these pathological subjects show a sort of motor clumsiness caused by phenomena of weakness, spasticity, and tremors. It is therefore necessary to resort to customised therapeutic strategies, which also involve orthoses that will be listed later, in addition to pharmacological approaches or those using brain-computer interfaces (BCI). We will now detail the different and most common neurological pathologies[6].

### 2.3.1 Upper limb impairment induced by stroke

Stroke represents one of the main causes of upper limb dysfunction: 80% of survivors present hemiparesis characterized by loss of dexterity on one side of the body and weakness. Very often, this motor deficit is caused by damage in the corticospinal tract, which damages voluntary motor control. This causes muscle weakness and spasticity. Other motor deficits include a reduction in strength, altered "fraction ability" of movement, and an anomalous muscle co-activation pattern, which often leads to inefficient and compensatory movement strategies. Spasticity is caused by the loss of supraspinal inhibitory control: this causes muscle hypertonia, painful contractures of the flexor muscles (in the elbow, wrist, and fingers), and diffuse muscle stiffness. In other words, the subject is unable to open the hand [7].

### 2.3.2 Upper limb impairment induced by multiple sclerosis

Multiple sclerosis is an autoimmune disease that affects the central nervous system, causing progressive motor and sensory deterioration. About 40% of patients are affected by upper limb impairment in terms of coordination and motor control. Patients also present weakness and spasticity. This symptom mostly affects the flexor muscles of the elbow and wrist, limiting the ability to grasp objects[8].

### 2.3.3 Upper limb impairment induced by Parkinson's Disease (PD)

Parkinson's disease (PD) is characterized by the progressive degeneration of dopaminergic neurons in the basal ganglia, leading to bradykinesia, rigidity, and resting tremors. These symptoms severely compromise upper limb function:

- Bradykinesia means slowness of movement, whilst rigidity increases resistance to passive movement, reducing coordination and making it difficult to initiate voluntary movements.
- Tremors: Resting tremors (4-6 Hz) often affect the hands, interfering with fine tasks such as buttoning clothes or writing.
- Freezing of movement: Upper limb akinesia can cause sudden stops in movement.

### 2.3.4 Upper limb impairment caused by cerebral palsy

Cerebral palsy (CP) and upper limb dysfunction. CP results from an early brain lesion that affects motor control and coordination. Upper limb deficits vary based on the type of CP:

- Spastic CP: Increased muscle tone makes voluntary arm movement and fine motor skills difficult.
- Dyskinetic CP: Involuntary movements (dystonia, athetosis) hinder the controlled use of the hand.
- Ataxic CP: Poor balance and coordination affect reaching and grasping movements.

## 2.4 Classifications of orthoses for the upper limb

It is important to observe the upper limb devices already present on the market or in advanced development phases, in order to draw inspiration for the design of a new orthosis, avoid certain errors, and implement improved solutions compared to what already exists.

In this section, the main devices currently available will therefore be presented.

They will be catalogued based on their power source: devices powered electrically, through pneumatic force, or through shape memory alloy materials. Each actuation method has its pros and cons.

Speaking of electrically powered orthoses, these are orthoses with a high degree of precision and control, but which require considerable energy expenditure to be activated.

Orthoses with pneumatic force actuators allow very high loads to be exerted but are often bulky.

Orthoses with SMA actuators therefore represent a new possibility today in the world of medical devices: they allow precise movements to be produced with little energy and little bulk.

It should be specified that the cataloguing done here is not the only one possible: in other texts or documents, orthoses may be catalogued according to their purpose, distinguishing those used during rehabilitation from those used during normal daily activities.

### 2.4.1 Orthoses with electric actuation

MyoPro Orthosis [10]

This is an electrically powered exoskeleton for the upper limb.

It weighs approximately 2 kg, and its price is not clearly defined but it could be in the tens of thousands of euros, like its competitors.

It works by using the neuromuscular signals produced by the patient which, once amplified, activate electric motors for muscle movement. It is therefore composed of electromyographic sensors, electric motors, and a very lightweight fabric structure. It ensures 3 degrees of freedom and the possibility of performing elbow flexion/extension movements, forearm pronation-supination, wrist flexion/extension, and assisting the fingers in grasping and manipulating objects.


**Figure 7 Myo Pro**

IronHand [11]

This is a hand orthosis designed to be worn for long periods, reducing fatigue due to repetitive daily activities and increasing grip strength.

It weighs approximately 2 kg and its price is around 10,000 euros.

It is composed of an interface capable of detecting the user's movements and intention, force and pressure sensors integrated into the hand, and electric motors.

It ensures several degrees of freedom and allows finger flexion and extension movements and thumb abduction and adduction.

**Figure 8 IronHand**

ExoGlove Poly [12]

This device is made of polymeric material and aims to help patients recover hand functionality. It uses external actuators which, in combination with cables that replicate the position of human tendons, allow the patient to recreate natural finger movements.

Each finger is controlled by two artificial tendons: the electric motor, by shortening the length of these cables, allows flexion and extension movements and recreates the necessary tension to hold the grasped object in position.

The strong point of this device is clearly its lightness and comfort.

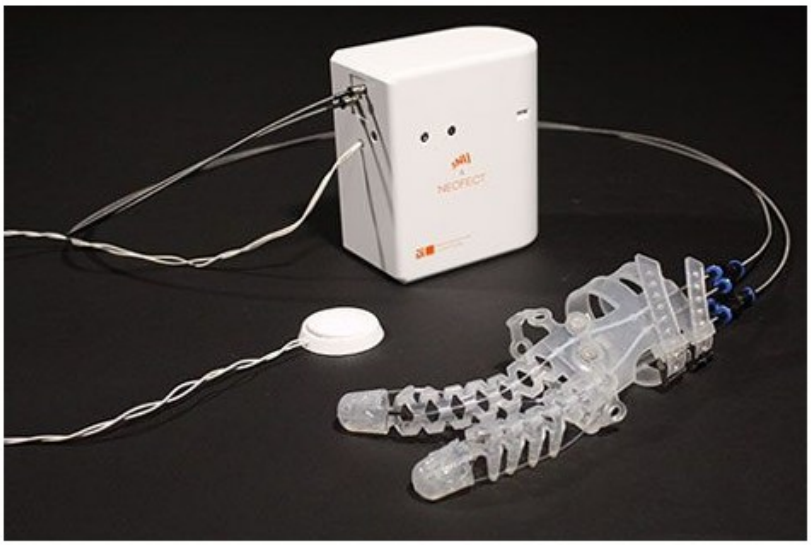

**Figure 9 ExoGlove Poly**

### 2.4.2 Orthoses with pneumatic actuation

Exo-glove PM [13]

This is a device designed to support people with motor difficulties in the hand. It can be highly customised as it is created in modules that can be assembled, which is certainly one of its strong points. Its main purpose is to improve the ability to grasp and manipulate objects, especially during daily activities. The finger actuation system is divided into four different actuators, corresponding to the various interphalangeal joints, plus one actuator for the carpometacarpal joint.

It generates very high forces: the smallest actuator, h=8 mm, can hold a 1.1 kg cylindrical object in position.

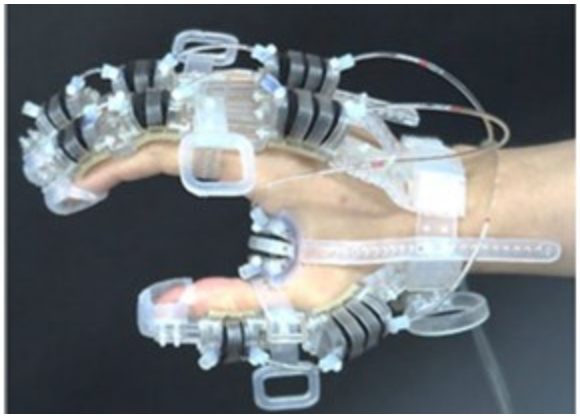

**Figure 10 Exo-glove PM**

PNEU-WREX [14]

This is a pneumatically actuated exoskeleton designed for arm and hand rehabilitation. It uses pneumatic compression systems, "pneumatic muscles" that create a compression effect through compressed air and passive extension via a spring. It features 5 degrees of freedom for shoulder, elbow, and wrist movement.

### 2.4.3 Orthoses with SMA actuation

Compared to the devices presented so far, the category of exoskeletons made with shape memory alloy (SMA) offer several advantages. In fact, they are lighter, have a reduced volume, and can generate high force despite having a very compact design. These aspects lead to a clear improvement in comfort for the user and allow for natural movements. Most of the prototypes used so far are wearable: being very compact and light, the hypothesis of bench-top or hybrid orthoses is not considered. The actuators are activated and controlled, for the most part, by a microcontroller.

Elbow Exoskeleton [15]

The structure of this device is largely composed of SMA springs and wires, with the integration of some 3D printed parts. To isolate the shape memory alloy parts, which can reach temperatures of 150°C during their operation, a PTFE tube is used, which lowers the sheath-skin contact temperature to 25°C. It is an actuator that supports elbow movement. To allow for extension and flexion movement, a pulley is inserted that transforms the linear motion of the actuators into rotational motion. It can generate a torque on the elbow of up to 10.62 Nm.

Flexible prosthetic [16]

This prosthesis emulates the behaviour of a wrist. It is composed of SMA wires and springs that emulate the role of the muscles involved in the movements of the muscle. This device, weighing 50 grams, was assembled with a robotic hand and forearm. The entire prosthesis reaches a weight of 400 grams and is capable of offering exceptional flexibility thanks to the return force of the SMA actuators. It has been subjected to load and stress tests, showing excellent results.

GLOVE-SSCS [17]

A further rehabilitation device, more similar to what is intended to be designed with this project.

It is a glove composed of a composite structure. We have a first external, active layer, consisting of SMA springs that provide the motive force for flexion and extension.

Then there are: a manganese layer that converts the axial movement of the springs into a flexion and extension movement, a layer consisting of a flexion sensor, and a nylon layer in contact with the skin.

For the flexion movement, a single SMA spring is used, whilst for the extension movement, two are used.

This is because the extension movement requires a greater SMA spring length than flexion. This device can allow movements in two directions: the flexion range is 90-110°, that of extension is 30-40°. The glove temperature oscillates between 35 and 67°C, while the surface temperature is between 32 and 36°C.

The current used in the two movements is 3A, with a voltage between 5V and 7V.

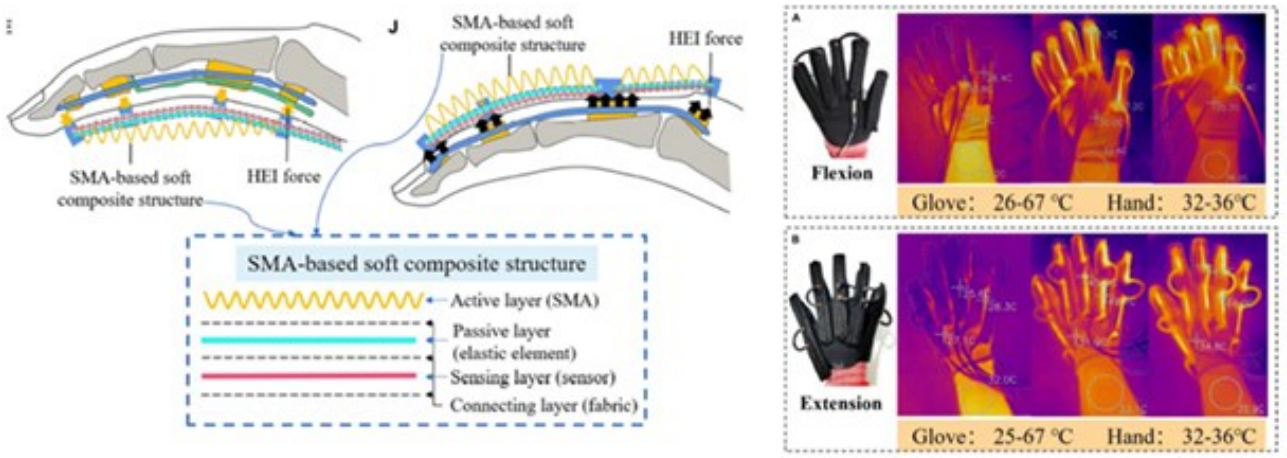


**Figure 11 Glove SSCS: layer and temperature**

## 2.5 Differences between SMA actuation systems

The project requires the use of alloys composed of smart materials as the actuation system for the upper limb orthosis. Considering this, it is necessary to mention the two different configurations of these actuation systems: SMA wire systems and SMA spring systems.

