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COGNITIVE AND MOTOR REHABILITATION
SYSTEM FOR HOME-THERAPY
DEVELOPMENT OF AN ACTIVE HAND EXOSKELETON
AND AN AI-BASED VIRTUAL ASSISTANT

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Abstract

NOWADAYS stroke is the third leading cause of disability worldwide. Every year, more than 6.1 million people are affected by stroke. One of its most common symptoms is contralateral hemiplegia, which particularly involves the hand. This thesis aims to develop a rehabilitative hand exoskeleton focused on the needs of users (therapists and patients) and the challenges still open in the literature, to bring the therapy to the patient's home. In addition, a 3D virtual assistant with natural language processing capability can provide help and encouragement. A desktop application integrates the two systems with passive, active and cognitive exercises based on activities of daily living to reduce the current therapy abandon rate. The results that emerged from the preliminary evaluation sessions with the patients of the Villa Beretta rehabilitation centre on comfort, usability and willingness to use the system are promising.

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List of Abbreviations

A

ABS	acrylonitrile butadiene styrene
ADL	activities of daily living
AM	additive manufacturing
API	Application Programming Interface
ASR	Automatic Speech Recognition

B

BOM	bill of materials
-----	-------------------

C

CAD	computer-aided design
CMC	carpometacarpal [joint]
CNS	central nervous system

D

DALY	disability-adjusted life years
DIP	distal interphalangeal [joint]
DM	Dialog Management
DR	Dictation Recognizer

F

FDM	fused deposition modelling
FK	Forward Kinematic

List of Abbreviations

FMA Fugl-Meyer Assessment

G

GUI graphical user interface

I

IK Inverse Kinematic

IP Internet Protocol

J

JSON JavaScript Object Notation

K

KR Keyword Recognizer

L

LiPo Lithium polymer

LMC Leap Motion Controller

LU Language Understanding

M

MAS Modified Ashworth Scale

MCP metacarpophalangeal [joint]

N

NLG Natural Language Generator

NLP Natural Language Processing

P

PCB printed circuit board

PIP proximal interphalangeal [joint]

PLA polylactic acid

PTFE polytetrafluoroethylene

PWM pulse width modulation

R

REST REpresentational State Transfer

ROM range of motion

S

SDK software development kit
SL stereolithography
SLS selective laser sintering
STL Standard Tessellation Language
STT speech-to-text
SUS System Usability Scale

T

TCP Transmission Control Protocol
TPU thermoplastic polyurethane
TTS text-to-speech

U

UDP User Datagram Protocol

W

WHO World Health Organization

Y

YLD years lived with disability
YLL years of life lost

CHAPTER *1*

Introduction

1.1 Aim of the thesis

According to the United Nations, we are experiencing a social transformation: the world population is ageing. In 2019 one in eleven people in the world will be over 65-year-old [112]. A longer life brings new opportunities, but it can cause an increase incidence of diseases such as stroke. Nowadays, it is estimated that more that 6.1 million people had a stroke worldwide. According to the Global Burden Disease study, stroke is the third cause of disability [59].

A stroke can be defined as a neurological deficit due to a central nervous system infarction or haemorrhage (intracerebral or subarachnoid) [94]. Stroke symptoms vary depending on the type, the severity and the location in the affected area of the brain. However, there are some similarities. One of the most common consequences is contralateral hemiparesis. It involves weakness the side of the body opposite to the harmed brain hemisphere. The most affected parts of the body are limbs, particularly hands.

To regain dexterity to perform activities of daily living, post-stroke patients have to undertake as soon as their conditions have been stabilized a rehabilitative therapy. It can be a long process that usually requires the

patient to move to the rehabilitative clinic periodically and frequently to perform exercises. It has a high social and economic impact on the patient and his/her family and, in the long-term, can lead to the abandon of the therapy. Moving the rehabilitation at the patient's home, when it is possible, allows greater flexibility and increases the sense of autonomy of the patient.

This topic is becoming more and more relevant among scientific literature, and several mechatronic devices for rehabilitation have been developed [3, 50, 76]. These devices seem to be beneficial to rehabilitate the upper limb. However, there are still some open challenges. They include lack in comfort [22], components' development and packing to be transported [50], elevate cost to permit home-based devices adoption [72], the intimidating aspect [76], and the portability [3].

One aim of this thesis is to move a step further developing a portable hand exoskeleton for hand rehabilitation that could be used at patients' home with the help of their family: HANDY. The design process involved also possible users of the device: medical professionals and bioengineers employed at the Villa Beretta rehabilitation centre plus some post-stroke patients. I think that having feedback from the medical perspective is a fundamental advantage for the development of an effective device.

A further issue connected with traditional rehabilitative therapy, related also with the social and economic impact on patients and families, is the therapy abandon rate. Some patients experience difficulties in interacting with these innovative devices, others feel loneliness feeling. This leads me to the second aim of this thesis: the development of a virtual assistant that could be the linking element between patients and therapists. Starting from users' needs, a combination of 3D modelling and Natural Language Processing techniques resulted in MAIA. It is a robot-like 3D virtual character that is able to understand and interact with people using natural language, providing encouragement and assistance.

Moreover, another primary cause of the therapy abandon is the monotony of the therapeutic exercises. Especially in view of an home-therapy setting, it would be necessary an application that includes different types of customised exercises depending on the patient's conditions. For this reason, I developed a desktop application for both therapists and patients. It includes predefined passive repetitive movements, active exercises where the patient drives HANDY with her/his healthy hand thanks to an optical sensor (a Leap Motion controller), and a more engaging serious game based on an activity of daily living that combines motor and cognitive aspects of the disease. It allows me to combine HANDY and MAIA with therapeutic

exercises, offering patients a different, and possibly more engaging, approach to their rehabilitation. Furthermore, therapists can not only use the application to customize the therapy but also monitor and record patients' signs of progress throughout the execution of exercises instead of only in the assessment phases, as it happens commonly.

1.2 Structure of the thesis

This thesis is structured in 7 chapters.

Following this introduction, the second chapter describes briefly the main anatomical concepts related to the human hand, the stroke disease and highlights the limitations and advantages of traditional and innovative rehabilitative techniques.

The third chapter summarizes the principal milestones in the development process of the HANDY exoskeleton. They are grouped logically into its three main components: structure, drive and electronics.

Chapter 4 is dedicated to the final prototype of HANDY. It starts with the computer-aided design of all its parts. Then, it proceeds with a section dedicated to the additive manufacturing technology used to produce these components. Following sections explain the actuation system, the electronic components and how HANDY is controlled. Finally, the final assembly is presented.

The fifth chapter analyses the development process of the assistant MAIA. Initially, the virtual 3D model and then the AI-based algorithms dedicated to natural language processing.

The final application that assembles both HANDY and MAIA and adds different exercises is explained in chapter 6, differentiating the therapists' and patients' sides. It also includes a description and results of the preliminary validation session with patients.

The last chapter summarises the conclusions and possible future work of the thesis.

CHAPTER 2

Medical outline and literature review

This chapter aims to introduce the topic of the thesis describing the context and the reasons that make this work relevant. It starts with a brief analysis of the anatomy and biomechanics of the human hand allowing a better comprehension of the synergies that govern the motor and sensory capacities of this complex organ. Then it moves through the description of the stroke disease. Particularly, definitions of different types with the related symptoms and its global burden which places it among the main causes of disability today. Finally, it highlights the advantages and limitations of standard and innovative rehabilitative techniques for the hand.

2.1 Hand biomechanics

The preliminary step for the development of a safe and effective hand exoskeleton is the knowledge of the biomechanics and anatomy of the human hand. In this section, I desire to present a brief overview about its main anatomical aspects to better understand the concepts and decisions discussed in the following chapters of the thesis.

2.1.1 Overview of the hand anatomy

The human hand is an extremely complex and adaptable body part. It allows performing complex manipulations with various degrees of precision and force. The initial state of the grasp corresponds with the resting posture assumed by a hand described by Taylor and Swartz [104]. The wrist is dor-siflexed 35° from the forearm. This position, also, ensures the maximum possible prehensile force. The fingers are more and more flexed from the second to fifth. Cutkosky in his paper [32] presents a taxonomy of different grasps in a hierarchical tree graph. He starts from two main categories: power and precision. Power emphasizes on stability and security. Precision highlights sensitivity and dexterity. Then considering geometrical and task-related factors, it results in 16 different types of grasp. Furthermore, Kamper et al. [62], in their study, found out that the movement of fingertips while grasping an object tends to follow a curved trajectory. For items of different size, fingertips tend to follow different portions of the same path instead of moving along a new one. According to these results, it is possible to identify some prehension patterns to reach and grasp an object.

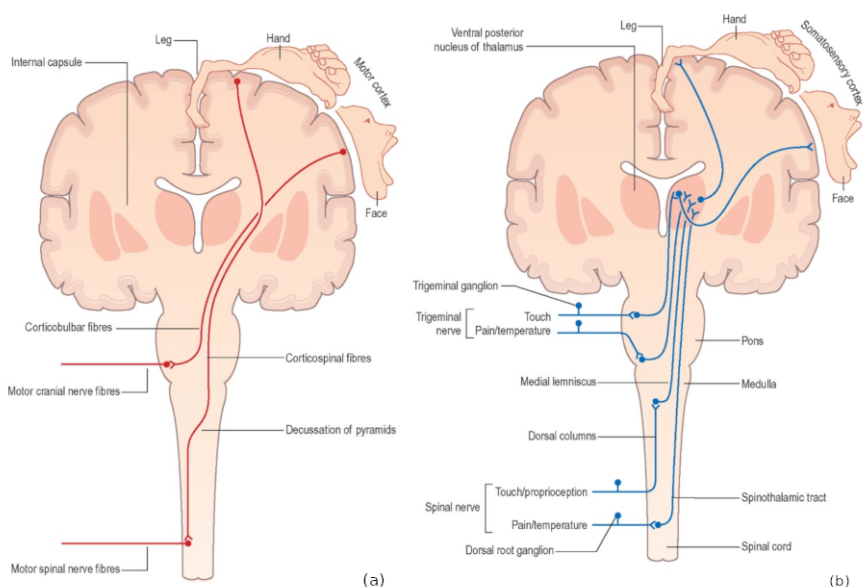


Figure 2.1: *Oversimplified representation of the cortical motor (a) and sensory (b) pathways of neurons. The cortical homunculus shows the wide areas of the brain related to the hand [100]*

Furthermore, it is an extremely important sensory organ. It has a large

number of receptors, especially on fingertips. Without these pieces of information, we would not be able to perceive several qualities of an object and it would be more complex to understand and interact with our surroundings. For instance, we could not interpret surface roughness, temperature, shape, and thickness.

From the brain's perspective, when stimuli from the environment activate sensory receptors, afferent impulses reach the central nervous system (CNS) through the spinal nerves. On the other hand, when stimuli originate from the motor cortex of the brain, they cross to the contralateral side and descend throughout the length of the spinal cord until the peripheral effector organs [100].

In Figure 2.1 can be seen as an oversimplified representation of the ascending (a) and descending (b) pathways. It also shows a cortical homunculus inspired by the one defined by Penfield and Boldrey in 1937 [85]. It represents graphically how body parts are organized in the motor and sensory cortex of the brain. The location shows which area controls the corresponding body part and the altered proportions of the homunculus depict the extension of that area. The dimension of the cortex area is not proportional to the dedicated body part's size, but rather to their capability in performing fine movements and perceive stimuli from the environment [28]. For this reason, the hands occupy a big area in both the motor and sensory cortex. On this last point, we can think about touch acuity. It is the capability to discriminate two neighbouring points on the skin. The minimum separation, also called the two-point threshold, perceived on the fingertips can be as small as 2mm, while on the forearm is about 30mm [19].

Before moving to the next chapter dedicated to the literature review of hand mechatronic devices used for post-stroke rehabilitation, I decided to briefly present an overview of the hand anatomy. Behind the capability to perform a vast number of movements and activities of daily living, there is a complex structure of rigid and soft tissue.

2.1.2 Bones and joints

Bones

The skeleton of the hand consists of 27 small bones: 8 in the carpus, 5 metacarpals bones and 14 phalanges in fingers (5 proximals, 4 intermediate and 5 distals); as can be seen in Figure 2.2.