### 2.5.1 Actuation with SMA wires

Shape memory wires are very thin filaments of alloy that change their length based on their temperature. The underlying principle is the phase transition from martensitic to austenitic. When the wire is heated, using electric current, the temperature reaches the austenitic transformation threshold, causing the wire to contract, normally by 4-8%. This contraction generates a force that can be exploited to create movement.

Once the wire cools, it returns to its original length and allows the cycle to be repeated. A fundamental parameter is the size of the wires: a thicker wire is able to generate greater force but requires more time to heat up (and subsequently to cool down): this reduces the response speed. Analysing the energy density, in SMA wires it is very high: they allow a significant force to be generated in a very small space.

The negative side of this configuration is represented by the thermal efficiency, which is very low, about 10-15%, and depends on both the electrical resistance and the speed of dissipation during cooling. Furthermore, SMA wires can degrade after repeated thermal cycles, leading to a progressive reduction in the force generated and the ability to recover the original shape.

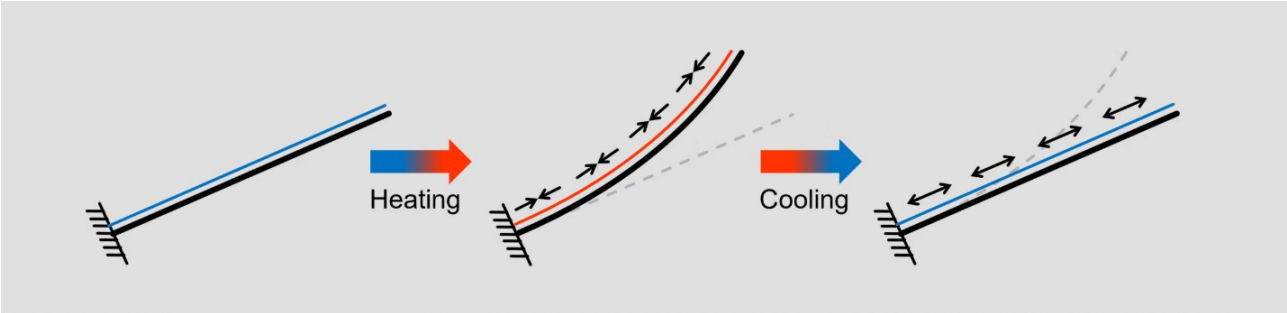


**Figure 12 Example of SMA wires actuators: this is the model used in our hand device**

### 2.5.2 Actuation with SMA springs.

The operating principle is the same as SMA wires; what changes is the configuration into a helical or spiral structure, which allows elastic energy to be stored more efficiently. This structure allows for more complex movements such as compression and torsion which, in the case of use in exoskeletons, translates into angular or rotational movements. The spiral structure of the spring allows the movement produced by the phase transition to be amplified, generating rotation or compression. For this reason, they are considered more efficient than wires in terms of stored energy. This configuration also finds its limit in heat dissipation, like SMA wires. SMA springs are particularly appreciated for applications where significant rotational movement or torsional force is required.

| Characteristics | SMA Wires | SMA Springs |
|---|---|---|
| Force | High | Moderate |
| Deformation | 4%-8% | > 10% |
| Response time | Fast | Slow |
| Energy efficiency | Medium | Low |
| Compactness | Very compact | Less compact |
| Applications | Small and precise movements | Large and fluid movements |

**Figure 13 Summary table of two different SMA configuration systems**

In conclusion, as shown in the summary table, both solutions can be well adapted for use in exoskeletons. The choice of the best technology to use must be made by evaluating the movement required by the actuators, the available space to insert them, and the energy efficiency.
A very compact device must have an equally compact power supply system. On the other hand, for a device designed for wide movements requiring high force, the compactness criterion is not as fundamental as that of energy efficiency.

# CHAPTER 3

# DESIGN AND IMPLEMENTATION OF A HAND ORTHOSIS PROTOTYPE

## 3.1 Introduction

After analyzing the characteristics of other devices and the problems encountered in pathological subjects, the focus shifted to the conception and design of a new hand orthosis prototype, combining the know-how of MOVEO and 2SMArtEST in their respective fields.
The project was divided into the following work phases:

- conceptual phase;
- choice of material;
- Integration with fabric and first prototype;
- experimental phase and adjustments;
- final prototype.

## 3.2 Conceptual phase

A study was undertaken to determine which configuration might be the most suitable to satisfy all those activities required during rehabilitation, such as the different grasps of various objects seen in Chapter 2, and which configuration was also the most functional in biomechanical terms; that is, the method that was as similar as possible to the natural behaviour of the hand and therefore most useful for a pathological subject in a rehabilitation setting.

The first idea involved positioning the actuators on the dorsum (back) of the fingers, with the necessary wiring for power running over the dorsum. In this way, the palm remained free of encumbrance, and there was no risk of damaging, touching, or compromising the actuators during grasping exercises. In other words, the actuator in this position guaranteed support without becoming an obstacle.

This configuration also had biomechanical motivations: based on what was seen in the previous chapter, in patients with neurological pathologies, the movement that is often most complex is extension: many subjects present a closed limb and have difficulty opening it. Having external support from the actuators to favor this movement seemed the best decision to take.

Regarding the ease of wearing, a hypothetical velcro strap to be positioned at the wrist level was also considered. This opening would allow the glove to be worn more easily and also to be adjusted.

Another evaluation was made regarding the fit: the doubt was whether to create a glove that completely covered the hand or whether to remove pieces of fabric in places where it was not necessary, for example, on the palm and the underside of the fingers. This approach would leave the patient with a greater sensation of freedom and would result in a decidedly lighter device.

The final aspect concerned the finger's return movement: extension was achieved thanks to the actuator, but a system also needed to be devised to ensure a flexion movement when the actuators were off. After carrying out some evaluations, an elastic component was considered, and it was decided to keep this aspect on stand-by until we had obtained an effective sizing of the actuators.
After this initial design phase, we moved on to a phase of studying the components: both the technical materials and the actuators.

**Figure 14 3D rendering of the back of the hand with hypothetical SMA actuators**

## 3.3 Choice of material

Evaluating what was reported in the literature and what was requested by the project client, the important specifications were the following:

- **Easily wearable**: it must be easy to put on for all those patients who show difficulty in moving their hand;
- **Lightness**: as it is a wearable orthosis and is being developed to be worn during rehabilitation, and therefore for potentially long consecutive periods, a fundamental aspect is its weight, which must be reduced to a minimum.
- **Safety**: the chosen fabric must firstly guarantee comfort and protection from the heat generated by the actuators, and secondly, it must be non-toxic, non-allergenic, and must not cause skin irritation.

For reasons linked to the project timeline and to simplify the manufacturing processes, it was immediately decided to choose gloves already produced on the market, ranging from very different uses (work gloves, gardening, diving, snow).

There was a period of collecting models, followed by a more in-depth analysis of the technical characteristics of the fabric, considering that it was fundamental for the project that this material possessed the following specifications:

- Easily workable to make modifications and integrate with the actuators;
- Resistant to working temperature;
- Resistant to wear and multiple cycles of exercise;
- Soft, so as not to create a sensation of discomfort for the user;
- Non-toxic, cytocompatible, non-allergenic.

Of the various materials previously selected, three were evaluated: a Polyester glove, a Kevlar glove, and a Neoprene glove.

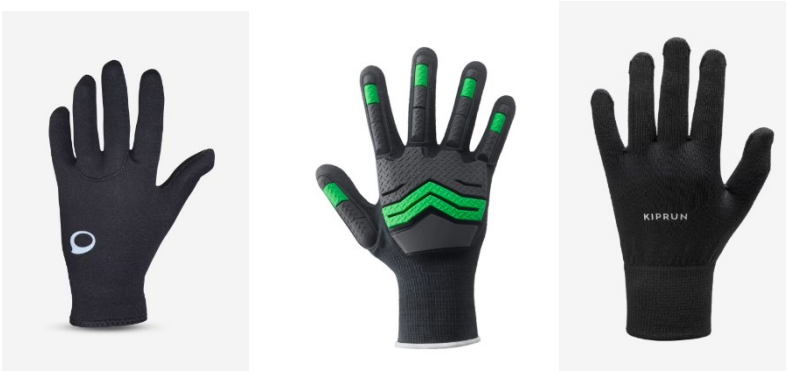


**Figure 15 3 different glove models**

Kevlar, a high-performance textile fibre, is distinguished by its exceptional mechanical resistance, particularly its very high resistance to traction, cutting, and perforation. This property makes it a highly effective reinforcement against extreme mechanical wear. On the thermal front, Kevlar demonstrates exceptional heat resistance, maintaining its structural integrity and not melting until decomposition temperatures of around 450°C. However, as a fibrous and intrinsically rigid material, its flexibility and elasticity are significantly lower than those of an elastomer.

Neoprene, classified as an elastomer, offers mechanical properties that include good resistance to wear, abrasion, and tearing, making it durable. In terms of comfort, this material is very flexible and elastic, maintaining these characteristics even at low temperatures. Regarding thermal resistance, Neoprene exhibits good stability with a typical operating range up to approximately +120°C, and it does not melt, also showing self-extinguishing properties. Its cellular form (foam) is commonly used to provide effective thermal insulation.

Polyester, as a synthetic fibre (PET) used in the textile field, presents a combination of lightness and good mechanical properties. In terms of comfort and flexibility, it is appreciated for its lightness, moderate elasticity, and ability to dry quickly, contributing to a pleasant sensation on the skin. Regarding wear resistance, Polyester demonstrates good resistance to abrasion and tearing (often improved with a PU or Nitrile coating) and is known for its dimensional stability. On the thermal front, it has a high melting point, over 250°C, but it is sensitive to heat and can soften or shrink if exposed to excessive temperatures. Furthermore, Polyester fabric offers variable thermal insulation capacity.

### 3.3.1 Final considerations on the material

The comparison between the materials highlighted that none of them individually satisfied all the project criteria, making it necessary to evaluate the best compromise between comfort, thermal resistance, and wear resistance:

- Kevlar proved to be the most resistant material to high temperatures and the most robust against wear. However, the selected model in pure Kevlar was too rigid (an intrinsic characteristic of high-strength fibres). This rigidity compromised the necessary dexterity and flexibility, proving incompatible with the project for its primary use.
- The polyester glove showed a good sensation of comfort and lightness, typical of synthetic fabrics. On the other hand, this lightness could not guarantee sufficient thermal insulation and good resistance to wear in demanding environments, compromising durability.
- It was therefore decided to use a Neoprene glove, which offered an excellent compromise between all the requirements. The elastomer guarantees the flexibility and softness necessary for comfort, while its 2mm thickness ensured good thermal insulation (thanks to its cellular structure) without significantly compromising softness and the sensation of lightness (compared, for example, to greater thicknesses or a rigid Kevlar glove).

## 3.4 Evaluations of the actuators provided by the partner company

After the theoretical evaluations and the choice of the most suitable glove model and having obtained the actuators provided by the partner company, the experimental phase began.

The actuators had power cables that ran over the base containing the shape memory alloy.

This configuration proved to be dysfunctional, as the curvature of the actuator obstructed the cable's path. It was therefore necessary to undo the solder joints, reverse the wire's position, and solder again.

Subsequently, the actuators were operated according to the technical instructions, in order to evaluate the inclination range and compatibility with the positioning hypotheses previously discussed.