The carpus's bones are connected to the ulna and radius of the forearm and through radiocarpal and intercarpal joints allows the wrist movements. Particularly, we approximately have: both flexion and extension of 85° ,

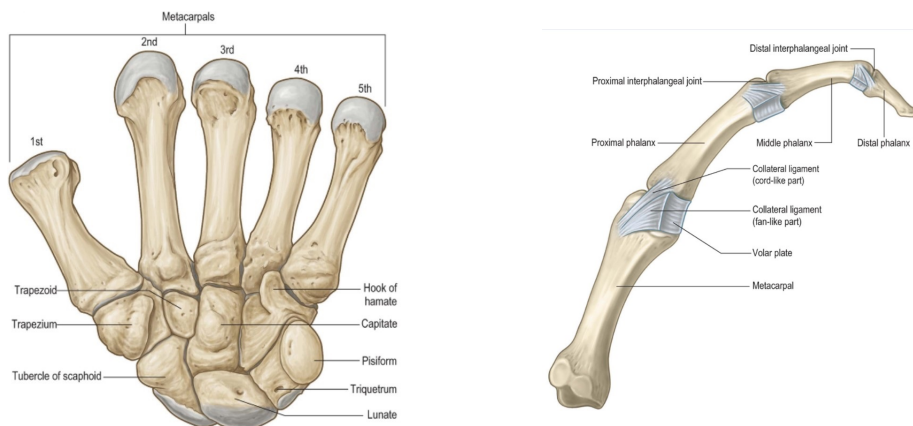


Figure 2.2: *Hand bones in carpus, metacarpals and phalanges [100]*

adduction (ulnar deviation) of 45° and abduction (radial deviation) of 15° [100].

The metacarpus is composed of five metacarpal bones. They are conventionally numbered in the radio-ulnar order from 1st to 5th. While the last four metacarpals are almost parallel, the first is rotated on its medial axis through 90° .

There are 14 phalanges in a hand: two in the thumb and three in each finger. Starting from the metacarpals bones, they are named proximal, middle and distal phalanges. The thumb does not have the middle one.

Joints

Carpus and metacarpus are connected by five carpometacarpal (CMC) joints. The first, at the base of the thumb, is a sellar joint. Its shape reminds a saddle and permits the rotation in two perpendicular planes. In the case of the thumb, flexion and medial rotation are coupled. This anatomical conformation, combined with the position of the 1st metacarpals, allows the thumb opposition, which is the principal factor of manual dexterity in human beings [100]. The other CMC joints are ellipsoid. They have a little motion, which increases moving in the radio-ulnar direction. Especially the 4th and 5th joints allow adapting the palm to a grasped object's shape and size.

The joints that connect metacarpals to proximal phalanges are called metacarpophalangeal (MCP) joints. They are usually classified as ellipsoid joints. This means two degrees of freedom because it permits flexion-extension and adduction-abduction. Also, rotation is possible, even though it cannot take place in isolation and only for a limited amount. Another

movement, called circumduction, can be seen as the succession of abduction, extension, adduction and flexion. The active range of flexion/extension is about $60/0^\circ$ for the thumb and $90/40^\circ$ for the other fingers [63]. The adduction/abduction range reaches about 20° in the 2nd finger and decreases in the others.

The interphalangeal joints can be divided into the proximal interphalangeal joint (PIP), between the proximal and middle phalanges, and the distal interphalangeal joint (DIP), between the middle and distal phalanges. They are both hinge joints. This type of link allows only one degree of freedom: the flexion/extension movement. The range of flexion increases moving from the 2nd to the 5th finger. It varies approximately from 90° to 135° . Similarly, the DIP flexion increases among fingers, but moderately. It changes from a bit less than 90° to 90° [63].

2.1.3 Soft tissues

The bones of our hands are surrounded by several soft tissues. They include muscles, tendons, nerves, blood vessels, ligaments, and synovial sheaths. It is the coordination of all these elements that allows human dexterity. Some of them are visible in Figure 2.3. There are numerous soft tissues in our hands. However, I prefer to do not dwell too much on this topic, but summarize the main concepts.

Ligaments

Ligaments are tissues that connect bones to other bones. Their main aim is to keep bones in place avoiding abnormal bending of joints. Considering, for example, one of the MCP, PIP and DIP joints reported in Figure 2.2, is it possible to identify collateral ligaments on the lateral-side and volar plate on the palmar-side. They prevent sideways and backwards bending of the joint respectively.

Muscles

Muscles are tissues that contribute to moving fingers by contracting. To obtain a gesture, two types of muscles intervene extrinsic and intrinsic muscles. The first, which includes long flexors and extensors, control gross movements. The intrinsics, on the other hand, control the fine motion of fingers. They comprise interosseous and lumbrical muscles.

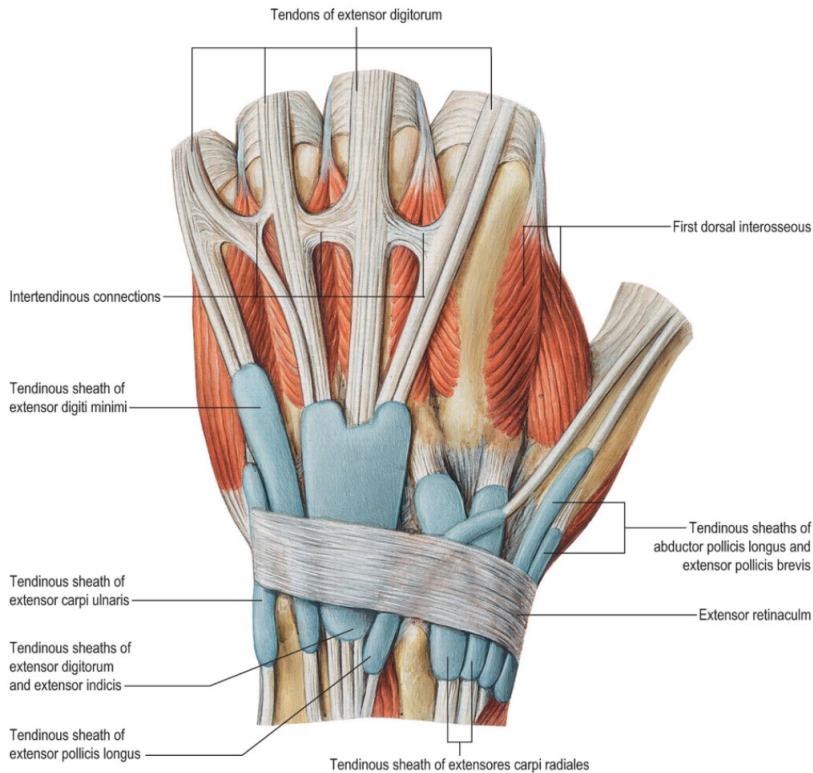


Figure 2.3: Examples of soft tissues present in the dorsal side of a hand [100]

Tendons

Tendons connect muscles to bones. There are numerous tendons in our hands. However, the primal subdivision is between flexor and extensor tendons. The ones located in the palmar side of the hand help flexion of the fingers and are called flexor tendons. On the dorsal side, there are extensor tendons, which are involved in the extension of the fingers.

Nerves

Nerves convey electrical signals from the CNS to muscles to control movements and from the hand to the CNS to transmit haptic feedback. Observing Figure 2.4, is it possible to distinguish the three main nerves in the hand: ulnar, median and radial. The ulnar nerve (■) crosses the Guyon's canal in the wrist and provides sensation to half of the ring finger and to the little finger. The median nerve (■) passes through the carpal tunnel of the wrist

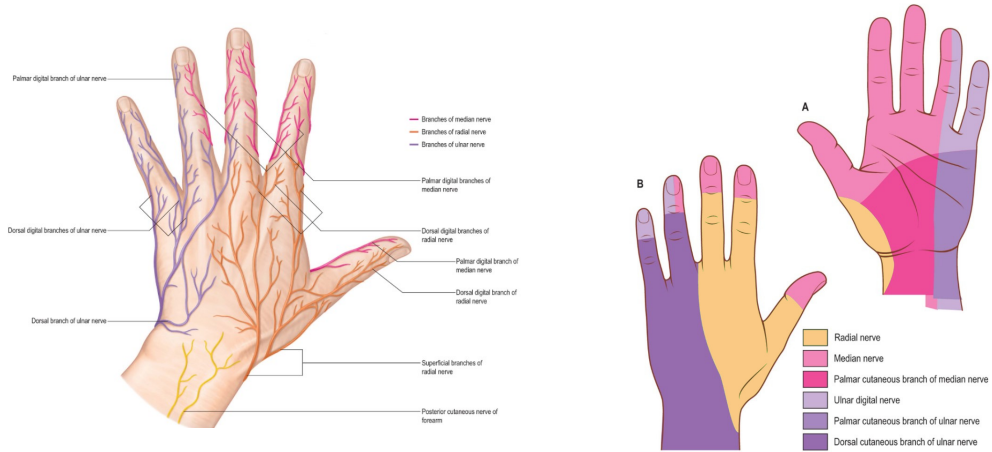


Figure 2.4: *Innervation of the hand. Is it possible to identify the ulnar (■), the median (■), and the radial nerves (■) [100]*

and provides sensation to the other fingers and the palmar-side of the hand. The radial nerve (■) provides sensation on the dorsal side of the hand from the thumb to the middle finger [100].

2.2 Stroke

One of the aims of this PhD thesis is to develop a hand exoskeleton for post-stroke patients. But, what is a stroke? And why it is so important nowadays? In this section, I will try to answer these questions starting from an overview of the central nervous system and then describing the stroke disease. It will be described as the global burden of stroke, and how rehabilitative therapy takes place currently.

2.2.1 Overview of the central nervous system

The human nervous system is the result of a long and elaborated evolutionary process. Thousands of scientists have been challenged to unveil the secrets of our nervous system. Despite the great advances on numerous fronts, our knowledge of neural function and organization is far from complete. It is mainly due to its complexity.

It is estimated that there are a number of intercommunicating neurons and cells in the order of 10^{10} . Furthermore, each neuron may make synaptic contact with thousands of other neurons [100]. However, it is due to this that we are who we are and can interact with the world.

Chapter 2. Medical outline and literature review

The majority of neuronal cells are included in the brain and spinal cord, which communicate with the rest of the body through the cranial and spinal nerves respectively. These nerves contain two different types of fibres:

- afferent fibres, that bring information from sensory receptors into the nervous system;
- efferent fibres, that convey instructions from the nervous system to peripheral effector organs.

By interconnections between afferent and efferent fibres, the nervous system cells can control several bodily functions and conscious awareness. The nervous system requires a high amount of energy to perform its activity. For this reason, the brain has a rich blood supply through a densely branching arterial network (Figure 2.5). It obtains about 15% of the cardiac output and uses 25% of the total oxygen consumption of the body.

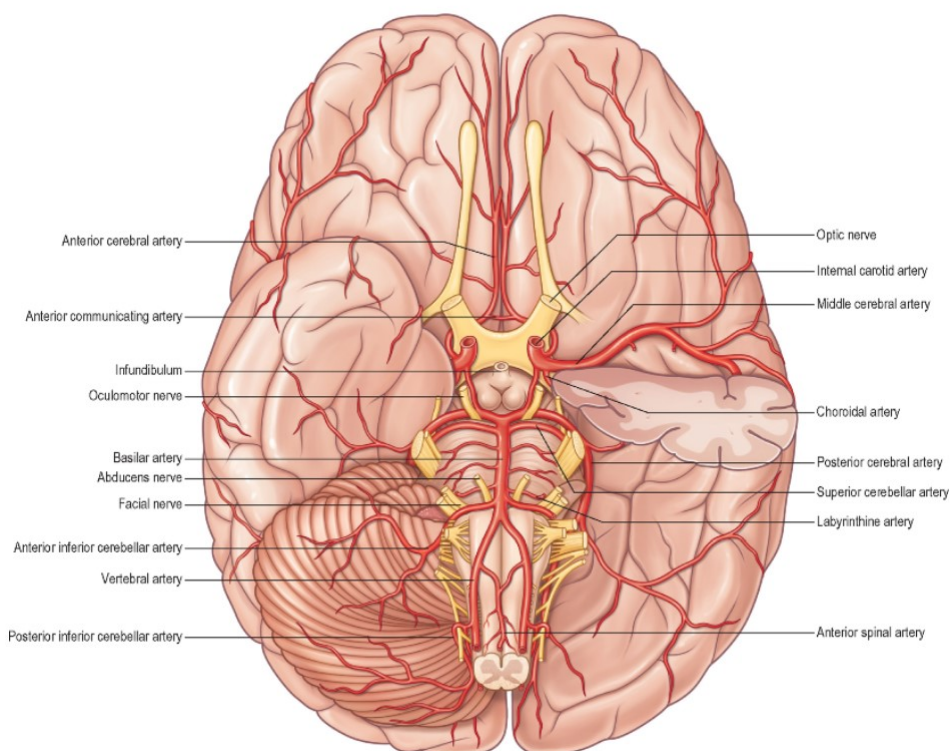


Figure 2.5: *The complex arrangement of the arteries on the base of the brain. [100]*

On the base of the brain, there is a complex circulatory anastomosis, the circle of Willis, that supplies the blood to the brain. It is composed of two internal carotid arteries and two vertebral arteries.

The primary purpose of the arrangement of the brain's arteries into the circle of Willis is to provide redundancy for the bloodstream. Due to the extreme importance of the blood supply to the brain, the circulation must never stop. If one of the arteries supplying the circle of Willis is blocked or narrowed, blood can flow from the other blood vessels. However, this process is not always as fast and efficient as it should be. An acute interruption of the bloodstream for a few minutes can cause permanent neurological damage or death [100].

2.2.2 Types of stroke

Classically, stroke has been defined as a neurological deficit due to a haemorrhage or infarction in an area of the central nervous system (CNS). The medical definition of stroke has been recently updated to account for advances in science and technology [94]. It states that the word "stroke" can incorporate several terms, including:

- CNS infarction: a brain, spinal chord or retinal cell death attributable to ischemia (lack of blood supply in a tissue) in two cases: if it lasts longer than 24h (or until death), or if there is an objective evidence (e.g. imaging or autopsy) that highlight an ischemic injury in a defined vascular distribution [94].
- intracerebral haemorrhage: a focal accumulation of blood, not caused by trauma, within the ventricular system or brain parenchyma [94].
- subarachnoid haemorrhage: bleeding between the pia mater and the arachnoid membrane of the spinal cord or brain (subarachnoid space) [94].

Based on these statements, we can define two main types of stroke: ischemic and hemorrhagic.

Ischemic stroke

An ischemic stroke occurs when a clot or a foreign mass obstructs a blood vessel, reducing the bloodstream to brain cells. The process can start in a big vessel, like the right common carotid artery, where there is a bifurcation or a bend. Here, the impact of the blood against the vessel walls may produce small abrasions. On these minimal lesions, cholesterol or calcium

can deposit and form atheromatous plaques. In these conditions, tiny pieces of plaque and clotted blood may travel in the blood flow to the brain. The foreign mass is called embolus. If it stops in a small artery, it can interrupt the bloodstream to a brain area, causing an ischemic stroke (Figure 2.6).

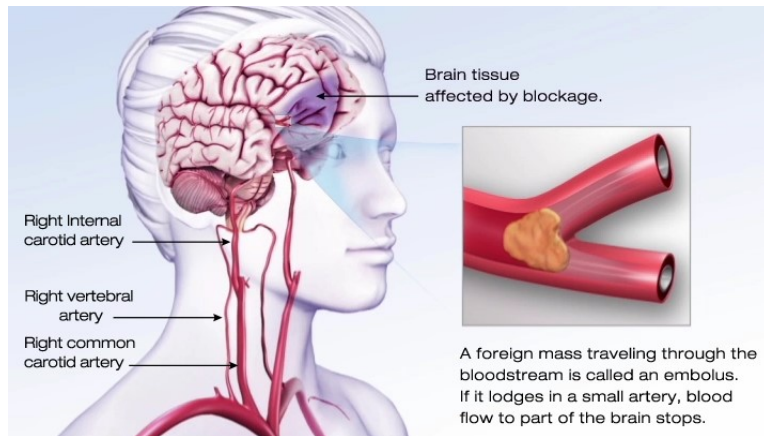


Figure 2.6: Ischemic stroke caused by an embolus. [6]

If the focal dysfunction caused by a clot last for less than 24h, it is called a transient ischemic attack (TIA) [94]. The only difference between TIA and ischemic stroke is that with TIA the blockage is temporary. Unlike a stroke, when TIA is over, there is no evidence and permanent injury to the brain [6].

Hemorrhagic stroke

A hemorrhagic stroke occurs when a damaged blood vessel breaks and bleeds into the surrounding brain area (for example due to aneurysms). It is divided into two categories depending on the site of the haemorrhage: intracerebral and subarachnoid, as defined by [94].

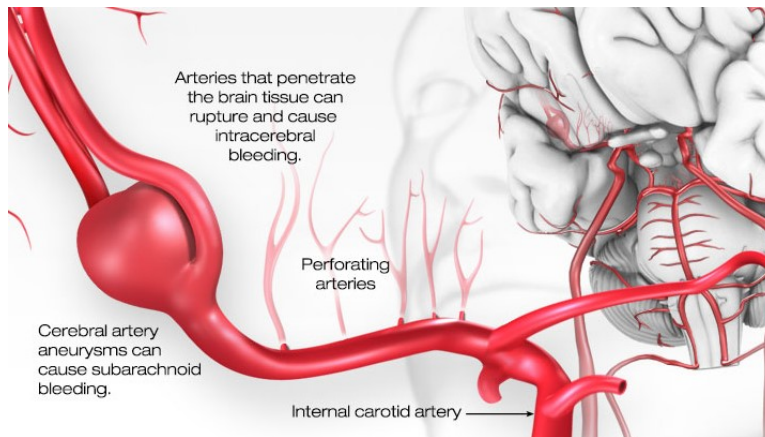


Figure 2.7: Hemorrhagic strokes. [6]

2.2.3 Stroke symptoms

The initial symptoms of stroke may vary depending on the type of stroke and the affected brain area. However, they can include:

- weakness or numbness of the face, arm, or leg, especially on one side of the body (hemiparesis)
- sensory disturbances
- difficulty speaking or understanding speech (aphasia)
- headache or memory problems
- trouble seeing
- dizziness or loss of coordination
- emotional disturbances

Even though the severity and duration of symptoms vary among different people, the evolution of a stroke has many general characteristics [5]. It is more related to where the focused damage is located than the mechanism that caused it.

Regarding the temporal evolution of symptoms, stroke can be subdivided into five main phases, as can be seen in Figure 2.8 [17].

One of the most common symptoms is contralateral hemiplegia. It is a more severe form of hemiparesis and lies in the paralysis that affects, partially or globally, the side of the body opposite to the harmed brain hemisphere.

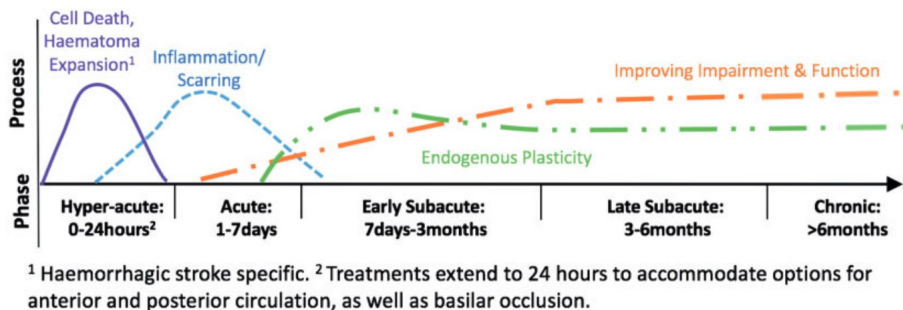


Figure 2.8: *Main phases and processes in post-stroke patients [17]*

The most involved parts of the body are limbs, particularly the upper ones. During the acute phase the muscles of the limbs are flaccid (lose their tone). After a few days or a few weeks, the muscular activity evolves. Some temporarily altered nerve fibres recover their functions and the paralysis stabilizes only in the affected body parts. At the same time, the muscles move from flaccidity to spasticity. The position of the limbs is usually characteristic. In Figure 2.9 there is a picture of a spastic hand of a post-stroke patient, with flexed fingers.



Figure 2.9: *Common hand position in post-stroke hemiparetic patients [118]*

In 1951, Twitchell [108] demonstrated that motor recovery starts immediately after the onset of stroke and follows a foreseeable pattern. These stages have been empirically described by Brunnstrom in 1966 [26]. As can be seen in Figure 2.10, a post-stroke patient can progress from flaccidity to full recovery moving through different levels of spasticity. However, not the totality of patients reach the full-recovery-stage, many of them stop

in the previous ones and remain permanently disable [26, 108].

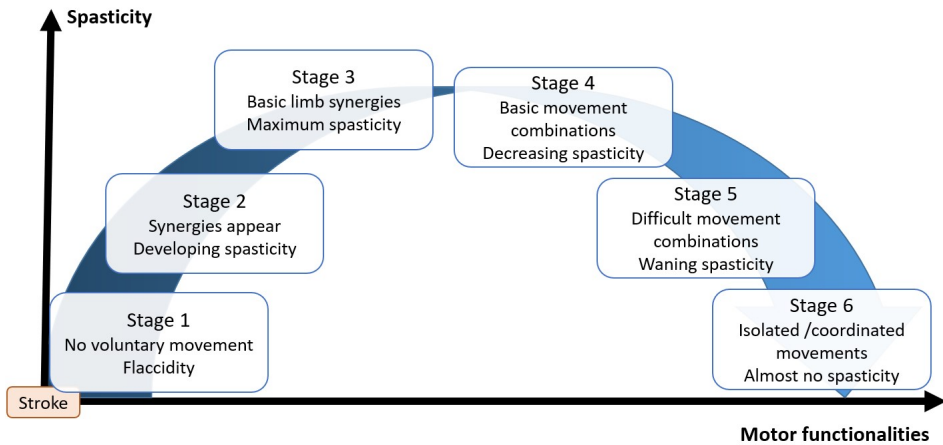


Figure 2.10: Graph that encapsulates the Brunnstrom's phases of stroke motor recovery

One clinical scale widely used by therapists measures spasticity in patients with lesions of the CNS is the Modified Ashworth Scale (MAS) [20]. Its scores are:

Table 2.1: MAS scores and relative descriptions [20]

Score	Description
0	No increase in muscle tone
1	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension
1+	Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the range of motion
2	More marked increase in muscle tone through most of the range of motion, but affected part(s) easily moved
3	Considerable increase in muscle tone, passive movement difficult
4	Affected part(s) rigid in flexion or extension

Another most widely used quantitative measures to assess sensory-motor impairment in post-stroke patients with hemiplegia is the Fugl-Meyer Assessment (FMA) scale [45]. It consists of items scored on a 3-point ordinal scale (0 = cannot perform the task, 1 = task partially performed, 2 = task fully performed). The maximum score is 226 points: the higher is the score, the better are the patient's sensory-motor functionalities. It assesses five domains: motor function, sensory function, balance, joint range of motion, and joint pain [43].

2.2.4 Epidemiology

The Global Burden of Disease Study reports that stroke is a leading cause of death and disability worldwide. In Figure 2.11 can be seen the global number of deaths (a) and disability-adjusted life years (DALY) (b) computed in 1990 and 2017. Both in 1990 and 2017, stroke was the second cause of death. In 2017 there have been about 6.1 million observed cases (11,02% of total deaths) [93]. Furthermore, based on DALYs, it is moved from the fifth to the third cause of disability in the world, with over 132 million DALYs lost in 2017 [61].

The DALY is an index of disease burden. According to the World Health Organization (WHO) definition, it is the sum of two components: the number of years lived with disability (YLD) and the number of years of life lost (YLL) due to premature death. Therefore, the sum of DALYs across the population highlights the difference between the real health status and the ideal one, where the population lives free of disease [116].

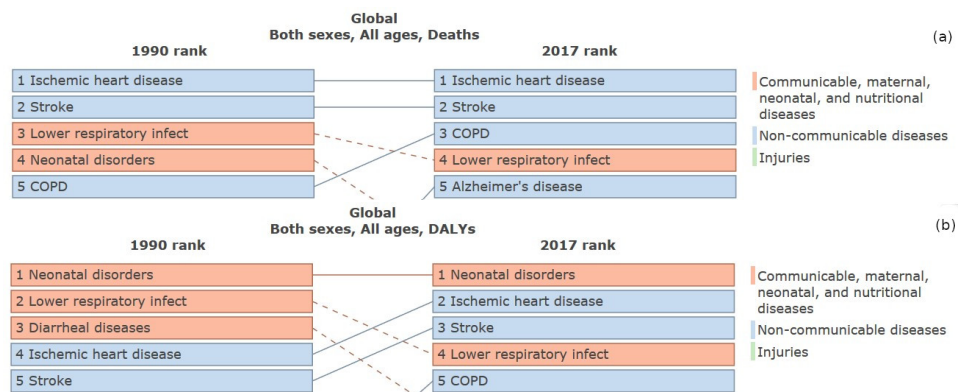


Figure 2.11: Global burden of stroke considering deaths (a) and DALYs (b). It accounted about 6.1 million deaths and 132 million DALYs in 2017 [59]

The YLD index is useful to understand the evolution and the global impact of stroke in terms of disability. In Figure 2.12, it can be seen a rising trend for YLDs, mainly due to ischemic strokes. There is a relevant factor that influences this evidence: the world population is ageing. According to the United Nations report, this can be the most significant social transformation of our century. It impacts nearly all sectors of society. It is estimated that, in 2019, one in eleven people in the world will be over 65-year-old [112].