The actuator model used is the "Curve plugged 3910E10" [18] with the following physical characteristics:

- Active length: 39 mm;
- Total dimensions: 59 mm x 10 mm x 1.8 mm;
- Total weight: 1.2 g

Speaking of the activation properties:

- Resistance: 0.4 Ohm;
- Necessary current and relative activation time:
    - 3 A for 15 s;
    - 4 A for 4 s;
    - 5 A for 1.3 s;
    -

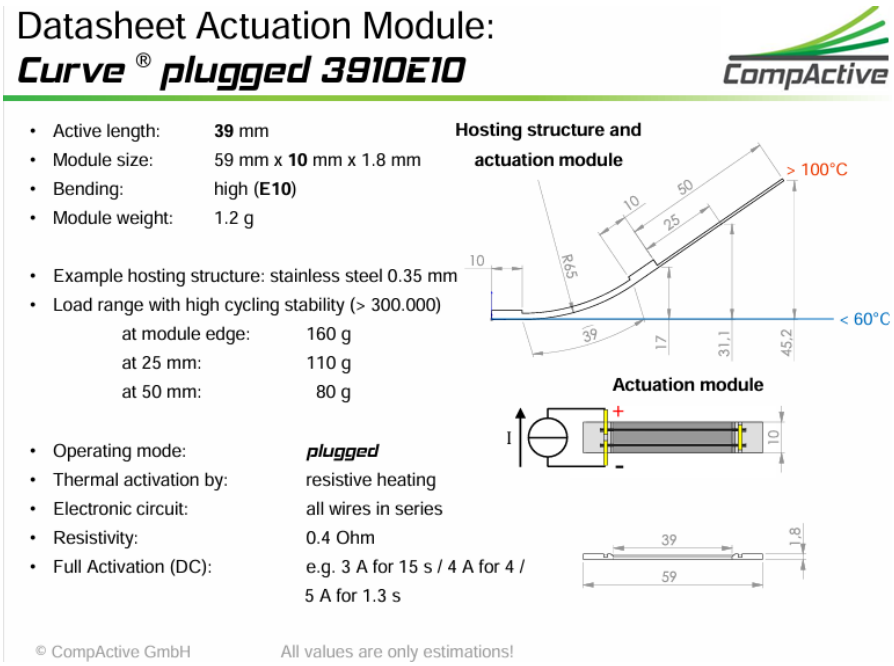


**Figure 16 Actuator datasheet**

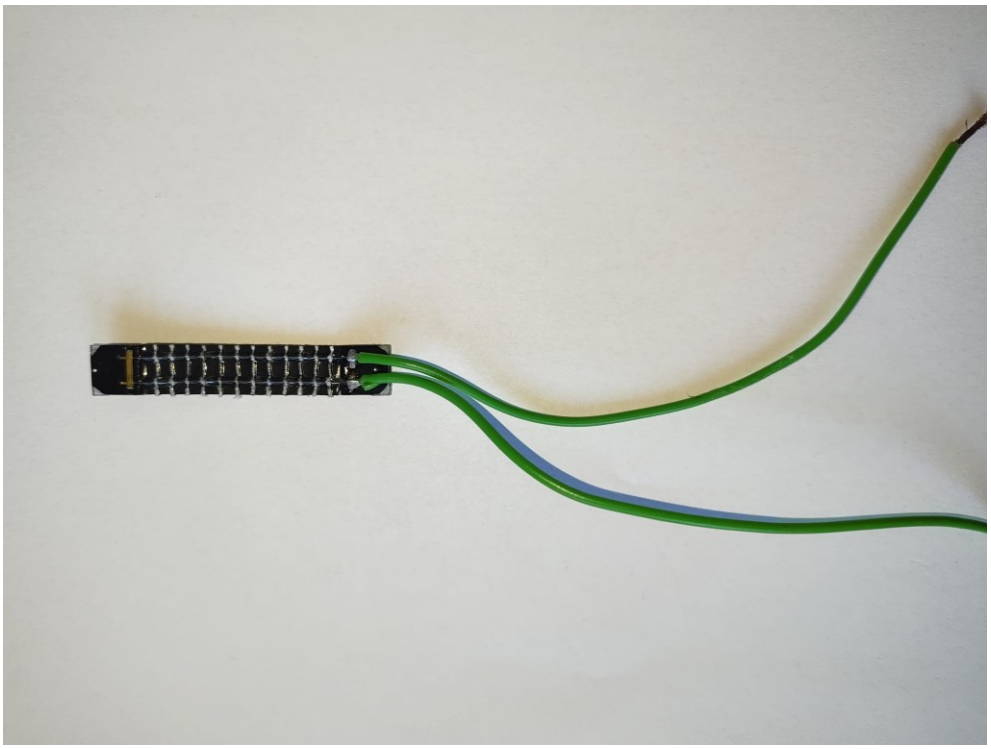

**Figure 17 Actuator Curve plugged 3910E10**

Following these parameters, an initial activation test was performed, simply by heating the SMA with a heat gun and consequently modifying the crystalline phase of the shape memory alloy. The test was then repeated once the actuator-glove integration was established, to evaluate any changes in the times and angles achieved.

From the very first test, it was observed that the actuator's curvature was good but that the actuator exhibited a convex activation and not a concave one.

At this point, it was necessary to revise the configuration initially conceived and consider a different position for the actuators on the glove.

The only viable solution was to insert the actuators inside the fingers, with the power cable running through the palm instead of the back of the hand.

This choice immediately raised some concerns, as the presence of both the actuator and the cable in that position made the gripping exercises less comfortable and less secure.

There was a risk that the actuators could move and that the grip of objects, intended for functionality testing, could be compromised. The positioning of the cables in this configuration also did not allow the glove to be lightened by removing fabric, as initially planned.

Given the considerable doubts surrounding this new configuration, other hypotheses were examined before confirming it and proceeding with further steps.
An initial idea was to use two actuators per finger: one actuator would be positioned on the palm side and would assist the flexion movement of the finger, while the other actuator would be positioned on the back of the fingers and would work in the opposite direction to its configuration.
Considering the dimensions and technical specifications, this hypothesis seemed rather unfeasible, but before ruling it out, the first prototype was built using removable clamps to hold the two actuators in place on a finger, and they were tested at different times: first the flexion actuator, then the extension actuator.
As suggested by theory, the practical test failed: the dimensions of the actuators and their nature and operating principle did not allow for this configuration.

For this reason, despite other rather similar ideas, it was decided to reconsider the initial hypothesis and integrate the actuators, one per finger, inside the fingers, despite numerous concerns in terms of comfort and functionality.
With this configuration, it was decided to remove the return-to-start system to avoid creating a device that was too complex and had too many points to monitor during use. It was decided to rely on the mass of the finger to return to position: the user will use their own effort to return the finger to a straight position; the glove will provide support for the flexion movement.
This last aspect suggested that the glove would be ineffective in rehabilitation contexts. As seen in Chapter 2, patients very often need support in the extension movement and not in the flexion movement.

Given the limited versatility of the actuator and its size, it was necessary to confirm an initial hypothesis: the thumb would be excluded from the actuation movement.
This is because, as seen previously, anatomically the thumb has its own peculiarities and also behaves differently from the other fingers in terms of kinematics.
It would have been necessary to design an actuation system specifically for this finger, which was not possible due to time constraints.
It was therefore decided to further limit the functionality of the glove.

This was a necessary compromise in order to complete the project and gather as much information as possible on the potential of this combination of technical fabrics and SMA actuators.

Having established the aforementioned positioning, the analysis moved on to integration with the fabric, evaluating different solutions to ensure user safety and adequate structural solidity. Two options were considered: a removable integration and a stable one.

A removable integration would have simplified donning and assembly operations: the user would first put on the glove and, subsequently, an operator would apply the actuators. To test this hypothesis, a layer of Velcro was inserted between the actuator and the glove.
Although the hold was very good, once the glove was worn, it generated a sensation of compression and discomfort, perceived even by healthy subjects, and potentially amplified in pathological patients.

In light of this, it was decided to opt for a stable integration, minimising the layers of fabric. Following this path, several possible solutions were evaluated.
The first idea was to integrate the actuator to the glove via sewing: this presupposed that the actuator was first adhered to a layer of fabric, and the latter would then be sewn onto the glove.

As seen in the case of velcro, inserting layers of fabric is not the best solution.
For this reason, the next idea, which was then pursued, was to integrate the actuator with a glue for plastic and fabric, resistant to high temperatures.

**Figure 18 removable (on middle) and stable (on index) integration on the palm of the hand**

The unknown factor of its effective resistance to movements and temperatures remained. To evaluate this aspect, a first single actuator positioned on the index finger was tested. After gluing the actuator, it was switched on and off for about 10 trials, and no detachments were noted. At the same time, the fabric showed no signs of damage.

The final precaution was to cover the actuator with a fabric, in order to avoid direct contact. It was seen that a small pocket, made of simple textile material, guaranteed good insulation, including thermal, so diverse analyses were not performed, considering it a non-critical point of the project.

## 3.5 First prototype and experimental phase

Once the first prototype was made, an activation test was carried out while wearing the orthosis, in order to evaluate its effectiveness. The test highlighted poor efficiency: the mass of the finger proved to be too high, preventing the actuator from functioning correctly.

A new actuator model with greater traction force was therefore requested. The new actuator supplied by the partner company was the Curve plugged M3920E20 [19]: compared to the previous model, observing the technical sheet, it presented larger physical dimensions (59 x 20 x 2.5 mm), with a more substantial shape memory alloy capable of generating more force than the previous model. The required current and activation times remain unchanged.

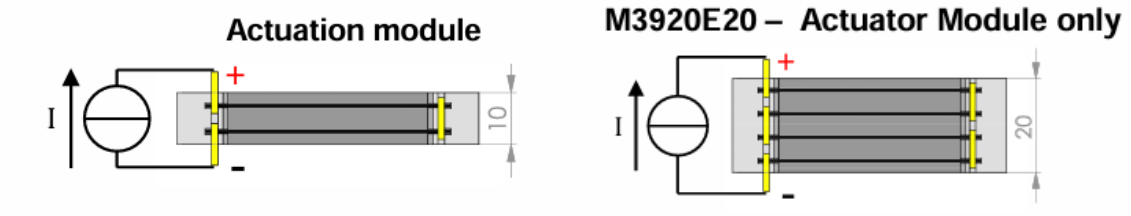


**Figure 19 Actuator model: the old one (left), the new one (right)**

Upon the first activation of the new model, it emerged that, as per the theory on SMA wires presented in Chapter 2, a larger wire corresponds to a greater generated force. Despite this, the angular excursion was not sufficient to guarantee the movement necessary for closing the hand.

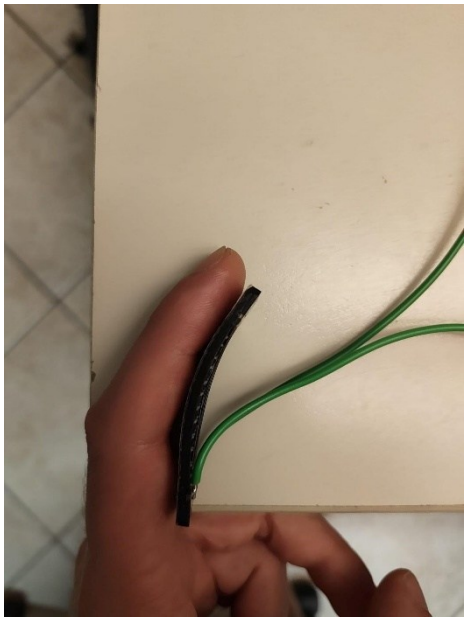

**Figure 20 first activation of new model**

### 3.6 Power supply system and final prototype

At this point, the actuator-glove integration was complete; all that remained was to establish the part relating to the power supply and control of the device.

Being developed for use in a clinical setting and not during daily activities, it is not necessary for the activation and control system to be inserted onto the glove or in its proximity, for example, on the wrist or forearm. It was therefore decided, in order not to add weight to the orthosis, to leave the cables free and simply lengthen them.

The best electronic schematic that could be created to meet these characteristics was then studied:

- Independent control of the individual fingers
- User friendly
- Not hindering the glove's mobility
- Safety of the circuit for the person controlling the activation and for the patient wearing it

To achieve this solution, 4 identical circuits were created, one for each finger. Each circuit is composed of the following components:

- one compartment for 2 x 18650 batteries of 3.7 V and 2600 mAh;
- 5 normally open buttons, rated for 6 Ampere
- 5 x 6.3 Ampere fuses

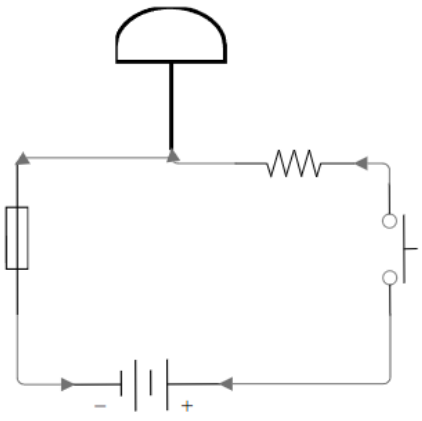


**Figure 21 circuit scheme**

After soldering the components together and inserting the fuses and batteries into their specific compartments, a functionality test was carried out to verify that everything was working.
At this point, before proceeding to the engineering tests, it remained necessary to organise the wiring so that it would not interfere during finger movements and would not be cumbersome, and to provide an orderly system to be able to activate the individual buttons in a simple and intuitive manner.