Another important aspect to consider is the number of years lost due to disability related to the age of the population. In Figure 2.13, it can be

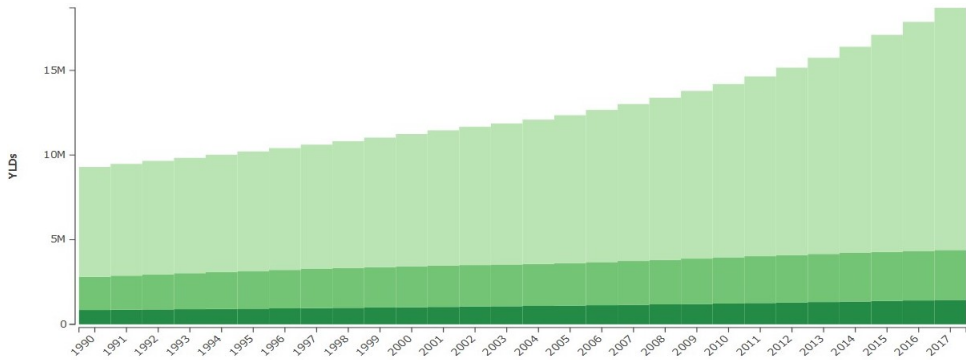


Figure 2.12: Temporal evolution of the number of YLDs due to stroke worldwide for both sexes and all ages, from 1990 to 2017 computed by [59]. It is divided in ischemic (□), intracerebral hemorrhagic (■) and subarachnoid hemorrhagic (■) stroke

observed that starting approximately from 50-year-old, there is a steep increment of YLDs due to stroke, primarily caused by ischemic strokes. This figure also highlights that the majority of stroke survivors are left temporarily or permanently disabled. This places a burden on family and society. According to these observations, we can understand why stroke is considered one of the leading causes of disability worldwide.

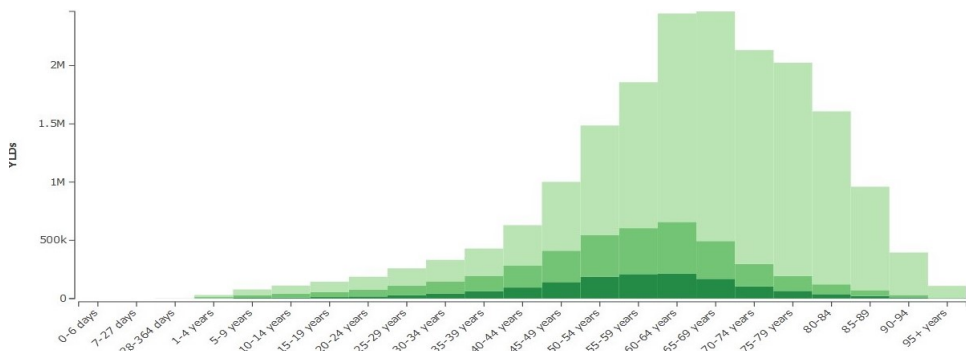


Figure 2.13: Number of YLDs based on the age computed by [59]. It is divided in ischemic (□), intracerebral hemorrhagic (■) and subarachnoid hemorrhagic (■) stroke

2.2.5 Rehabilitative therapy

Rehabilitative therapy plays a vital role in helping people who had a stroke. It can not reverse the brain damage and cure the disease, but it aims to support people to achieve the best possible quality of life after the stroke.

Rehabilitation involves a team of medical professionals due to the numerous aspects and symptoms caused by the accident. Physicians coordinate the long term rehabilitative program and care about the general health conditions of the survivor. Nurses help the patient learn new strategies about how to carry out the basic activities of daily living. Physical therapists treat motor and cognitive disabilities, help survivor to regain the use of stroke-impaired limbs and avoid the learned non-use behaviour (that happen when the patient tends to use only the healthy limb instead of the weakened one). Occupational therapists focus on improving the autonomy of the post-stroke patient in performing activities of daily living. Language pathologists help people with aphasia relearn how to communicate. Mental health experts work on the psychological consequences induced by the disease [81].

Rehabilitation begins as soon as the conditions of the patient have been stabilized. Medical professionals aim to evaluate the strengths and deficits of every patient because the types and the degree of disabilities are different and depend on the location and the extent of the brain damage. The assessment is obtained combining specialistic evaluations, functional scales (MAS, Fugle-Meyer, etc.) and instrumental exams. The outcomes of the assessment allow defining an ad-hoc individual rehabilitation project (that includes the general mid-long term goals) and individual rehabilitation plan (a more specific and detailed therapy program).

In the acute phase, the improvement margins are the highest. Concerning motor rehabilitation, patients start performing passive and active exercises to improve the motor conditions of their weakened limbs. Passive exercises are those in which a physical therapist moves the patient's limb repetitively, active exercises are performed by the patient with the supervision of the therapist.

Many stroke survivors are involved in the rehabilitation process together with medical experts for months or years after the disease. Even when the patient reaches the chronic phase, it is not stable. For instance, if a spastic hand is not continuously treated, it can return to the initial and more severe situation. Usually, it requires the patient to go to the rehabilitation clinic periodically and frequently to perform the therapy. It has a high social and economic impact on the patient and his/her family and, in the long-term, can lead to the abandon of the therapy. Moving the rehabilitation at the patient's home, when it is possible, allows greater flexibility and increases the sense of autonomy of the patient. Furthermore, in a stroke rehabilitation trial for balance and strength of the lower limbs in improving walking obtained equivalent results to the treadmill training in the clinic. However, one

of the main disadvantages of home-based programs is the lack of specialized equipment [81]. This does not mean only technologically advanced devices, but also that they must be suitable for a domestic adoption with non-expert users.

2.3 Devices for hand rehabilitation

In section 2.2 emerged that stroke leaves, every year, the majority of patients with mild to severe disability. In recent years, this aspect has induced a rapid expansion of mechatronic devices for hand rehabilitation (also called hand orthosis) as can be seen in recent research studies and reviews [3, 22, 76, 96]. In Figure 2.14, are shown some devices adopted in clinics. However, the number of commercial robotic devices is very limited [72] with respect to the quantity of prototypes developed in recent decades.

Hand orthosis can be categorized according to numerous parameters such as application field, mechanical mechanism and transmission, actuation, control strategy, etc. [22]. In this thesis, only robotic devices for a medical purpose will be considered, discarding the ones used for military [70] or industrial applications [37].

Considering the mechanical design of hand orthosis they are usually differentiated in end-effector and exoskeleton devices. Figure 2.15 shows two schematic representations of end-effector (a) and exoskeleton (b).

End-effector devices are connected to the patient hand only in its most terminal part [72]. They are usually coupled to or grasped by the patient's hand, such as the Armeo® (Figure 2.14 (a)) and the InMotionAR-M/HAND™ (Figure 2.14 (d)) respectively. The main advantage of an end-effector is its structure. It is mainly independent of the size and the proportions of a patient's hand. In the beginning, it allows an easier design process and later a faster setup in a clinical environment. However, the control of the position of the user's joints can be tough. All the other joints of the upper limb are moved indirectly by the device, therefore the position and force applied to them are not directly controlled by the device.

End-effector devices, compared with exoskeletons, fit different hand sizes and are usually ambidextrous. However, recent researches show that proximal joints training seems to transfer limited benefits to distal parts highlighting new opportunities for exoskeletons [3].

Examples of commercial exoskeletons shown in Figure 2.14 are the Hand of Hope [92] (c), the ExoHand [42] (g), the CyberGrasp [33] (h), and the Gloreha [56] (i).

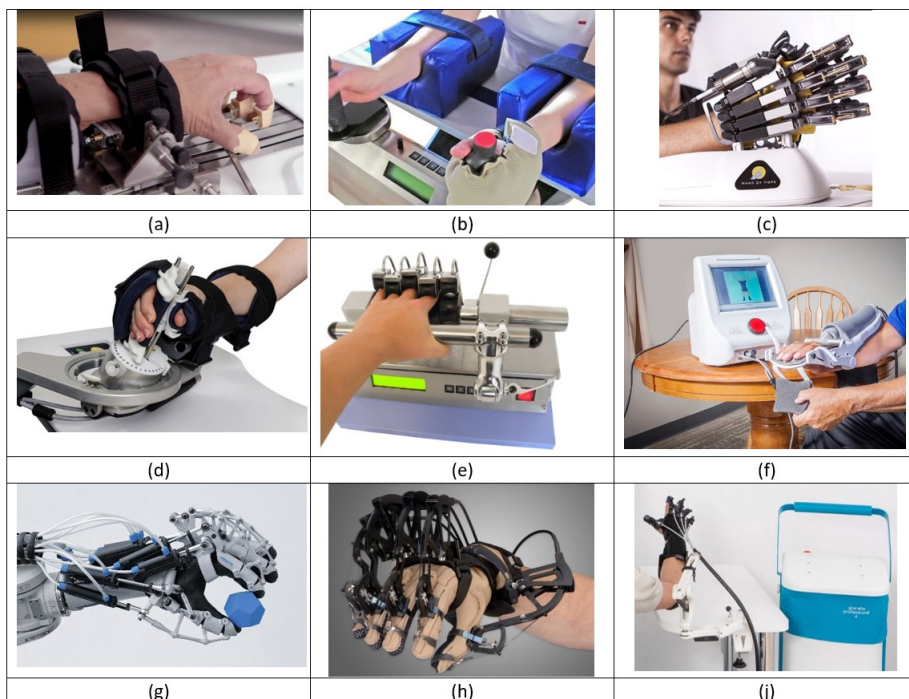


Figure 2.14: Commercial robotic devices for hand rehabilitation: (a) AMADEO® [109], (b) Bi-Manu-Track [90], (c) Hand of Hope [92], (d) InMotion ARM/HAND™ [18], (e) RehaDigit [91], (f) Hand Mentor Pro™ [79], (g) ExoHand [42], (h) CyberGrasp [33], (j) Gloreha [56]

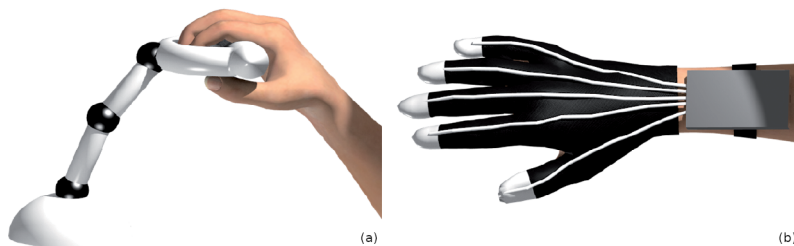


Figure 2.15: General scheme of end-effector (a) and exoskeleton (b) device. Adapted from [76]

Exoskeletons, overlay the patient’s hand. Due to their direct coupling with the fingers, they need to be designed keeping in mind some anatomical aspect of the upper limb, more than end-effector devices.

One important concern is the coincidence of the centre of rotation between fingers’ joints and device. Heo et al. in their article [50] list six so-

lutions to address it. If the exoskeleton is composed by rigid linkages, their centre of rotation should coincide with the anatomical ones, otherwise, it may causes collisions and pain on the hand. They can be placed on the side of the fingers, but it requires additional space. Another solution consists in using remote centres of rotation, but it requires the correct placement of all elements. Also using redundant linkage structure can solve the issue. The next solution adopts a tendon-driven mechanism connected to the fingers. Using soft actuated elements attached to the joints work in the same manner. Finally, it is possible to find in literature mechanisms with only the last segment is attached to the distal phalanx.

During the development process of an exoskeleton, lightness must be considered a high priority [50]. Examples of lightweight exoskeletons based on the tendon-driven mechanism are the Mano [89] and the tenoexo [51] devices.

An interesting trend is emerging in recent years: hand exoskeletons based on soft robotics. It is a section of robotics that deals with soft materials [96]. Examples of soft robotic hand exoskeleton are the Harvard Glove 2.0 [88] and the NUS Glove [119], shown in Figure 2.16. One of the main advantages of soft robots is its ability to adapt their shape to complex bodies. Furthermore, compared with exoskeletons based on rigid linkages, they seem to be more lightweight and compact [96]. However, many of them use pneumatic actuators, which require external pressure reservoir that generates force by inflating air in the flexible bodies.



Figure 2.16: Exoskeletons based on soft-robotics: the Harvard Glove 2.0 [88] (a), and the NUS Glove [119] (b)

2.4 Open challenges

Several studies show that hand training seems beneficial for the rehabilitative process of the upper limb damaged by a brain injury. This led to hundreds of scientific research studies concerning the development of hand orthosis. However, only a few devices are currently available in clinics and even less can be used in a domestic environment. Comparing reviews and papers on this field, it emerged that there are still some open challenges that need to be addressed in order for a prototype to be used within a rehabilitation program.

Firstly, we do not have to forget about the comfort of a device. A painful or annoying device it is unlikely that it will be used with perseverance and desire, as it should happen. One main cause of discomfort is the misalignment between the device and the human hand. It can damage skin and tissues [22].

Most of the advanced devices in this field have only been demonstrated in a laboratory setting. Usually, it happens because not all components are developed enough and packed to be easily transported and used in daily life. Challenges also involve reliable power source and wireless technologies [50].

Maciejasz et al. state that, even though numerous devices are technically advanced, there is still the need to reduce the cost of home-based devices that allows therapy based on activities of daily living [72].

The economical aspect is considered a big issue also by McConnell et al. as stated in their review [76]. They suggest that 3D printing technology could be a possible solution to build customized devices. They also report a usually underestimated concept: the appearance of the device. They state that: "if a machine appears intimidating, it may affect the patient's progress or desire to use the device". A valid solution that can prevent this negative consequence is to include therapists and patients into the development process [76].

Finally, one further big open challenge highlighted in numerous reviews is that many exoskeletons in literature lack of portability, while they should be portable to allow home and personal use [3].

Starting from this perspective, in this thesis we want to examine if it is possible to create a prototype of exoskeleton for the hand that can be used by post-stroke patients at their home. In particular, it would contain all the features previously mentioned that are often missing in the literature, such as portability, comfort (for example avoiding skin abrasion and misalignment), customization, and an affordable cost.

CHAPTER 3

Roadmap and milestones

In this chapter will be summarised all the steps that bring to the final prototype of HANDY starting from the needs of medical professionals and post-stroke patients, the possible target users of the device.

3.1 Evolution

In literature, there are pieces of evidence that the development of a medical device requires to consider the needs and capabilities of its users. In case of a rehabilitative exoskeleton, "users" are not only the patients but also the healthcare professionals who use the device to treat them [52]. Despite this, only a limited number of researches involve users during the whole development process. This process results challenging because it requires inevitably time and financial resources for the development team, patients and therapists. Furthermore, a test session of the device with users it has to satisfy ethic and safety requirements [75].

In this thesis, the aim is to develop a wearable hand exoskeleton to aid post-stroke patients to undertake rehabilitative exercises that would improve their conditions. User involvement has been a paramount aspect of the development process. Since the initial phases of the research, bioengi-

neers and medical professionals of of the presidium of the Valduce Hospital "Villa Beretta" in Costa Masnaga, specialized in the rehabilitative treatment of congenital or acquired diseases, have been involved in the development of the exoskeleton with meeting, interviews, focus groups, and test of the prototypes. Even though it was a labour-intensive strategy, it allows me to have always feedback from the viewpoint of a possible final user.

Regarding patients, they have been involved at the beginning to understand their needs. Particularly, they stated that the aspect of the device should be smooth and not bulky, it must be lightweight to enable rehabilitative sessions lasting several minutes, told us about the desire to be able to perform the exercises, etc. Then, only in the advanced phases of the development, some patients tested the device and provided us with their impressions regarding the comfort, and their willingness to use it in a clinic and possibly at home. We decided to include them for testing only with the latest prototypes because we wanted to be sure that the device was secure enough and comfortable to use.

The result of this procedure is the hand exoskeleton HANDY. It is described in detail in Chapter 4. Here are presented the main milestones of the development process and are highlighted the advantages, the limitations and the reasons behind a transformation from one prototype to the next one. Figure 3.1 summarises through an infographic the overview of the HANDY's roadmap. We can identify three main development strands:

- **Exo:** it includes all the elements of the exoskeleton connected to the patient's hand, which aim to guide the fingers during the flexion-extension movement. It consists of five main prototypes.
- **Drive:** it identifies the mechanical components (actuators, transmissions, couplings, external structure, etc.) that supply to the Exo the needed force to contrast the patient's hand spasticity and perform the desired movement. It involves two main steps.
- **Circuit:** it represents all the electrical and electronic equipment developed to interact with the actuators, providing instructions (position and speed) and receiving state information (measured position, current consumption, boards' temperature, etc.). It required two main prototypes in the roadmap.

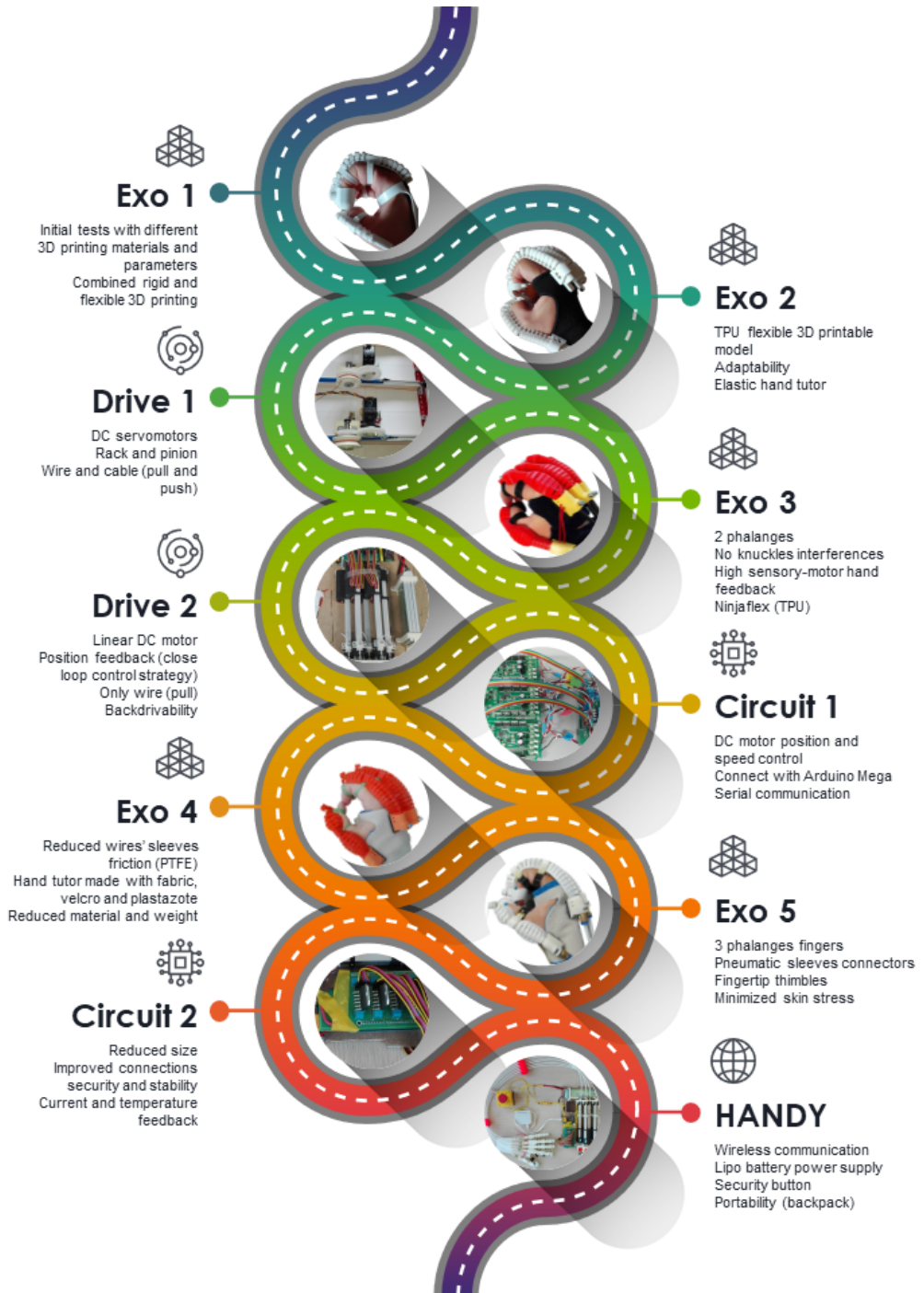


Figure 3.1: Roadmap and milestones in the development process of HANDY

3.2 Exoskeleton

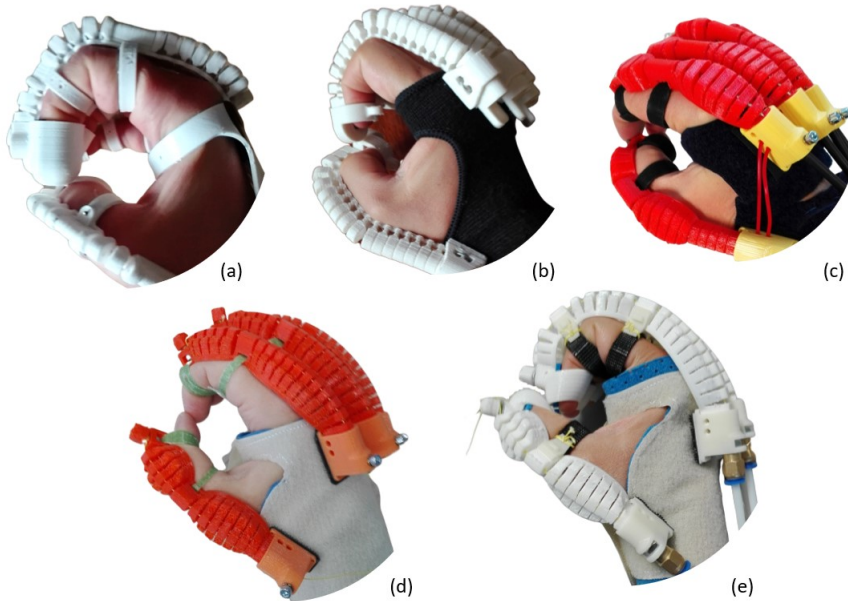


Figure 3.2: *Evolution of five prototypes for the exoskeleton*

The initial requirements and suggestions from the bioengineers and therapist from Villa Beretta regarded:

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

Considering the limited space on the hand and amount of supported weight, it was decided to use a remote actuation system. It inheres in placing the actuators not on the hand, but in an external structure and transmit

the force using Bowden cables. They are flexible cables that transmit mechanical force by the relative movement of an inner cable to a hollow outer cable cover.

The prototype (a) in Figure 3.2 represents the initial concept developed to satisfy the suggested requirements. It has elements placed on the dorsal side of the hand. Additive manufacturing technology allows to rapid prototype the concepts and to obtain, at the same time, a lightweight and inexpensive exoskeleton. I combined the polylactic acid (PLA) rigid material for the guiding elements and the thermoplastic polyurethane (TPU) flexible material for the base. The structure consists of multiple vertical and rigid elements over the knuckles connected to a flexible base. When the phalanges' joint flex, the rigid elements rotate and open like a bellows. Each element has a hole for the push-pull inner wire of the Bowden cable. This arrangement permits to guide the wire during flexion/extension and avoid hyper-extension creating a mechanical stopper. In this prototype, also the tutor was globally printed in TPU. However, due to the limited size of the building plate and the mono-extruder of the 3D printer (initially I used a Sharebot NG [97]), all the components needed to be fixed together manually during the post-processing. Furthermore, the length of the phalanges and the position of the elements on the tutor were fixed, limiting the versatility of the device to different hand sizes.

To overcome these negative aspects, in (b) the guiding elements over each finger were 3D printed in TPU. Moreover, the component did not have a subdivision between rotating elements over the knuckles and rigid ones in the middle of phalanges. These changes reduced notably the time required to produce the components and permitted higher adaptability of the model concerning the fingers' length. It is connected to the back of the hand with a rigid element, that resembles a tunnel, sewed on the tutor. This rigid component allows sliding the flexible part until it covers the finger correctly, and then fixes it passing a wire through the side holes of both components. However, the initial tests with both medical professionals and healthy subjects highlighted three main problems. Firstly, during flexion, the contact between the knuckles and the exoskeleton caused skin abrasion and discomfort. Secondly, the mechanical alignment between finger and exoskeleton failed while the user closed the hand. Thirdly, a rigid thimble placed on the distal phalanx limited the somatosensation feedback of the user and made it complex to interact with real objects.