**Figure 22 final prototype with power supply and control system**

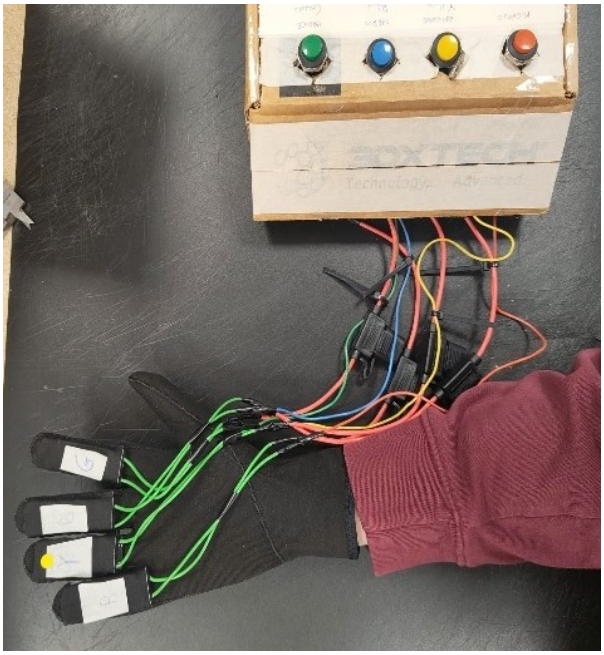

**Figure 23 prototype worn for the first time**

Thus, an enclosure was created, in a very prototypal way, in which to fix the battery compartments, cover the cables previously bundled together, and a shelf where the buttons could be positioned. The user interface was therefore clean, intuitive, and, above all, safe. At this point, we moved on to the test.

# CHAPTER 4
# FUNCTIONAL TESTS ON THE HAND ORTHOSIS

## 4.1 Introduction on test methods

The test protocol used to test the prototype involved evaluating the device as regards its suitability for use, comfort, perceived stability, as well as objective measurements of response speed and angular excursion achieved. The objective was to have data available to identify the optimal configuration that would allow freedom of movement and reduce the perceived pressure at the cutaneous and articular level during functional hand tasks.
The analysis is conducted in compliance with international standards relating to the safety, effectiveness, and usability of devices:

- IEC 62366-1:2015 - Application of usability engineering to medical devices;
- EN ISO 14971:2019 - Application of risk management to medical devices;

Subjective evaluation was carried out using standardised and validated tools, such as the Comfort Rating Scales, the User Experience Questionnaire, and the Visual Analogue Scale, in order to obtain systematic measures of comfort, ease of use, and user satisfaction. The expected results will contribute to defining the optimal configuration of the orthoses in terms of usability and safety, providing useful indications for user-centred design.

### 4.1.1 Usability Engineering

Usability Engineering (Human Factors Engineering) represents a fundamental approach in the design of medical devices, as it ensures their suitability for the intended use, safety, and effectiveness. At the same time, it allows for the reduction of risks arising from incorrect use, placing the user's experience at the centre of the development process.
According to the IEC 62366-1 standard, usability design must be strictly integrated with risk management (EN ISO 14971). This means that ergonomics and the characteristics of the user interface—that is, the set of contact points between the user and the device—must be designed and evaluated iteratively from the very first stages of development.
The final objective consists of reducing or eliminating the risks associated with improper use or physical fatigue, ensuring a safe, intuitive, and comfortable interaction.

The evaluation process is divided into two main phases:

- Formative evaluation: conducted during the development phases, aimed at verifying and optimising the user interface design. Through exploratory tests, direct observations, and qualitative feedback, ergonomic or functional criticalities were identified.
- Summative evaluation: carried out at the end of development on the definitive user interface. This evaluation aims to confirm that the device can be used effectively, efficiently, and safely. It includes controlled usability tests with direct observation of interactions and collection of subjective data via standardised questionnaires.

In both phases, the analysis focuses on the User Experience (UX) of the orthosis, which includes both physical dimensions (comfort, stability, freedom of movement) and psychological ones (trust, satisfaction, and perception of control). To obtain a complete evaluation, a multi-method approach was used, integrating objective and subjective measures, so as to directly link the usability test results to the user's overall perception.

1. Subjective measures:

- Comfort Rating Scales (CRS);
- User Experience Questionnaire (UEQ);
- Visual Analogue Scale (VAS).

2. Objective measures:

- Range of motion permitted by the actuators;
- Activation speed of the actuators.

## 4.2 Test Protocols

The evaluation protocol is designed to simulate representative use scenarios for the orthoses. Specifically, the evaluation aims to analyse: wearability, i.e., the ease of donning and adjusting the orthosis; perceived comfort, understood as pressure distribution, freedom of movement, and subjective feelings of discomfort ; and perceived stability. To test the hand orthosis, the flexion movements of each finger were evaluated with the subject seated at a table.

Participants

Due to time and organizational constraints, it was only possible to conduct an initial study with few participants. The study involved 4 healthy adult subjects aged between 24 and 42 years. For each participant, the following anthropometric data were collected, with the aim of correlating subjective perceptions of comfort and stability with individual morphological variables:

| **Parameter** | **Value (mean ± SD)** |
|---|---|
| Weight (kg) | 70.3 ± 8.8 |
| Height (cm) | 178 ± 5.9 |
| Age | 29 ± 8.7 |
| Waist circumference (cm) | 88.5 ± 3.1 |
| Chest circumference (cm) | 89.5 ± 13.1 |
| Right thigh circ. (cm) | 47.5 ± 5.1 |
| Left thigh circ. (cm) | 47.5 ± 5.1 |

Method

The participant, after being seated at the table, wore the glove on their right hand.

Subsequently, yellow adhesive markers were applied in correspondence with the interphalangeal joints.

At this point, the test supervisor took a photo of each finger in a straight position, with the hand supine and the actuator off.

After that, they activated one actuator at a time and took a photo of the finger at the maximum extension reached, following the timings indicated in the technical sheet.

They then proceeded to repeat the operation for the other fingers.

Once this first round was finished, they started again from the first finger.

This time, a photo was no longer taken; instead, the time necessary to reach maximum extension was timed, both with a stopwatch and with video, in order to have a double check on the validity of the data.

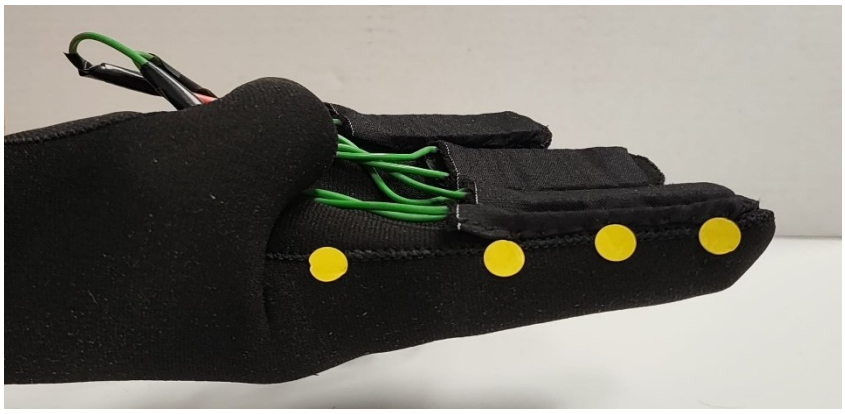

**Figure 24 actuators off**

**Figure 25 actuators on**

After acquiring the photos, in the ‘actuator off’ and ‘actuator on’ configurations, the angles were calculated using ImageJ software.
The various test protocols can be viewed in detail in the appendix A.

## 4.3 RESULTS

### 4.3.1 CRS

| Criterion | Mean (0 ÷ 10) | Std. Dev |
|---|---|---|
| Emotion | 2.9 | 2.71 |
| Adherence | 6 | 1.8 |
| Warmth | 2.3 | 1.7 |
| Perceived change | 3.8 | 1.5 |
| Movement | 3.5 | 1.3 |
| Anxiety | 0.2 | 0.25 |

The analysis of the results from the CRS questionnaire, administered to four participants after using the rehabilitation orthosis with Shape Memory Alloy (SMA) actuators integrated into a neoprene glove, allowed for the evaluation of the users' subjective response.

The scores obtained show good adherence to the device (mean 6 ± 1.8), indicating that the participants perceived it as comfortable and easy to wear.

The perception of warmth generated by the actuators was moderate (2.25 ± 1.7), suggesting an adequate level of thermal comfort during use.

The criteria related to perceived change (3.75 ±1.5) and movement (3.5 ± 1.3) show a positive evaluation, with a perceived improvement in motor skills, although not yet optimal. The very low value for anxiety (0.125 ± 0.25) indicates that the device did not generate discomfort or worry in the subjects. The criterion linked to emotion (2.9 ± 2.71), however, shows high variability, highlighting individual differences in affective response.

Overall, the data indicate good acceptability and tolerability of the device, with positive feedback in terms of comfort and perceived effectiveness. It is, however, advisable to extend the experimentation to a larger sample to consolidate these observations and to investigate the subjective differences detected.

### 4.3.2 UEQ

| Contrasting Adjectives | Mean ( 0 ÷ 7 ) | Std. Dev |
|---|---|---|
| Annoying/Pleasant | 4 | 1.4 |
| Not understandable/Understandable | 5.5 | 0.6 |
| Creative/Unimaginative | 2.5 | 0.6 |
| Easy to learn/Difficult to learn | 2 | 0.8 |
| Valuable/Inferior | 2.8 | 0.9 |
| Boring/Exciting | 4.8 | 1.8 |
| Not interesting/Interesting | 5.7 | 0.5 |
| Unpredictable/Predictable | 4.5 | 0.5 |
| Fast/Slow | 3.5 | 1 |
| Conventional/Original | 2.5 | 0.6 |
| Obstructive/Supportive | 5.5 | 0.6 |
| Good/Bad | 2.3 | 0.5 |
| Complicated/Easy | 5.5 | 0.6 |
| Unattractive/Attractive | 5.3 | 0.5 |
| Usual/Modern | 5.3 | 0.5 |
| Unpleasant/Pleasant | 5 | 0.8 |
| Secure/Insecure | 2 | 0 |
| Activating/Drowsy | 2.5 | 0.6 |
| Meets expectations/Does not meet expectations | 2.8 | 0.5 |
| Inefficient/Efficient | 5 | 1.4 |
| Clear/Confusing | 2.3 | 0.9 |
| Not pragmatic/Pragmatic | 5 | 0.8 |
| Tidy/Overloaded | 3 | 1.4 |
| Inviting/Uninviting | 2.3 | 0.9 |
| Likeable/Hostile | 2 | 0.8 |
| Conservative/Innovative | 6 | 0 |

The User Experience Questionnaire (UEQ) is a validated instrument for the evaluation of the overall user experience, which is the user's subjective experience during interaction with the device. The UEQ provides a multidimensional evaluation comprising:

- Pragmatic Quality: the ease of donning and doffing the orthosis, perceived stability during ambulation (walking), control of the device, and effectiveness in performing functional activities.
- Hedonic Quality: overall pleasantness, aesthetic appeal, and positive perception of the design.

The UEQ utilizes semantic differential scales, in which the user evaluates pairs of opposing adjectives (for example, "complicated - simple," "boring - stimulating") on a scale from 1 to 7.
The analysis of the data collected via contrasting adjectives relating to the hand orthosis highlights an overall positive perception in terms of innovation, functional support, and comprehensibility.
Users rate the orthosis as innovative (Mean=6, Std. Dev=0), understandable (Mean=5.5, Std. Dev=0.6), supportive (Mean=5.5, Std.Dev=0.6), and pragmatic (Mean=5.0, Std. Dev=0.8), with consistent opinions on these aspects.

Aesthetic elements are also favorably perceived, with high scores for attractiveness (Mean=5.3, Std.Dev=0.5) and modernity (Mean=5.3, Std. Dev=0.5).
However, significant critical issues emerge related to the ease of learning (Mean=2.0, Std. Dev=0.8), perceived security (Mean=2.0, Std. Dev=0.0), and social compatibility or acceptability (likeable/hostile: Mean=2.0, Std. Dev=0.8), suggesting that the initial interaction and the perception of reliability could represent barriers to effective use.

Further aspects, such as originality and creativity, show low mean values (Mean=2.5, Std. Dev=0.6), indicating an experience perceived as not very distinctive or as conventional.
Some items, including emotional involvement (boring/exciting: Mean=4.8, Std.Dev=1.8) and perceived efficiency (Mean=5.0, Std. Dev=1.4), show high variability among users, suggesting significant subjective differences in the user experience.

Overall, the data indicate that the orthosis possesses solid strengths in terms of functionality, support, and innovation, but requires targeted interventions to improve the ease of learning, perceived security, originality of the experience, and the emotional consistency perceived by users.