In (c) is visible one of the major innovation of the exoskeleton that permitted to solve both issues of mechanical alignment and knuckles contact emerged in the previous prototypes and visible in some experimental and

commercial devices (such as [56,84,89,120]). It lies in an innovative design of the flexible components (the orange part in Figure 3.2 (c)) that presents ovoid and concave surfaces in the areas over the fingers knuckles. during the flexion, it deforms sliding on the sides of the finger and covering the knuckles without touching them. It enables, at the same time, stabilizing the position of the guiding element and avoiding skin abrasion. The negative side of this design is the limited adaptability to different hand length. However, considering the reduced cost and production time due to the additive manufacturing technology and the aim of home-therapy, also the therapists agreed with this decision. The pros introduced in this design overcome the cons of a limited versatility. It is also visible that (c) covers only the proximal and middle phalanges, leaving the distal one free and maximising the somatosensation feedback. The flexible elements have been 3D printed using NinjaFlex [83], a patented TPU material. The connection elements are still present, made in PLA (in yellow), but have been modified to fix also the Bowden outer cables that guide the push-pull cables. They also have a strip of Velcro sewed on their bottom side to adjust the position of the component on the tutor, based on the hand sizes (for both length and width).

In (d) I focused on decreasing the amount of material without compromising the resistance of flexible components. It reduces production cost and time. Moreover, it improves comfort by reducing the weight and increases the flexibility of the part. With this prototype, it increases also the sensitivity on the security of the device. Firstly, the screw placed at the end of the flexible part, over the middle phalanx and used to fix the pulling wire, was covered with a flexible cap in TPU to prevent unwanted wounds. Secondly, in case of necessity, the tutor should be easily removed. For this, I moved from an elastic commercial hand tutor (visible in (b)) to the one I manually made with Velcro strips for the closure. Thirdly, the inner material of the tutor had to be specific for skin contact. To satisfy this requirement, I added a thin layer of Plastazote® [121], a non-toxic flexible material widely used in healthcare.

During a further focus group with medical experts emerged that some patients necessitate that the guiding element is connected to all phalanges, even the distal one. For this reason, in (e), the flexible component presents three concave ovoid surfaces, one per knuckles, and a thin thimble made in TPU. The latter allows a more stable connection with the finger, compared to a strip of Velcro, and, at the same time, does not limit excessively somatosensation feedback from the environment. The upper inner surface of the thimble (where there is the nail) is also covered by the soft Plastazote.

The middle and proximal phalanges are still fixed by Velcro, but it is sewed to rigid interchangeable partial rings 3D printed in acrylonitrile butadiene styrene (ABS). These rings improve the stability of the main flexible element on the finger. Furthermore, the rigid element used to connect the flexible one to the hand tutor has been made in ABS and has a new design. It allows coupling with the Bowden outer cable using a nut and a threaded pneumatic push-in fitting. The Bowden tube has been changed with one in polytetrafluoroethylene (PTFE) reducing its weight and increasing the flexibility maintaining a low friction coefficient [41]. Moreover, also the main colour of the filament has been changed in white following medical and literature suggestion [29].

Figure 3.3 summarises how much the five prototypes satisfy six properties/characteristics:

- **Grasping real object:** identifies the capabilities for the prototype to allow the user grabbing and interact with real objects. It depends on the relative position of the device compared to the user's hand and the shape of its elements placed on the palmar side of the hand. All prototypes are placed on the dorsal side of the hand. Theoretically, this permits to grasp objects. However, the thimbles in (a) were too rigid and in (b) their shape, designed to connect a pulling wire below the fingertip, impeded a firm grip. Prototypes (c) and (d) did not have thimbles and was connected to the proximal and middle phalanges of fingers using Velcro strips, allowing to grasp objects. The last design (e) still uses Velcro strips but has also a thimble. However, it is thin and 3D printed using a flexible material. It can adapt itself to the real object shape, enabling the interaction.
- **Somatosensation feedback:** refers to all sensations/signals received by the CNS from the somatosensory receptors of the skin (it is also known as the sense of touch). This property is related to the amount of skin that not covered by other rigid elements. It increases from prototypes (a) to (d) that has free fingertips and small bands of Velcro and permits perceiving the shape and the roughness of an object. The last design (e) can also provide somatosensation feedback. Even though less than (d) because it has thimbles, being flexible they allow perceiving the shape of a grasped object.
- **No contact with knuckles:** means how the device interacts with the human fingers while opening them. Both prototypes (a) and (b) have linear dorsal elements that while finger flex, they come into contact

with the knuckles causing discomfort and skin abrasion. In (c) I introduced one of the biggest improvements of HANDY. The flexible elements are not more linear, but over the knuckles, the shape became ovoid and concave. It allows the Exo to pull the finger limiting the contact with the skin during extension. In (d) and (e) I improved the shape so that the surface leaned to finger's sides during flexion.

- **Non-antagonistic drive:** signifies whether the actuators and the transmission system obstacles user voluntary movements or not. For instance, if the rehabilitation exercise involves opening the hand, is the patient able to open the fingers as much as possible or the device impedes the action? Till prototype (c), therapists suggested controlling both flexion and extension of the fingers. It required a rigid push-pull cable inside each dorsal structure. However, this obstacle the voluntary movement of the user. For this reason and considering the flexed position of the spastic hand in a post-stroke patient, we decided to focus only on the extension of the fingers. From Exo (d) I used a braided wire to open the fingers to not interfere with the patient's volition. However, the prototypes (d) and (e) are designed to be easily adapted for the usage with push-pull cables instead of the wire, to transform the device for patients with flaccidity that require assistance in both extension and flexion of the fingers.
- **Mechanical alignment:** consists in keeping the Exo elements placed on the user fingers aligned with them during flexion-extension and adduction-abduction movements. Two aspects upgrade this property in the HANDY development process. The first is the shape of Exo with ovoid concave surfaces, introduced with (c) that improves the alignment during flexion-extension. The second is the rigid connection element combined with Velcro between the Exo and the patient's phalanges, used only in (e), that enhances the stability also for adduction-abduction.
- **Adaptability:** is related to the Exo versatility for different hand sizes. Exo (a) has low adjustability because the length of finger segments are defined and it is a unique system, with all parts glued together. (b) has a higher level of adaptability among all prototypes. The 3D printed element is connected to the tutor with another element that resembles a gallery. It can slide inside the 'gallery' to adapt the device to the fingers' length. Furthermore, due to it is linear, it is also independent of the fingers' width. From Exo (c) to (e) the adaptability is limited. They can adapt moderately to different hand dimensions (using

few sizes) considering that the phalanges are fastened using Velcro to adapt fingers' width and the dorsal flexible parts are connected to the hand tutor using Velcro, that can be translated along the metacarpus to fit the joints' position.

- **Comfort:** it depends on how a user perceives the worn device. Even though it is a subjective and qualitative property, it is associated with several quantitative aspects, many of them related to all the previous properties. During the roadmap, I aimed to improve the global comfort of the exoskeleton. Moving from push-pull rigid cable to braided wire I was able to notably reduce the weight on the hand due to the sleeves and increasing also the flexibility of the latter to better follow the arm posture and movements of the user. Changing the shape of the Exo Fingers on the knuckles from linear to ovoid and concave I reduced undesired pressure and friction with the skin. Adding Plasta-zote to the glove it becomes more breathable and soft.

	Exoskeletons					Legend:
	(a)	(b)	(c)	(d)	(e)	
Grasping real objects	⚠	⚠	✅	✅	✅	Low ❌
Somatosensation feedback	⚠	⚠	✅	✅	✅	Medium ⚠
No contact with knuckles	❌	❌	⚠	✅	✅	High ✅
Non-antagonistic drive	❌	❌	❌	✅	✅	
Mechanical alignment	❌	❌	⚠	⚠	✅	
Adaptability	❌	✅	⚠	⚠	⚠	
Comfort	❌	❌	⚠	⚠	✅	

Figure 3.3: Summary of exoskeleton's evolution

3.3 Actuation system

The next element that changed considerably during the development process that leads to HANDY is its actuation system. Since the beginning of the research, it has been decided to use a remote actuation system with Bowden cables. This system can have two configurations: push-pull or pull only, depending on the type of inner cable is used. Bowden cables suited the needs of the exoskeleton.

Considering the push-pull configuration, because it is the most adaptable to the user needs, it demands a linear motion of the inner Bowden cable. Furthermore, preliminary tests have shown that to completely flex and

extend a hand it has been required about from 4 to 6 cm of stroke, depending on the hand size and the mechanical backlash. Moreover, it has been decided to use five actuators, to permit the patient to perform the widest variety of rehabilitative exercises, leaving each finger independent from the others.

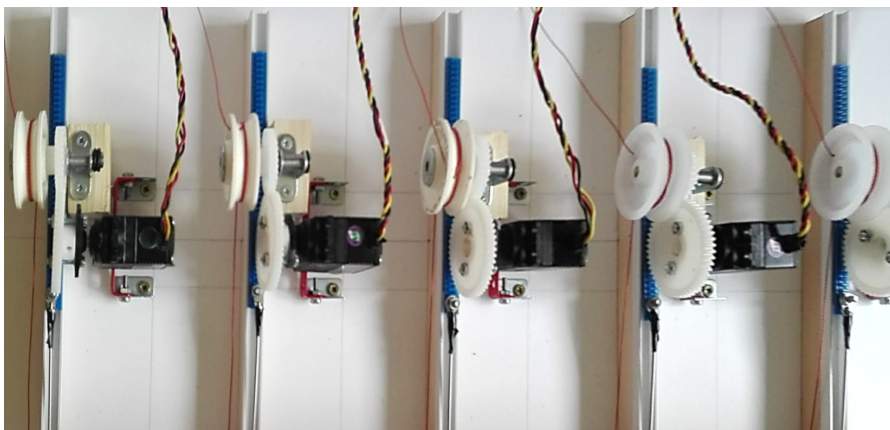


Figure 3.4: *First prototype of actuation with servomotors and rack-pinion*

When the Exo2 prototype (Figure 3.2 (b)) was finished, I decided to test it to verify that its operating principle satisfied the requirements imposed by the users. To obtain the first results, I build a simple actuation system based on the rack and pinion configuration with some components readily available. Rack and pinion is a mechanical type of linear actuator where a circular gear (pinion) engages a linear one (rack), translating rotational motion into linear motion. Figure 3.4 shows a picture of the arrangement. Five rotational digital servomotors Hitec HS-7955TG have been coupled with resin gears with a nominal diameter of 40mm. The pinion interlocks with a rank that translating inside a guide push or pull a Bowden inner cable. Furthermore, to assist each cable in the finger flexion (pushing), it was added a pulley rigidly connected to another gear engaged with the pinion. When the pinion rotates anticlockwise, the pulley rotates clockwise and pull a wire fixed on the bottom side of the thimble placed on distal phalanx in Exo2. Progressing in the development process and designing Exo3 (Figure 3.2 (c)), the second gear with the pulley was not necessary anymore. Even though the basic setup based on mechanical actuators with servo motors and rack-pinion worked, it highlighted several aspects to improve. They involved the elevate amount of space required to place actuators plus rack and pinion setup, the elevate backlash between rack and pinion causing unreli-

able behaviour, and the open-loop control due to the type of servo motors and the setup (I could set the desired position of the servo's gear but I could not verify the actual position of the rank).

Based on these considerations, it has been decided to use directly five more reliable linear actuators. Hydraulic, pneumatic and electro-mechanical linear actuators have been compared considering cost, availability, size, weight, and control system. Hydraulic and pneumatic actuators have been discarded due to their higher weight and space required, coupled with an external reservoir and more complex setup and control than electro-mechanical actuators. The electric micro linear actuators from Actuonix Motion Devices [2] seemed promising for my purposes, and particularly, the T16-P miniature track actuator with feedback made available in 2017. The track configuration, compared to the standard one with a rod, uses a mounting block that travels along a track rather than extending rod [57]. This means that a T16 requires almost half-space for the same stroke. Considering the requirements in terms of stroke, force and position feedback, I decided to use the T16-100-22-12-P. The abbreviation stands for model T16 (track) with 100mm stroke and gear option 22:1 (peak power point 40N at 26mm/s and peak efficiency point 25N at 34mm/s) rated at 12V with potentiometer position feedback. Furthermore, they weigh only 119g each. Figure 3.5 shows the arrangement of the five Actuonix T16-P.

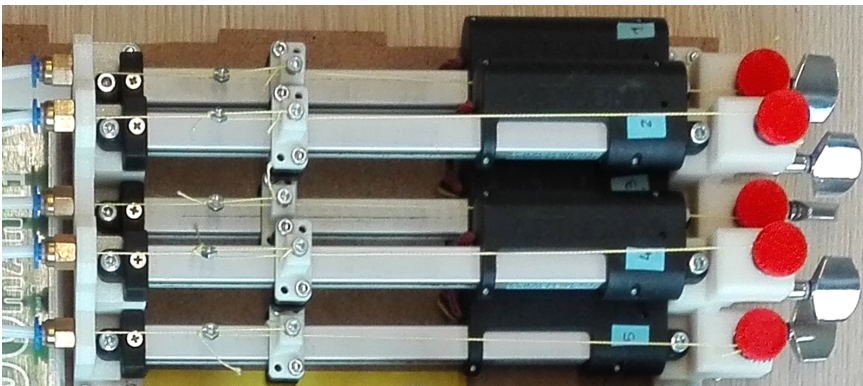


Figure 3.5: *Final actuation setup with linear actuators*

3.4 Electronics

Once the linear actuators have been chosen, the first step was to verify their characteristics. One element to take into consideration of the T16-P is that, unlike servo motors, it has only two wires to control speed and direction

(red: Motor V+ (12V), and black: Motor V- (Ground)). The direction depends on the polarity of the two wires, and the speed is modulated changing the driving voltage. The desired position of the block on the T16 can be set using the feedback provided by the internal potentiometer of the linear motor. The linear actuator has to move in the correct direction until it reaches the right position. To do so, a potentiometer, an Arduino Uno board [8], and an h-bridge DC dual motor driver board, have been combined, as can be seen in Figure 3.6. The potentiometer sets the desired position. The Arduino Uno board reads the analogue value of the potentiometer and provides the signals for speed and direction needed to the motor driver board, based on the error between the desired position and the one measured from the T16. The motor driver board modulates the driving voltage and set the output polarity to move the actuator correctly. In this setup, a Rigol DP832a programmable DC power supply [58] was used (Figure 3.6 (b)). It not only provided the correct input voltage equal to 12V but measured also the amount of current absorbed by the actuator during the test. The average value with no resistance load was about 0.149A.

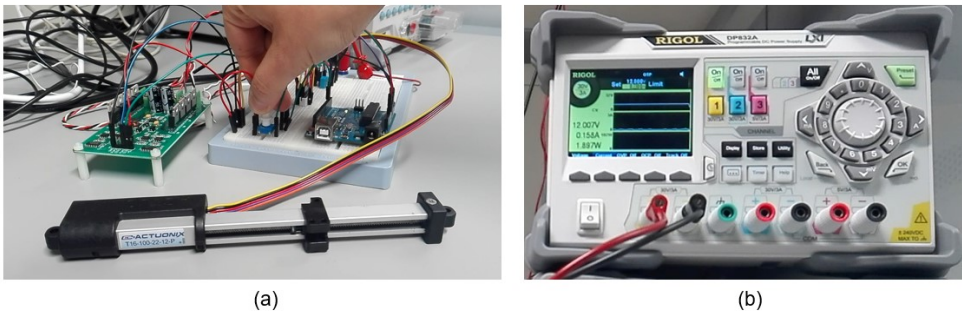


Figure 3.6: Preliminary tests on the position control of linear actuator using a potentiometer (a) using the Rigol DP832a programmable DC power supply to monitor the amount of current absorbed (b)

The next step consisted in controlling all five actuators. It required a new setup (Figure 3.7) with three DC dual motor driver boards, a small board created to arrange the input-output wires, and an Arduino Mega 2560 Rev3 board [7] because the number of pins in the Arduino Uno was insufficient. This time, the desired position of each actuator was controlled with serial communication between a PC and the Arduino board.

Once it was verified that the actuators respond correctly to the instructions provided by a PC, it was decided to design a specific and compact printed circuit board (PCB) that allows to control the actuators eliminating tangled jumper wires and, at the same time, increasing the stability and

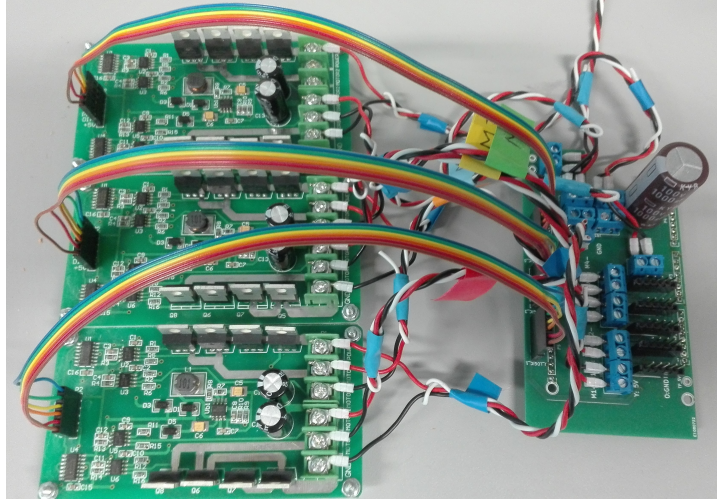


Figure 3.7: *First electronic setup that allows to control the position of all five T16-P linear actuators*

reducing signal noise. The final result is visible in Figure 3.8. As can be seen, it has been designed based on the Arduino Mega 2650 Rev3 footprint so that they can be connected directly. A more detailed description of its design, components, and characteristics are described in Chapter 4.

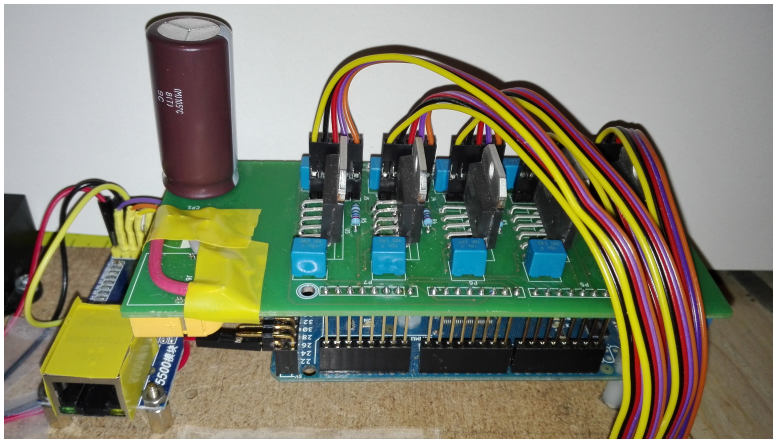


Figure 3.8: *Final layout and electronic boards used in HANDY*

CHAPTER 4

HANDY

In this chapter, it will be explained more in detail all the constitutive elements of HANDY, how they have been designed and created and the reasons behind certain decisions. In particular, how the mechanical parts have been designed and produced using additive manufacturing, how HANDY is able to help patients performing flexion using actuators and how the electronic components have been created and used to control them.

4.1 Computer-Aided Design

I decided to start with the description of all components that have been created from scratch and designed using a parametric computer-aided design (CAD) software: Autodesk Inventor® Professional 2018 (called only Inventor from now on) [12]. All parts I designed for HANDY can be logically split in two categories: components related to the finger assembly, and all other parts, including the ones used as structural elements.

4.1.1 Finger assembly

Figure 4.1 shows a rendering of the Index. The main architecture and components are common among all Fingers. They are highlighted in Figure 4.2 and described in the bill of materials (BOM) (Table 4.1).

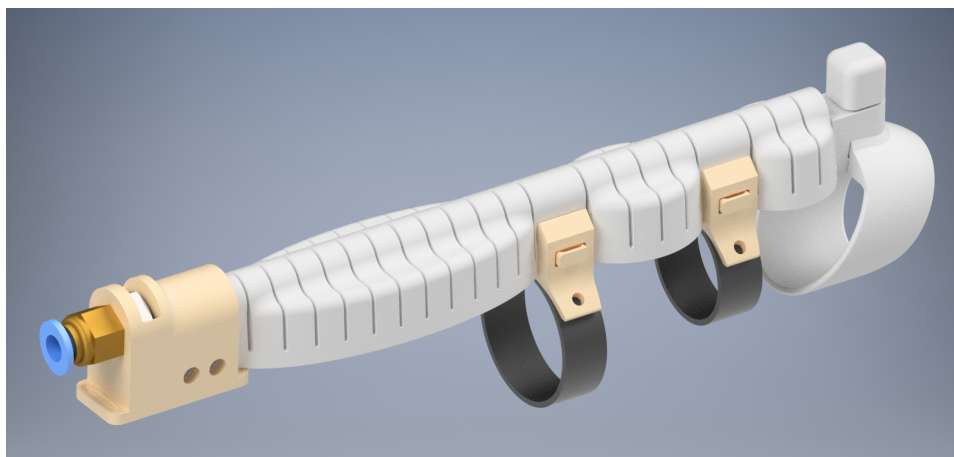


Figure 4.1: Render of Index Finger

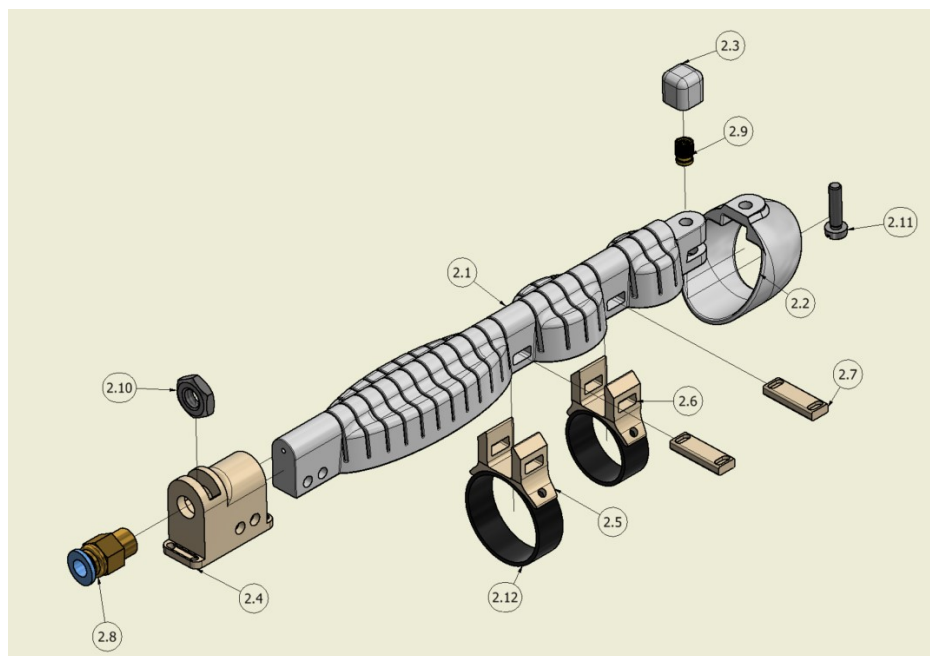


Figure 4.2: Exploded view of the Index Finger

Table 4.1: BOM of the Index related to Figure 4.2

Item	Qty	Part name	AM	Description
2.1	1	Body_2B	F	Flexible Index body size B
2.2	1	Thimble_33	F	Flexible thimble to fix the Finger_2B to the patient's distal phalanx
2.3	1	Stop	F	Flexible cap to fix and cover the screw
2.4	1	FingerLock	R	Rigid locking system used to fix the Finger_2B to the Bowden tube and the glove
2.5	1	Ring_25	R	Rigid part of ring with a diameter of 25mm, used to fix the Finger_2B to the patient's proximal phalanx
2.6	1	Ring_20	R	Rigid part of ring with a diameter of 20mm, used to fix the Finger_2B to the patient's middle phalanx
2.7	2	RingLock	R	Rigid element used to fix the Ring_20/25 to the Finger_2B
2.8	1	BrassPneumM6		Brass M6 thread male straight push in fitting for the Bowden tube and the FingerLock
2.9	1	BrassInsertM3		Brass M3 threaded insert for plastic
2.10	1	ISO4035_M6		Hexagonal nut M6 for the BrassPneumaticM6
2.11	1	ISO1207_M3x12		Screw M3x12
2.12	2	Velcro		Graphical representation of the velcro strips sewed to the Ring_20/25 and used to fix the patient's finger

Looking at Figure 4.2, it is possible to notice that the core element of the assembly is the Body (item 2.1). It is connected by the Thimble (item 2.2) to the patient's distal phalanx and to the proximal and middle phalanges (excluding the thumb) by two strips of Velcro (items 2.12). Initially, I inserted the strips directly inside the Body's cavities above the phalanges. However, during flexion movement and due to their flexibility, they did not fasten the finger firmly but rotated prejudicing both the pulling force and comfort. For this reasons, I 3D printed in ABS two partial Rings (items 2.5 and 2.6) with different diameters, sewed the Velcro strips to them and fixed them to the Body with a removable RingLock each (items 2.7) made in ABS.