### 4.3.3 VAS

| Criterion | Mean ( 0 ÷ 10) | Std. Dev |
|---|---|---|
| Comfort | 6.13 | 1.33 |
| Fit/Adherence | 7.18 | 1.06 |
| Pressure/Soreness | 2.18 | 1.09 |
| Bulkiness/Limitation of movement | 2.5 | 1.35 |
| Ease of donning/doffing | 5.2 | 1.59 |
| Perceived warmth | 1.53 | 2.37 |

A subjective evaluation scale based on the Visual Analogue Scale (VAS) was developed, aimed at identifying the subjective sensation of each participant.

The questionnaire requires the participants to express their perception regarding the following aspects:

- Comfort
- Fit
- Pressure
- Bulkiness
- Ease of donning/doffing
- Perceived warmth

For each aspect, the participant indicates their sensation on a scale ranging from 0 to 10.

The following cut-off criteria are used to evaluate the results:

- 0 to 4 mm "no perception",
- 5 to 44 mm "slight perception",
- 45 to 74 mm "moderate perception",
- 75 to 100 mm "severe perception".

From the processing of the collected data, overall positive evaluations emerge.

The mean scores for comfort (6.13 ± 1.33) and fit (7.18 ± 1.06) fall within the "moderate" perception range, indicating good acceptability of the device and an adequate adaptation to the user's hand.

The values obtained for perceived pressure (1.78 ± 0.69), bulkiness (2.5 ± 0.95), and perceived warmth (1.53 ± 1.97) instead fall within the "slight" range, signaling reduced mechanical and thermal interference during use.

The ease of wearability (5.2 ± 1.59) also shows a "slight" perception, suggesting a good level of usability, although with room for improvement in the donning phase.
Overall, the VAS evaluation confirms that the device exhibits good ergonomic and comfort characteristics, with high tolerability and a positive perception by users**.**

### 4.3.4 Measurement of the angles of the different joints

The analysis of the data shows that the mean joint excursions obtained with the orthosis are significantly lower than the reference values in the literature, collectively settling at between 11% and 26% of physiological movement.
The CMC joints are completely inactive, as expected, since the device is not designed to act on this level. The MCPs reach mean values between 15% and 18%, while the PIPs show a slightly lower excursion (12-17%), followed by the DIPs, which present the highest percentages (19-26%) and therefore the best overall mechanical response.

However, the resulting range of motion can be considered not very functional from a rehabilitation perspective, as it is insufficient to reproduce daily gestures or complete physiological motor patterns. This limitation can be attributed to several design factors, including the force generated by the Shape Memory Alloy (SMA) actuators, the transmission of movement along the phalanges, and the rigidity of the glove material.

Overall, the results confirm that the orthosis is capable of generating a safe movement, but that the mechanical efficiency can be further increased to make it more functional and higher-performing in a rehabilitation setting. Subsequent development can therefore focus on optimising the active force and dynamic comfort, improving the balance between the device's efficiency and usability.

Misurazione degli angoli delle diverse articolazioni:

| *Index* | *partecipant 1* | *partecipant 2* | *partecipant 3* | *partecipant 4* | *data in literature* | *mean* | *%* |
|---|---|---|---|---|---|---|---|
| CMC | 0 ° | 0 ° | 0 ° | 0 ° | 5 ° | 0 ° | 0 % |
| MCP | 18,98 ° | 12,797 ° | 10,54 ° | 17,034 ° | 90 ° | 14,84 ° | 16,49 % |
| PIP | 22,65 ° | 16,98 ° | 21,03 ° | 11,932 ° | 110 ° | 18,15 ° | 16,5 % |
| DIP | 21,83 ° | 17,802 ° | 29,87 ° | 13,151 ° | 85 ° | 20,66 ° | 24,31 % |
| | | | | | | | |
| *Medium* | *partecipant 1* | *partecipant 2* | *partecipant 3* | *partecipant 4* | *data in literature* | *mean* | *%* |
| CMC | 0 ° | 0 | 0 | 0 ° | 5 ° | 0 ° | 0 % |
| MCP | 17 ° | 15,074 ° | 12,3 ° | 16,92 ° | 90 ° | 15,32 ° | 17,02 % |
| PIP | 14,2 ° | 16,91 ° | 23,96 ° | 12,137 ° | 110 ° | 16,8 ° | 15,27 % |
| DIP | 18,3 ° | 18,208 ° | 24 ° | 19,57 ° | 85 ° | 20,02 ° | 23,55 % |
| | | | | | | | |
| *Ring* | *partecipant 1* | *partecipant 2* | *partecipant 3* | *partecipant 4* | *data in literature* | *mean* | *%* |
| CMC | 0 ° | 0 ° | 0 ° | 0 ° | 10 ° | 0 ° | 0 % |
| MCP | 18,432 ° | 14,653 ° | 12,8 ° | 10,24 ° | 90 ° | 14,03 ° | 15,59 % |
| PIP | 10,238 ° | 15,781 ° | 20,68 ° | 13,383 ° | 120 ° | 15,02 ° | 12,52 % |
| DIP | 15,372 ° | 26,98 ° | 28,08 ° | 17,507 ° | 85 ° | 21,98 ° | 25,86 % |
| | | | | | | | |
| *Little* | *partecipant 1* | *partecipant 2* | *partecipant 3* | *partecipant 4* | *data in literature* | *mean* | *%* |
| CMC | 0 ° | 0 ° | 0 ° | 0 ° | 15 ° | 0 ° | 0 % |
| MCP | 19,44 ° | 11,74 ° | 13,092 ° | 21,82 ° | 90 ° | 16,52 ° | 18,36 % |
| PIP | 16,71 ° | 19,939 ° | 14,931 ° | 13,074 ° | 135 ° | 16,16 ° | 11,97 % |
| DIP | 12,57 ° | 10,4 ° | 25,78 ° | 18,53 ° | 90 ° | 16,82 ° | 18,69 % |

**Table legend:**

- **CMC** - Carpometacarpal joint;
- **MCP** - Metacarpophalangeal joint;
- **PIP** - Proximal interphalangeal joint;
- **DIP** - Distal interphalangeal joint;
- **Angles** are expressed in degrees (°).

### 4.3.5 Actuation speed

A further objective analysis concerned the activation speed of the Shape Memory Alloy (SMA) actuators, evaluated in terms of the time necessary to reach the maximum angular excursion for each finger.

The experimental results showed mean activation times between approximately six and eight seconds. These values are slower than those reported in the datasheet for the same type of actuator, which refer to ideal laboratory conditions with constant power supply and actuators free from mechanical constraints.

The observed differences are to be considered consistent with the prototype's operational context, in which the actuators are integrated within the glove and powered by a battery-powered circuit. The rigidity of the neoprene fabric, the mechanical resistance due to structural constraints, and the current activation being lower than the nominal one indeed determine a more gradual heating and a slower dynamic response.
This behaviour, while ensuring safe and controlled operation, is not very functional for dynamic applications or for rehabilitation exercises that require rapid and repeated movements.

To improve performance, it will therefore be appropriate to intervene on the intensity of the activation current and the flexibility of the support materials, as well as evaluating a more precise thermal control system that allows for optimizing response times without compromising user safety.

### 4.3.6 Quantitative analysis of performance differences

As highlighted in the previous paragraphs, the objective results of the prototype proved to be non-functional, with a significantly low average ROM (11-26% compared to the physiological one) and slow actuation times (6-8 seconds).

The qualitative analysis identified the rigidity of the neoprene glove as a possible main cause, together with the mass of the finger.

Using the technical data of the Curve plugged M3920E20 actuator, we also attempted to conduct a more qualitative analysis to explain these results.

The technical data sheet indicates a nominal load range of 470 g applied at a distance of 25 mm from the hinge.

By converting this data into torque (Torque = Force × distance), it is possible to estimate the nominal active torque that the actuator is capable of generating:

T = (0.470 kg • 9.81 m/s^2) • 25 mm = 115.3 N • mm

This torque must counteract a total resistive torque given by the sum of three main components:

1. the gravitational torque generated by the mass of the finger,
2. the intrinsic passive stiffness of the MCP, PIP and DIP joints of the healthy subject
3. the elastic return torque introduced by the glove material

The experimental results (ROM 11-26%) are therefore the quantifiable consequence of a performance imbalance, where the Torque Resistive $T_r$ is greater than the Torque Active $T_a$.

The torque generated by the M3920E20 actuator was insufficient to overcome the imposed load.

The movement therefore stopped prematurely as soon as the resistive $T_r$, increasing with the angle of flexion, reached equilibrium with the active $T_a$.

This imbalance also explains the discrepancy in actuation times. The nominal times indicated in the data sheet (e.g. 4 A for 4 s or 5 A for 1.3s) are valid under nominal load conditions.

The experimental times of 6-8 seconds are a clear symptom of an actuator operating in an overload situation.

An SMA actuator working against a load close to or above its mechanical limit takes much longer to complete the phase transition and stroke.

In conclusion, the performance failure of the prototype is not attributable to a defect in the SMA technology itself, but to an incorrect engineering coupling between the actuator and the load.

It is important to emphasise that these quantitative analysis, which in an ideal work timeline should be conducted a priori for the correct sizing of components, was in this case performed a posteriori.

This approach was not the result of a methodological choice, but rather of concrete design constraints: the tight deadlines did not allow for the necessary preliminary estimates to be made.

The analysis was therefore used as a diagnostic tool to investigate and explain the non-functional results obtained during the tests.

# CHAPTER 5:
# DESIGN AND IMPLEMENTATION OF A PROTOTYPE ORTHOSIS FOR THE SHOULDER

## 5.1 Introduction to shoulder devices

Upper limb orthoses are devices developed to support and assist the movement of joints such as the shoulder, elbow, wrist, and hand, with the aim of improving motor functionality and reducing muscle fatigue associated with pathologies and neuromuscular deficits. These systems find wide application both in the rehabilitation field, for the recovery of compromised motor skills, and as assistive aids, to facilitate daily activities.

## 5.2 Anatomy of the shoulder

The shoulder district is explored in depth here, consisting of several bones such as the clavicle, the scapula, and the humerus, and several joints. The glenohumeral joint is certainly the most important. We then find the sterno-clavicular joint and the acromion-clavicular joint, which constitute the shoulder girdle. They are the two bony structures that connect the upper limb to the trunk. There are also two other joints of lesser importance because they do not have a true articular surface: the sub-acromial joint and the scapula-thoracic joint.

Speaking of the shoulder joint, the glenohumeral joint, the articular heads are represented by the humeral head and the glenoid cavity. This cavity has a slightly hollowed shape, is lined with cartilage, and accommodates a spherical surface much larger than itself, with a 4:1 ratio.

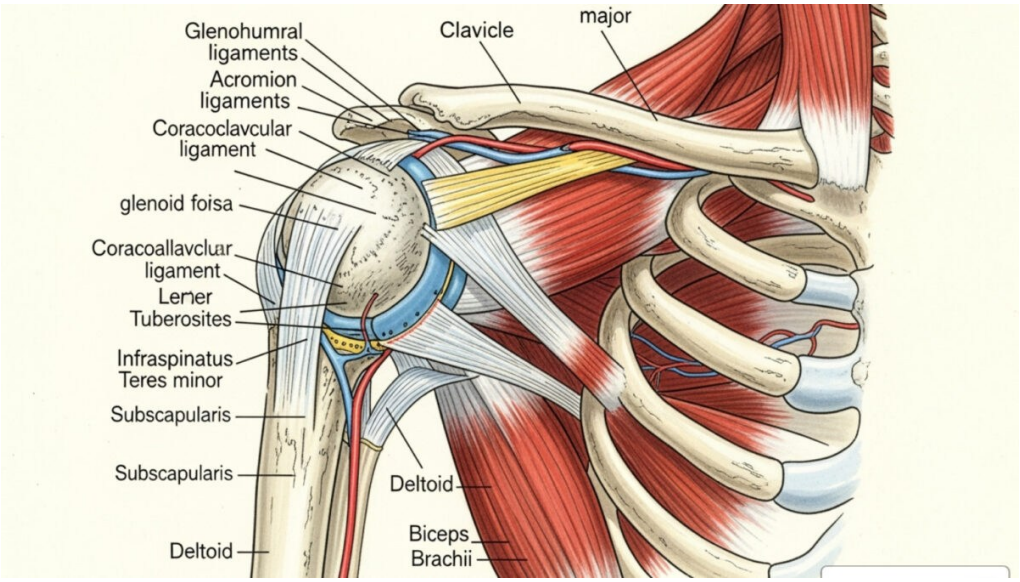


**Figure 26 Shoulder diagram**

What envelops the joint is the capsule. It is inserted outside the glenoid cavity and leaves the apex part free. The capsule has a recess, called the axillary recess, which represents the "safety space" that allows a large range of motion. The axillary recess flattens when the upper limb first performs abduction and then elevation. The fibrous capsule also has openings through which an extension of the synovial membrane passes, anteriorly, to protect the passage of a tendinous structure called the "tendon of the subscapularis muscle".

The glenohumeral joint is spherical, which entails advantages and disadvantages. The advantages are represented by the great freedom of movement. What constitutes a disadvantage, however, is instability. In fact, it is one of the joints most subject to dislocation, i.e., the loss of normal relationships between the articular heads. It is a joint that is reinforced by three tendinous structures and sees the presence of three ligaments that take the name of glenohumeral ligaments: one superior, one middle, and one inferior.

There are also several ligamentous bands that serve to reinforce the joint, but the fundamental role is played by the tendinous components. Superiorly we have the tendon of the supraspinatus muscle; posteriorly there are two other tendons, namely the tendon of the infraspinatus muscle and that of the teres minor; while anteriorly there is the tendon of the subscapularis muscle. It is these 4 tendinous structures that reinforce the joint anteriorly, posteriorly, and superiorly. On the inferior side, there is no reinforcement: there is only the axillary recess, to allow the capsule to expand.

A brief exploration of the muscles present in this area that allow the shoulder's dynamics. The supraspinatus muscle, the infraspinatus muscle, and the teres minor insert on the greater tubercle of the humerus.
The subscapularis muscle inserts on the lesser tubercle instead. The muscle most affected in shoulder pathologies is the supraspinatus.
Its role is important for the abduction movement. External rotation is instead possible thanks to the infraspinatus muscle, whose fibres have an ascending course from the spine of the scapula to the humerus.

It also ensures the dynamic stability of the shoulder. The teres muscle plays an important role in external rotation and shoulder stability. Other muscle we mention is the subscapularis muscle, which acts on medial rotation and also contributes to shoulder stability.

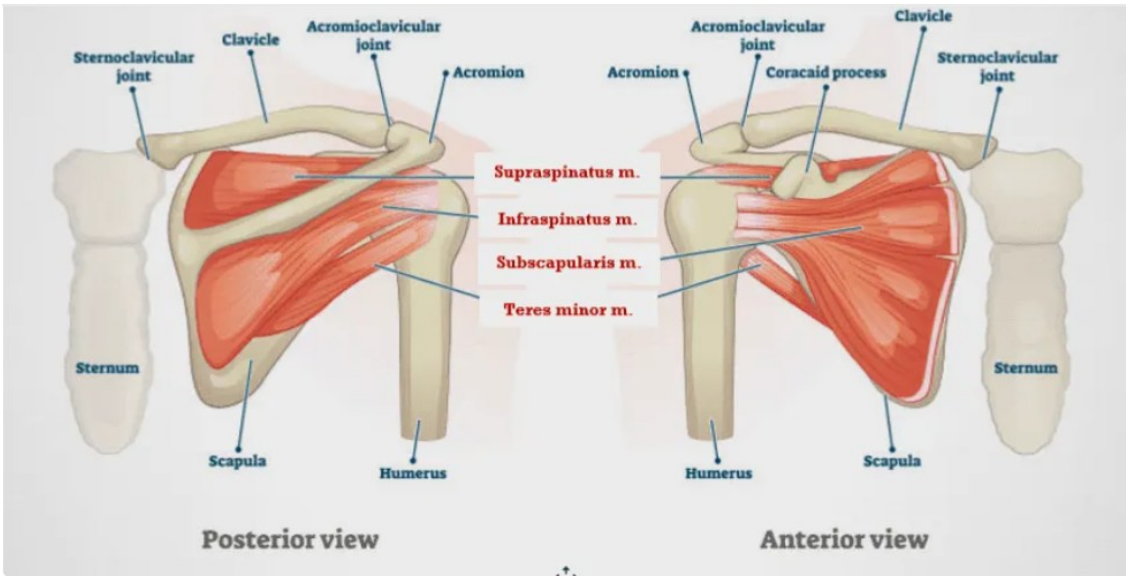


**Figure 27 Shoulder muscles: supraspinatus, infraspinatus and subscapularis detail**

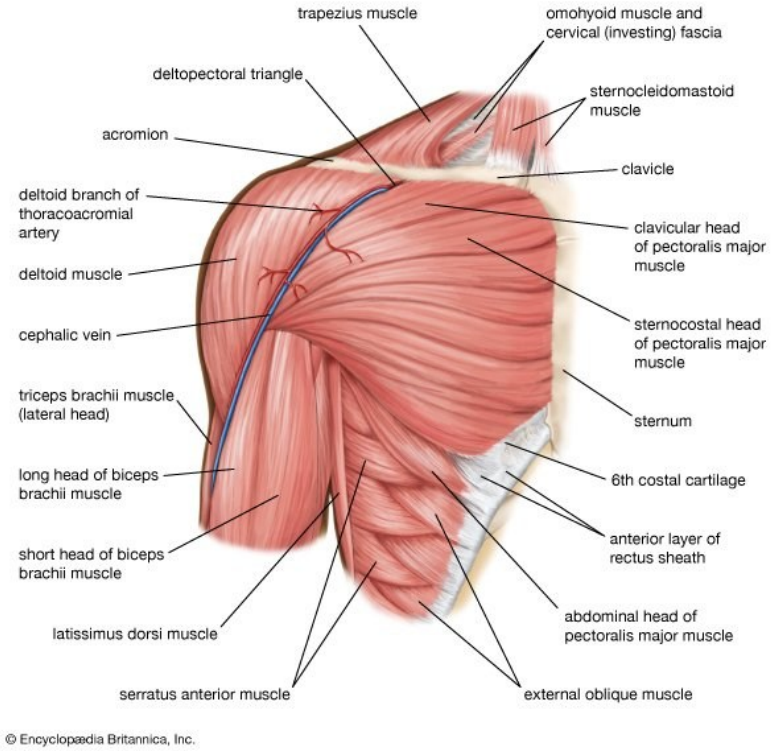


**Figure 28 Shoulder muscles: deltoid and pectoralis details**

Our device will primarily assist the patient in the abduction movement and will therefore assist the deltoid muscle. Specifically, this muscle is divided into three heads (or fascicles):

- the anterior head
- the acromial head
- the spinal head (or posterior head)

This muscle inserts onto the lateral third of the clavicle, then continues along the acromion, and extends posteriorly along the spine of the scapula. The three heads remain functionally independent. The anterior head performs flexion, in addition to assisting in internal rotation. The posterior head, conversely, performs extension and external rotation. The middle head (or acromial head) works during abduction.

The pectoralis major muscle (or great pectoral muscle) plays a minor but important, role in the abduction process. It is the principal muscle of the chest, shaped like a fan, occupying most of the anterior thoracic wall.

It is subdivided into three parts:

- The clavicular head
- The sternocostal head
- The abdominal head

This muscle is involved in movements of the trunk, respiration, and, importantly for this thesis, also in movements of the arm.

In fact, it is implicated in the movements of arm flexion, adduction, and rotation, working in conjunction with other muscles, including the already mentioned deltoid and supraspinatus.

## 5.3 Design and implementation of the prototype

Following the analysis of clinical needs and after observing other shoulder devices, the focus shifted to creating a new orthosis model, combining shape memory alloy actuators with technical fabrics, as was done with the hand device.

This orthosis, in line with the project's objective, had to be conceived to meet these characteristics:

- lightness;
- functionality;
- ease of wearing;
- safety;

The project followed these phases:

- Conceptual phase, in which the focus was on functional requirements and the first preliminary sketches were created.
- Digital CAD modelling, through which the preliminary sketches were translated into virtual models;
- Physical prototyping, from the digital 3D model to the actual creation of a physical prototype.
-

This iterative approach made it possible to develop modular and flexible solutions, suitable for responding to the diverse and personalized needs of the end-user. Each of the cited phases will now be addressed specifically.

The initial phase of the project was dedicated to the study and definition of an optimal configuration for an exoskeleton intended to assist shoulder movement. In particular, upon actuating the actuator, the device must assist the patient in the abduction movement.

The main objective was to identify a structural solution that would effectively house the actuators, while ensuring freedom of movement, comfort, and stability during use. The design process began with the creation of a conceptual sketch aimed at exploring the general architecture of the device.

In this first proposal, a main rigid structure was hypothesized: located in the clavicular area, extending over the pectoral area, and conceived to act as the load-bearing element for the shape memory alloy (SMA) actuator.

The actuator's operation generates a force directed from the shoulder towards the forearm. The rigid part and the transverse strap are tasked with anchoring this section in position, thereby generating a resistant force in the opposite direction. This configuration aims to exploit the rigidity of the support to transfer the forces generated by the actuator in a controlled manner, whilst simultaneously maintaining a balanced distribution of loads on the chest surface

To complete the rigid part, the model includes two elastic fabric elements with containment and stabilization functions.
The first consists of a horizontal band positioned at the sternum level, with the function of closing the device and keeping it adherent to the user's body, preventing unwanted displacement during activation.
The second element consists of an elastic band arranged diagonally across the chest, designed to counterbalance the forces generated by the actuator, improving the overall balance of the system and contributing to the uniform distribution of pressure on the body. The concept also includes the creation of an anchoring armband intended for the proximal segment of the arm.
This component consists of a rigid section dedicated to attaching the distal end of the actuator and an adjustable Velcro strap, designed to adapt to different bicep circumferences and ensure stable yet comfortable fastening.

Overall, this preliminary configuration allowed for the exploration of the mechanical interactions between the rigid (grey parts of the figure 29) and flexible components (black parts of the figure 29), laying the foundations for subsequent design iterations.

The analysis conducted on this first model highlighted the potential for integration between textile materials and SMA actuators, as well as the need to further optimise the geometry and positioning of the constraints to improve the dynamic response and overall ergonomics of the system.

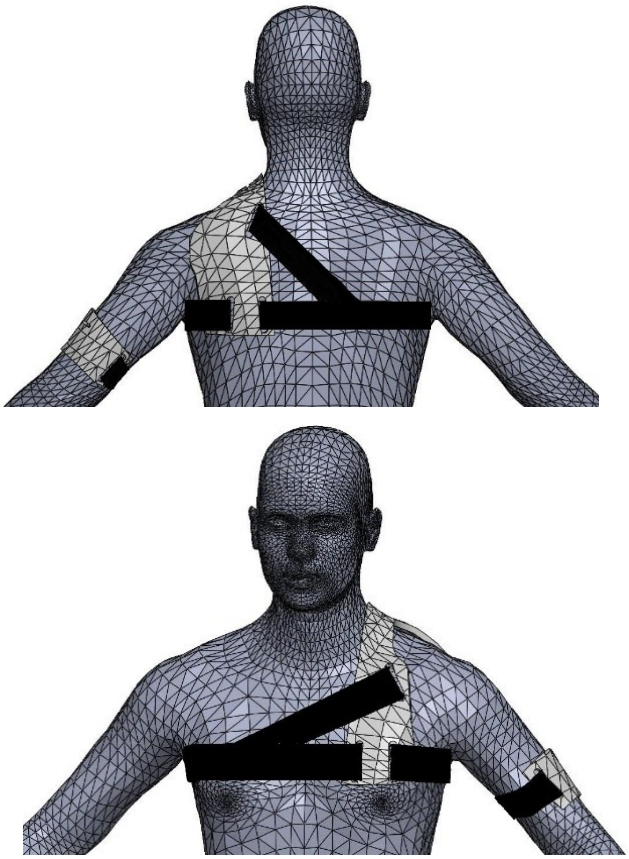

**Figure 29 First development hypothesis: back and front view**

After this first project sketch, the second phase was undertaken: 3D models were created, and subsequently, the rigid part was printed.

The mobile parts were made using elastic technical fabrics and velcro for the adjustable closure.

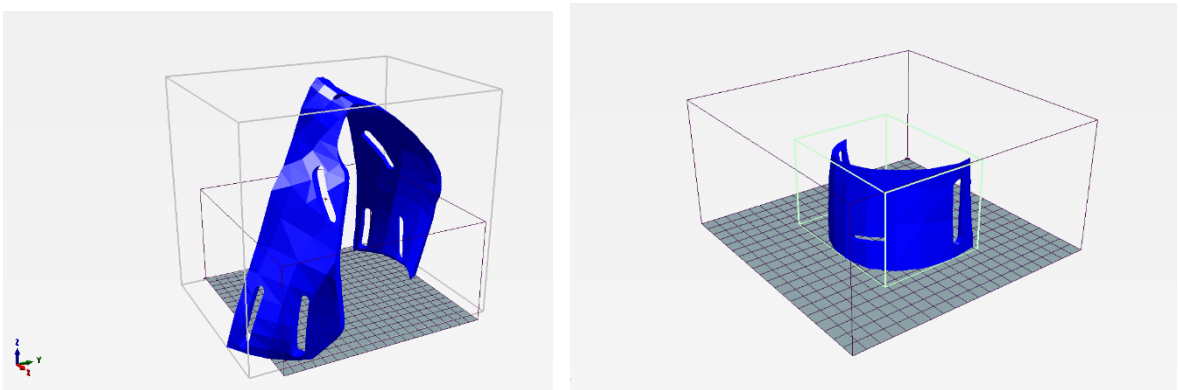

**Figure 30 3D model of rigid parts: chest part (on the left) and forearm (on the right)**

**Figure 31 Rigid parts 3d printed and with Velcro: chest part (on the left) and forearm (on the right)**

**Figure 32 first prototype worn for the first time**

In this phase, some comfort tests were also carried out to understand the critical issues and improve them before creating a functional prototype. After the first wearability test, it was realised that the rigid part, while offering good support for the actuator, transmitted a sense of constriction to the user and was not very customisable in terms of size.

Another critical point concerned the two fabric closures: the transverse belt caused discomfort as it passed very close to the neck. Its configuration had been designed to balance the downward force of the actuator, which tended to drag the rigid part, and therefore could not be removed, but needed to be redesigned.

After these analyses, a second model was created, initially built with a simple fabric (cordura). In this version, the rigid part was removed, and a repositioning of the transverse strap was considered. Specifically, the rigid structure was replaced by a fabric part, which was more comfortable and better adaptable to the user's chest ergonomics.
The transverse closure was repositioned to avoid contact with the neck and, at the same time, maintain the balance of forces generated by the actuator.
In the new configuration, the strap was rotated by 90° compared to the initial version: it starts from the centre of the chest, passes over the shoulder not involved with the device, and rejoins posteriorly.

**Figure 33 First fabric prototype without actuator**

After creating a rudimentary version of the new prototype without actuator integration and analysing the various critical issues, the final phase of the prototyping process was entered. We proceeded to design a more advanced variant, using more suitable technical fabrics and more precise dimensions. It was decided to use different overlapping fabrics, combining their characteristics.
The innermost layer, made of a lightweight and porous material called Airshell, aims to offer comfort to the user. A layer of grey cordura, resistant to the stresses generated by the actuator and to wear over time, was applied onto it using fusible interfacing.
On the front side, a layer of velvet was also added for anchoring the straps.
The two straps, horizontal and transverse, are made of 4 cm wide nylon tape. On the rear side, they are sewn to the cordura-Airshell body, while on the front side, they adhere via Velcro, allowing the orthosis to be worn and adjusted.

The position of the transverse strap was returned to that initially planned in the first rendering, as it guaranteed a more stable balancing of the forces generated by the actuator compared to the 90° rotated version.

To eliminate the discomfort around the neck experienced with the first version, as mentioned above, the cross strap has been positioned slightly lower and made adjustable with a velcro closure.

The transverse strap is also present posteriorly: by adjusting the attachment on the Velcro, it is possible to modify both the circumference around the torso and the height of the device.

The same criterion was adopted for the actuator's support to be positioned on the bicep: a layer of cordura lined internally with lightweight material to increase its comfort.

Adjustment is achieved via two velcro closures.

**Figure 34 Details of the torso part (left) and the armband (right): the cordura is visible in grey and the velvet in black, intended for the velcro adhesion. Actuator is the blue part**

After completing the creation of the fabric parts for the torso and arm, the focus shifted to creating the integration system with the actuator. This phase represented a crucial step, as the interface between the actuator and the textile modules must ensure mechanical stability, ergonomics, and morphological adaptability to the user, without compromising freedom of movement. The actuator used, supplied by the company 2SMArtEST, has the following dimensions: 16.5 x 7.5 cm with a thickness of 2 cm. Actuator consists of a series of SMA springs positioned in series with each other and enclosed in a fabric bag, as shown in the figure 31 (blue part).

The design of the mounting system was guided by the need to obtain a stable but adjustable anchoring, capable of adapting to different body configurations and variations in positioning along the upper limb. To this end, a system based on two 1.5 cm wide nylon tapes was developed, coated respectively with velcro (hook) and velvet (loop fabric).

This solution allows a wide range of vertical adjustment and correct positioning of the actuator relative to the textile structures.

**Figure 35 Details: actuator integration**

The tape is fixed onto the torso part via double stitching, while on the armband, it was achieved using a sliding buckle fixed with a nylon cord sewn under the velvet. This allows adjustment both in height and along the bicep circumference, giving the system two degrees of freedom in positioning the actuator.

Once all components were created and the dimensions defined, a wearability test of the complete device was carried out.

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**Figure 36 Final prtotype**

Compared to the first prototype, which contained rigid parts, the sensation is that of a lighter, less bulky, and overall, more comfortable device. Wearability is practical and fast: it can be done almost completely autonomously by the patient. The only element that is more complex to adjust autonomously is the posterior strap; all other adjustments are simple and accessible.

Passive mobility was tested with torso rotations and movements of shoulder abduction, adduction, flexion, and extension.

In all these conditions, the device proved to be stable and did not generate discomfort or constriction.

# CHAPTER 6
# TEST PROTOCOL for SHOULDER ORTHOSIS: COMFORT and WEARABILITY

## 6.1 Introduction

Following the directives already mentioned in Chapter 4, the shoulder orthosis prototype was also subjected to appropriate tests. As there was no way to operate the actuator, in this case, the tests primarily concerned the aspects of comfort and wearability.

Since these parameters are directly linked to the work carried out at Moveo, the results assume particular value in evaluating the quality of what was conceived and created.

Participants were asked to perform abduction, adduction, and subsequently flexion and extension movements of the shoulder.

At the end of these exercises, they were asked to walk and to keep it on for about five minutes.

Subsequently, participants were administered a Comfort Rating Scale (CRS), a User Experience Questionnaire (UEQ), and a VAS sheet in order to evaluate subjective parameters related to the medical device. These sheets are included in the appendix B.

## 6.2 CRS

The data analysis highlights a rather high standard deviation for some criteria, due to the limited sample size (n=4). The range of values was from 0 to 10.

| Criterion | Mean (0 ÷ 10 ) | Std dev |
|---|---|---|
| Emotion | 5.4 | 4.34 |
| Adherence | 7.1 | 0.25 |
| Warmth | 2.6 | 2.9 |
| Perceived change | 2.5 | 2.1 |
| Movement | 7 | 1.2 |
| Anxiety | 0.25 | 0.5 |

**Figure 37 CRS results**

Despite this variability, it emerges that the device is perceived as well-adhering (mean=7.1) and allows adequate freedom of movement (mean=7.0). These results indicate good overall ergonomics and suggest that the shape and materials of the orthosis ensure a correct balance between stability and comfort. The low mean value for anxiety (0.25) confirms that the orthosis is easy to wear and does not generate discomfort, favoring prolonged use without distress.

The reduced scores related to warmth (2.6) and perceived change (2.5) can be attributed to the test conditions in inactive mode.

It is plausible that these parameters, particularly perceived change, will increase in subsequent tests with the device active, providing more complete indications of functional efficacy and sensory perception during use.

Overall, the preliminary data suggest that the orthosis possesses good comfort and acceptability characteristics, representing a promising basis for further developments.

## 6.3 UEQ

The analysis of the UEQ data relating to the shoulder orthosis highlights an overall positive evaluation in terms of usability and user experience.

| Contrasting Adjectives | Mean ( 0 ÷ 7) | Std. Dev |
|---|---|---|
| Annoying/pleasant | 5.3 | 1.5 |
| Incomprehensible/comprehensible | 6 | 0.8 |
| Creative/unimaginative | 3.3 | 1.9 |
| Easy to learn/difficult to learn | 2.5 | 2.3 |
| Highly valuable/of little value | 3 | 1.8 |
| Boring/exciting | 4.8 | 2.2 |
| Uninteresting/interesting | 6 | 0.8 |
| Unpredictable/predictable | 4 | 1.2 |
| Fast/slow | 4 | 0.8 |
| Original/conventional | 2.8 | 0.9 |
| Obstructive/supportive | 5.8 | 0.9 |
| Good/poor | 2 | 0.8 |
| Complicated/easy | 5.8 | 1.5 |
| Repulsive/attractive | 5.8 | 1.5 |
| Usual/modern | 6 | 0.8 |
| Unpleasant/pleasant | 5.5 | 1 |
| Safe/unsafe | 2.3 | 0.5 |
| Stimulating/soporific | 2.3 | 0.9 |
| In line with expectations/not in line with expectations | 1.8 | 0.5 |
| Inefficient/efficient | 5.3 | 0.9 |
| Clear/confusing | 2 | 0.8 |
| Unpragmatic/pragmatic | 5.3 | 0.9 |
| Tidy/cluttered | 1.8 | 0.9 |
| Inviting/uninviting | 1.8 | 0.9 |
| Friendly/hostile | 1.8 | 0.5 |
| Conservative/innovative | 6.3 | 0.9 |

**Figure 38 UEQ results**

The high scores observed for the dimensions understandable (6.0 ± 0.8), supportive (5.8 ± 0.9), and interesting (6.0 ± 0.8) indicate that users perceive the device as clear, functional, and motivating to use.

At the same time, the positive evaluation in terms of efficient (5.3 ± 0.9) and pragmatic (5.3 ± 0.9) suggests adequate effectiveness in fulfilling the intended therapeutic function.

However, critical issues emerge in relation to the ease of learning (2.5 ± 2.3), perceived safety (2.3 ± 0.5), and conceptual clarity (clear/confusing = 2.0 ± 0.8), which indicate a potential need for improvement in initial orientation, user trust, and communication of functionalities.

From an aesthetic point of view, although the orthosis is perceived as modern (6.0 ± 0.8) and innovative (6.3 ± 0.9), the relatively low scores for original/conventional (2.8 ± 0.9) and creative/unimaginative (3.3 ± 1.9) suggest room for improvement in terms of creative and distinctive design.

Overall, the UEQ data indicate that the orthosis offers a positive and functional user experience, while highlighting specific areas for intervention aimed at optimising learning, the perception of safety, and aesthetic appeal.

# CHAPTER 7
# CONCLUSION

## 7.1 Introduction and method

Once the design and testing phase of the two orthoses produced was completed, and having analysed the data obtained, the produced result was discussed.
To do this, a previously outlined method was followed, in order to have an objective evaluation that was not conditioned by personal feedback or other parameters.
The considerations started from these questions:

- Does the device respond to the clinical needs identified following the design?
- Is it a functional and efficient device?
- Is there future potential for the project?
- By answering these questions, we drafted an end-of-project report.

## 7.2 Considerations on the hand orthosis

The work carried out on the hand orthosis was certainly more methodological and in-depth compared to what was done for the shoulder; for this reason, the final considerations will be more thorough and detailed.

In order not to lose track, it is useful to answer the initial questions. Let's start by considering whether this device can meet the required clinical needs. It is evident, evaluating the data presented in Chapter 4, that the answer is no.

In patients with neuropathologies, assistance is required in the extension movement and control over spasticity. Both of these aspects cannot be resolved using this device.

The problem related to the extension movement had already been evaluated during the design phase, once the actuation models were received. Unfortunately, the project timelines did not allow for the development of new SMA systems; for this reason, it was chosen to support the flexion movement and still collect as much data as possible on the effectiveness of SMA alloys in this scenario.

Regarding spasticity, no control-support system was explored in depth. We were confronted with the need to have an orthosis that was as light and wearable as possible and, to respond to this request, the glove was lightened as much as possible.

Another critical aspect concerns the movement of the thumb: the final configuration of the glove does not include any actuator to support the thumb. This is due to the configuration and the movement generated by the actuators, which made their insertion on the thumb prohibitive and counterproductive.

For rehabilitation purposes, however, it is of vital importance to have a system that also works on this finger.

One need only consider that all the grasps seen in Chapter 2 involve this finger. If a pathological subject is unable to move it, any solution found for the remaining four fingers will never be truly functional.

The actuation speed is also not functional for rehabilitation purposes: not only is it slow, as stated in Chapter 4, but it also appears non-functional.

On this topic, as discussed in the same chapter, the engineering analysis of the design was conducted retrospectively to validate the causes of the performance failure. In an ideal project timeline, this analysis should be carried out beforehand. This was not possible due to the project timetable: this aspect also becomes crucial when working on large projects involving multiple parties but with very tight deadlines.

Despite this limitation imposed by external factors, the primary objective of studying the feasibility of the project was still achieved

## 7.3 Considerations on the shoulder orthosis

The shoulder orthosis project was certainly less in-depth and less developed than the hand orthosis, and this was for various reasons.
First of all, it was a device idea that emerged during the course of the work, precisely from evaluating the effectiveness of the developed actuators integrated with highly technical fabrics, as achieved in the lower limb orthosis (which is not presented here but which represented the initial part of the AGE-IT spoke 9 project).
Consequently, as there was neither an in-depth investigation of clinical needs nor a specific request from the project client, the work was more exploratory and had the sole aim of collecting as much data as possible on this proposal.

The orthosis was only tested whilst inactive; for this reason, we can define it more as a work on design and comfort rather than on functionality.
That said, it was certainly work carried out with method, with many analyses and logical considerations which led, with data in hand, to positive feedback from the test participants.
This demonstrates that the comfort aspect can be considered fully satisfied.

It certainly needs to be expanded with functionality tests. This is to understand both whether the durability of the fabrics and the actuator-fabric integration system is stable, and whether an orthosis that works in this way during the abduction and adduction phase can be useful for subjects with shoulder pathologies.

In this anatomical area, which is subject to frequent dislocations as seen in Chapter 5, an important role for this device in daily or work-related tasks should not be excluded, to avoid fatigue of this anatomical district in patients with neuro pathologies or patients subject to chronic joint instability.

For a future in the rehabilitation field, an in-depth study is necessary on the loads involved and on current rehabilitation dynamics, in order to make a contribution that is not only functional but also innovative.

## 7.4 Future aspects

The work carried out in recent months shows its critical issues but also represents a solid foundation for developing future orthoses that combine SMA alloys with technical materials to create lightweight and low-bulk devices.
Some improvements are easily implementable; others require more in-depth studies.

Regarding aspects for easy improvement, we find the power supply system, which can be simplified and made "cleaner", and the wearing system: lightening the fabric part where it is not necessary and inserting Velcro straps at the wrist level to ensure easy wearability.

Speaking of future developments, the biological role of tendons, their movement, and their arrangement will certainly need to be investigated further. In general, the aspect of finger flexion and extension, anatomically speaking, is an aspect that deserves to be studied in more detail in order to better understand its mechanisms and be able to emulate them more precisely.

SMA alloys, even in their cable configuration, have nonetheless shown themselves capable of generating movement. If their arrangement were not pre-established in commercialised models but was studied by replicating the tendinous and muscular structures, this would bring greater benefits in terms of movement.
Furthermore, knowing the correct contraction of these materials also allows for greater control over the temperatures necessary to actuate them and, consequently, facilitates the choice of materials to use to protect the patient.

Another important point is the evaluation of the energy consumption of such devices. In the glove prototype, a current varying from 3 to 5 amperes was insufficient to create adequate flexion. This aspect must also be rigorously evaluated when deciding to develop this technology. Consequently, the shape and positioning of the SMA actuator must be optimised to reduce energy consumption.

A shorter-term solution, to validate the project and ensure it also helps the flexion part, would be to conceive a return-to-position system for the finger. The simplest way, initially planned and then left on stand-by, was to use elastic components on the dorsal side of the fingers as a return path.
To implement this system, control over the forces, masses, and moments involved is required, to ensure that this system does not oppose flexion when the actuator is on, and that it has the necessary force to return to alignment when the actuator is off.

In conclusion, we can be satisfied with what has been produced from the point of view of comfort, patient safety, lightness, and innovation. The combination of SMA alloys and technical fabrics, as mentioned, leaves considerable room for improvement and is certainly positioned among the possible innovations in the orthoses field, with a view to creating orthoses that are not only functional but also lightweight, practical, easy to use autonomously, and capable not only of restoring a function but also of positively impacting people's daily lives.

# APPENDIX A

## TEST PROTOCOL for HAND ORTHOSIS WITH SMA ACTUATORS

## TEST 1
## EVALUATION OF THE BENDING ANGLE OF INDIVIDUAL FINGERS

**Objective:** To measure and quantify in degrees the maximum bending angle of the individual fingers obtained thanks to the shape memory (SMA) actuators.

### Materials & Tools:

- Glove orthosis prototype
- Camera placed on the table
- White background
- Reference ruler
- Stickers/references on the phalanges
- ImageJ Software

**Participants:** 4 healthy subjects, age 18-50; right hand dominant.

### Experimental Setup:

Hand in prone position, slightly raised from the supporting surface.
Camera perpendicular to the finger's length, at a fixed distance of 25 cm.
White background.

### Procedure:

1. Wear the glove and place the hand on the surface.
2. Apply adhesive markers on the phalanges to standardize the reference.
3. Place a white sheet behind the first finger (right index).
4. Take photo with actuator off (baseline = 0°).
5. Activate the actuator; after 10 s, take photo at maximum movement.
6. Turn off the actuator.
7. Repeat the test for the remaining fingers.
8. Perform 2 trials per finger for each participant.
9. Upload the images to the ImageJ software for angle analysis.

## Data Analysis-Results:

Measure the maximum flexion angle for each finger and participant.

Compare baseline (0°) vs active actuator.

Calculate mean and standard deviation and Compare the values with those indicated in literature

## TEST 2
## EVALUATION OF THE TIME REQUIRED TO REACH MAXIMUM BEND

**Objective:** To measure the time required for each finger to reach the maximum bending angle, comparing the experimental values with the times stated in the technical data sheet.

### Materials & Tools:

- Glove orthosis prototype
- Video camera placed on the table
- White background
- Reference ruler
- Stopwatch

**Participants**: 4 healthy subjects, age to be defined, right hand dominant.

### Experimental Setup:

Hand in prone position, slightly raised.

Video camera perpendicular to the finger's length, fixed distance 25 cm.

White background.

### Procedure:

1. Wear the glove and place the hand on the surface.
2. Insert white sheet behind the finger to be tested (right index).
3. Start video recording.
4. Activate the actuator and simultaneously make a reference gesture in the video (start).
5. When the finger reaches the maximum angle, visibly mark in the video (stop) and turn off the actuator.
6. Repeat for each finger.
7. Perform 2 trials per finger for each participant.

### Data Analysis / Results:

Measure the time between start and stop from the videos.

Calculate mean, standard deviation per finger/participant.

Compare the values with those indicated in the technical data sheet

# APPENDIX B

## Evalutation test for orthosis:

### *1)* Visual Analogue Scale (VAS) -only for hand orthosis

**Comfort complessivo** :


0 = “Per niente confortevole” — 100 = “Estremamente confortevole”

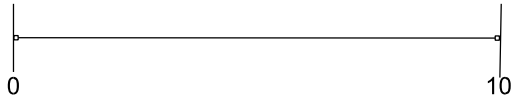
**Vestibilità / aderenza:**


0 = “Molto scomodo / mal adattato” — 100 = “Perfetta aderenza, molto comodo”

**Pressione / dolorabilità:**

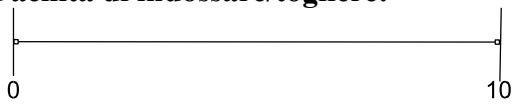

0 = “Nessuna pressione / dolore” — 100 = “Molto pressione / dolore”

**Ingombro / limitazione di movimento:**



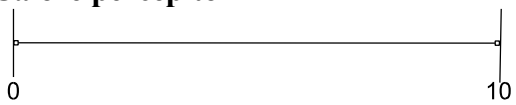

0 = “Per niente ingombrante / nessuna limitazione” — 100 = “Estremamente ingombrante / limita”

**Facilità di indossare/togliere:**




0 = “Molto difficile” — 100 = “Molto facile”

**Calore percepito**:



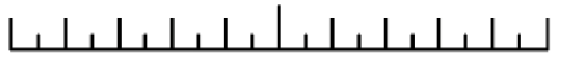

0 = “Non percepito” — 100 = “Molto caldo”

## Comfort Rating Scales (CRS) - Used for both orthoses

**“Inserisca per favore il Suo giudizio:**
Per valutare il nuovo prodotto La invitiamo a compilare il seguente questionario. Si tratta di dimensioni soggettive che consentono di valutare diversi aspetti della percezione di comfort durante l’utilizzo del prodotto, quali emozione, adesione, calore, cambiamenti percepiti, movimento e ansia

Scelga in modo spontaneo senza troppi ragionamenti.
Non esiste una risposta “giusta” o “sbagliata”, ma è importante la Sua opinione personale!”

Emozione



Basso Alto

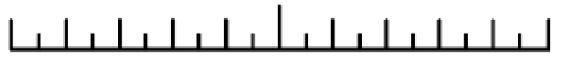
Adesione

Basso Alto

Calore

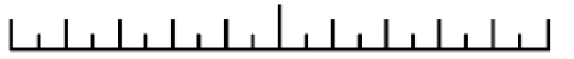
Basso Alto

Cambiamenti percepiti



Basso Alto

Movimento



Basso Alto

Ansia

Basso Alto

# User Experience Questionnaire (UEQ)- Used for both orthoses

**Inserisca per favore il Suo giudizio**

Per valutare il nuovo prodotto La invitiamo a compilare il seguente questionario. Si tratta di coppie di caratteristiche, in antitesi tra loro, che il prodotto può avere.

Esempio:

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| attraente | ○ | ⊗ | ○ | ○ | ○ | ○ | ○ | non attraente |

Con questa valutazione Lei dichiara di stimare il prodotto più attraente che non attraente.

Scelga in modo spontaneo senza troppi ragionamenti.

Non esiste una risposta "giusta" o "sbagliata", ma è importante la Sua opinione personale!

Ora inserisca per favore la Sua valutazione del prodotto. Per ogni coppia di aggettivi è possibile dare una sola risposta.

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | | |
|---|---|---|---|---|---|---|---|---|---|
| fastidioso | ○ | ○ | ○ | ○ | ○ | ○ | ○ | piacevole | 1 |
| incomprensibile | ○ | ○ | ○ | ○ | ○ | ○ | ○ | comprensibile | 2 |
| creativo | ○ | ○ | ○ | ○ | ○ | ○ | ○ | privo di fantasia | 3 |
| facile da apprendere | ○ | ○ | ○ | ○ | ○ | ○ | ○ | difficile da apprendere | 4 |
| di grande valore | ○ | ○ | ○ | ○ | ○ | ○ | ○ | di poco valore | 5 |
| noioso | ○ | ○ | ○ | ○ | ○ | ○ | ○ | appassionante | 6 |
| non interessante | ○ | ○ | ○ | ○ | ○ | ○ | ○ | interessante | 7 |
| imprevedibile | ○ | ○ | ○ | ○ | ○ | ○ | ○ | prevedibile | 8 |
| veloce | ○ | ○ | ○ | ○ | ○ | ○ | ○ | lento | 9 |
| originale | ○ | ○ | ○ | ○ | ○ | ○ | ○ | convenzionale | 10 |
| ostruttivo | ○ | ○ | ○ | ○ | ○ | ○ | ○ | di supporto | 11 |
| buono | ○ | ○ | ○ | ○ | ○ | ○ | ○ | scarso | 12 |
| complicato | ○ | ○ | ○ | ○ | ○ | ○ | ○ | facile | 13 |
| repellente | ○ | ○ | ○ | ○ | ○ | ○ | ○ | attraente | 14 |
| usuale | ○ | ○ | ○ | ○ | ○ | ○ | ○ | moderno | 15 |
| sgradevole | ○ | ○ | ○ | ○ | ○ | ○ | ○ | gradevole | 16 |
| sicuro | ○ | ○ | ○ | ○ | ○ | ○ | ○ | insicuro | 17 |
| attivante | ○ | ○ | ○ | ○ | ○ | ○ | ○ | soporifero | 18 |
| conforme alle aspettative | ○ | ○ | ○ | ○ | ○ | ○ | ○ | non conforme alle aspettative | 19 |
| inefficiente | ○ | ○ | ○ | ○ | ○ | ○ | ○ | efficiente | 20 |
| chiaro | ○ | ○ | ○ | ○ | ○ | ○ | ○ | confuso | 21 |
| non pragmatico | ○ | ○ | ○ | ○ | ○ | ○ | ○ | pragmatico | 22 |
| ordinato | ○ | ○ | ○ | ○ | ○ | ○ | ○ | sovraccarico | 23 |
| invitante | ○ | ○ | ○ | ○ | ○ | ○ | ○ | non invitante | 24 |
| congeniale | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ostile | 25 |
| conservativo | ○ | ○ | ○ | ○ | ○ | ○ | ○ | innovativo | 26 |

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