At the extremity of the Finger, there is a screw used as rigid element to fix the pulling wire. The head is completely inside the TPU Body to avoid contact with the user's nail that can cause discomfort. To cover the extremity and to prevent unintentional wounds, I built the flexible Stop (item 2.3). It has inside an M3 brass insert (item 2.9) that allows to tighten and block the screw.

The rigid FingerLock (item 2.4) attaches the Body to the Glove, thanks to a small piece of Velcro sewed below its base. Using Velcro, the FingerLock can be detached, worn by the patient and reattached based on his/her hand size. The FingerLock also permits to fix firmly the extremity of the Bowden tube using a push-in fitting (item 2.8) and an M6 nut (item 2.10). The two through holes on the side of both Body and FingerLock permit to block the two parts, one with respect to the other, and to group all fingers together, to keep them in order and do not lost them, by using a strand (for instance I used a red filament as shown in Figure 4.22).

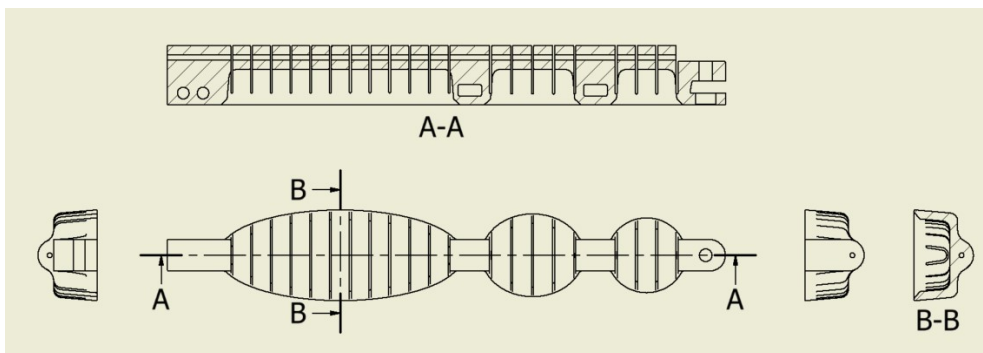


Figure 4.3: *Drawing of the Index Body*

One goal of the Body is to act as a guide for the wire and prevent hyper-extension of the finger. However, we need to take into account that it needs to be comfortable. An obstacle in a rehabilitation program is the device discomfort. One of the main causes of discomfort and frustration is the misalignment of the anatomical and mechanical joints. It can generate undesired pressure and tissue damage [22]. To prevent this consequences, I decided to model its internal shape for minimize contacts between the flexible element and the user knuckles. As can be seen in the drawing in Figure 4.3, each knuckle is covered by an elliptic concave surface. Each is divided in multiple segments that permit the Body to flex together with the finger.

Before obtaining the final result, I tuned several parameters with the aims of: minimizing the material (reducing production time and cost), obtaining a correct compromise between strength and flexibility and, least but not last, improving its comfort and its appearance. I would cite one example concerning the skin abrasion and how to reduce it. During the flexion, the Body wraps the finger joints sliding on both sides of knuckles. If the contact surface is not wide enough, the movement generates an excessive pressure that, after several repetition, can result annoying or painful. After

numerous tests tuning the angle and the height of the chamfer at the internal edge of the oval cavities (visible in the sections of the drawing in Figure 4.3), I was able to reduce the pressure on the skin and improve the comfort without compromising its resistance.


In the right-hand side of section A-A of the drawing (Figure 4.3), it is visible the connection for the thimble. The latter is not only used as fixing element between the Finger and the distal phalanx of the patient. It is a valid support during the mounting phase of the exoskeleton. We need to remember that patients with hand spasticity keeps his/her fingers flexed (Figure 2.9). It could be difficult for therapists to open a finger and, at the same time, fix the Velcro strip. On the other hand, the therapist can help the patient to wear the Glove, wrap the thimble on the patient's distal phalanx, stick the FingerLock to the glove at the right position and use the actuators to slightly pull the patient's finger up. Now, the therapist can more easily fix the other two phalanges to the Body using the Rings with Velcro strips.

Automatic design tool

The length and width of the oval cavities above the knuckles in Body and the Thimble's diameter define the size of a Finger. Even though it is fairly adaptable, people's hands can differ a lot. At the beginning, as highlighted in Section 3.1, I tried to obtain a model that could fit all hand sizes. However, they resulted in not optimal devices for several aspects, including force distribution, alignment and comfort. In HANDY I abandoned that idea. Considering also the time and cost to build customized Fingers, I decided to exploit the power of a parametric CAD system and design a tool that automatically generates the parameters needed by Inventor from a few basic measurements of the patients' hand. Changing the parameters in the tool, the CAD automatically modifies the Finger's parts that only need to be exported as Standard Tessellation Language (STL) files and 3D printed.

I decided to use Microsoft Office Excel to define parameters because it is widely used and known and also is compatible with Inventor. Figure 4.4 shows the input window of the tool. While for the joints' width the fingers need to be measured from therapists, for the length I used a different approach. Buryanov et al. in their study [27] report the ratio between phalanges' dimension of the same finger. On the other hand, Aydinlioğlu et al. [14] state the proportions of proximal, middle, and distal phalangeal lengths in comparison with each other. Combining the results of the two studies, starting from a single measure (in Figure 4.4 I used the middle phalanx of the index) it suggest the length of all other phalanges. However, therapist can always set manually the other measures if they prefer. The

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



The diagram shows a right hand with five fingers. Each finger is labeled with a number from 1 to 5, corresponding to the columns in the table. Colored lines and dots indicate measurement points: blue for the thumb (1), green for the index (2), yellow for the middle (3), red for the ring (4), and purple for the pinky (5). The lines represent the proximal, middle, and distal segments of each finger.

Figure 4.4: Part of the tool to generate Fingers’ parameters based on few measurements (highlighted in yellow) and a combination of Buryanov [27] and Aydinlioğlu [14] results about phalanges proportions

values in the 'Automatic output' are equal to the manual input if defined or computed automatically if the input is left empty. The CAD parameters derive for the width from the 'Manual input' table, and for the length from the 'Automatic output' table.

Considering that for home rehabilitation the tool can generate the parameters for fully customized Finger parts, I also decided to design four sizes (S, M, L, XL) based on mean values retrieved from literature [14,27,80,87] that could be used in clinics or rehabilitative centers. The models are attached to the glove with strips of Velcro and this guarantees some adaptability for slightly different hand sizes.

4.1.2 Structural and other parts

To obtain a compact layout of all HANDY’s elements, especially the linear actuators, I decided to design and produce with additive manufacturing technologies some structural parts, in ABS, to fix them. This production techniques offer a valid solution to create complex and customised shapes in a limited amount of time.

Figure 4.5 shows, in white, the BaseA and BaseB parts used to arrange the linear actuators so that they do not interfere with each other and occupy a limited amount of space, LipoFixI and LipoFixL utilized for the battery, and one out of five Prisms that are connected to the prismatic element of the actuators to pull the Bowden inner cables. In orange, are visible one out of two Bands used to fasten the Bowden tubes on the patients arm and

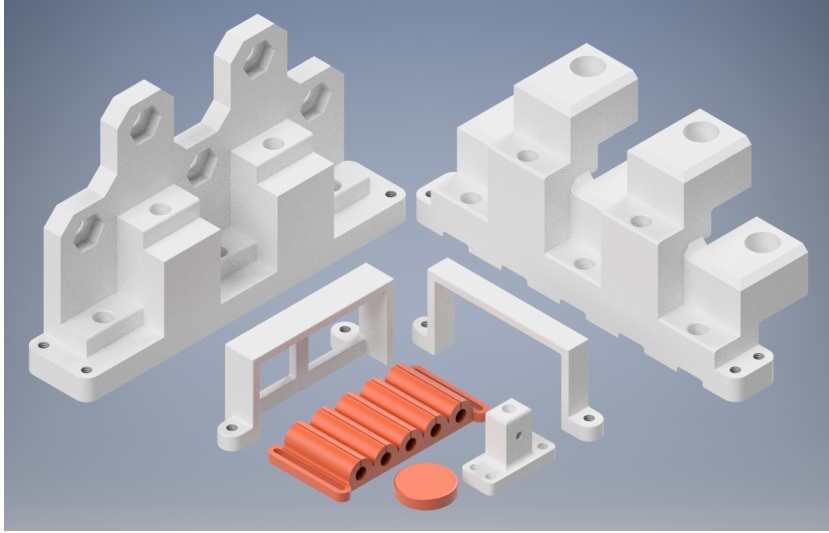


Figure 4.5: *Structural parts used to fix the linear actuators and the LiPo battery, 3D printed in ABS (in white); and the wrist band and the guitar peg's cap realised with flexible TPU (in orange)*

wrist, and one out of five Caps placed on the Guitar tuning pegs.

4.2 Additive manufacturing

HANDY is composed by several elements obtained by additive manufacturing (AM). Some are flexible because have to lead and accompany movements of the human hand and to adapt to its deformation caused by the move. Others require more strength, for example to fix the actuators, and are rigid. The column 'AM' in Tables 4.5 and 4.1 identifies all parts that have been created using the additive manufacturing process and whether they require flexible (F) or rigid (R) material.

4.2.1 Overview of additive manufacturing technologies

Even though the basis of additive manufacturing technology date back to 1980s [54, 64], is the last decade the period where we have seen a the steepest increment in both research studies and applications related to AM. The principle behind the additive manufacturing technology (also known as rapid prototyping or 3D printing) is that a three-dimensional model can be fabricated straightaway by adding material one layer after the other. Each layer is a cross-section obtained by slicing the original CAD model. The thickness of each step influences the accuracy of the result [44].

Nowadays, there are several AM technologies [82] and they are continuously increasing and improving. An interesting example of their classification can be found in the Pham's study [86]. He uses two main properties (the method used to create a layer and the adopted material) of AM to create a matrix to classify different processes. In 2009 ASTM F42 / ISO TC 261 committee on additive manufacturing was born. They are involved to create standards in all aspects of this topic [10]. Using this classification, we can group AM technologies in seven category [44].

- Vat photopolymerization: it uses a vat full of a liquid photopolymer. A ultraviolet radiation source (commonly a laser beam) hit the photopolymer that reacts and solidifies. This principle includes stereolithography (SL) technology.
- Material extrusion: it is currently the most diffuse technology on the market. It consist in melting a material and pushing it through a movable nozzle on a building plate. It includes fused deposition modelling (FDM) technology.
- Powder bed fusion: it employs a thermal source (usually a laser beam) to melt a thin layer of powder previously spread across and levelled on a building plate. It includes selective laser sintering (SLS).
- Material jetting: similarly to the principle behind common 2D printers, these machines have a print head that releases drops of liquid. However, in this case, the material is photosensitive and became solid when react with ultraviolet radiation.
- Binder jetting: like powder bed fusion, it involves levelled layers of powder. But instead of melting the material, this technology uses a nozzle to selectively release binder droplets in the powder bet, bonding the material particles of the new layer. It can also release colors particles to obtain a colorful product.
- Sheet lamination: this process consists in cut sheets of laminated material (for example paper or metal) bonded together using different techniques such as gluing or ultrasonic welding.
- Directed energy deposition: it melts the wanted material (polymers, ceramics and metals) simultaneously its deposition. It uses as heat sources a focused laser or electron beam.

In HANDY I used two different machines for the AM process of rigid and flexible parts: the *bq Witbox* [23] and the *Stratasys uPrint SE* [103]

respectively. They will be deepened explained in the following subsections. However, both machines are based on the Fused Deposition Modeling (FDM) technology. Figure 4.6 shows the schematic model of the *Witbox*. It is possible to see the filament that, guided by a Bowden tube, reaches the movable print head. The filament is heated, extruded through a nozzle and deposited on a printing bed.

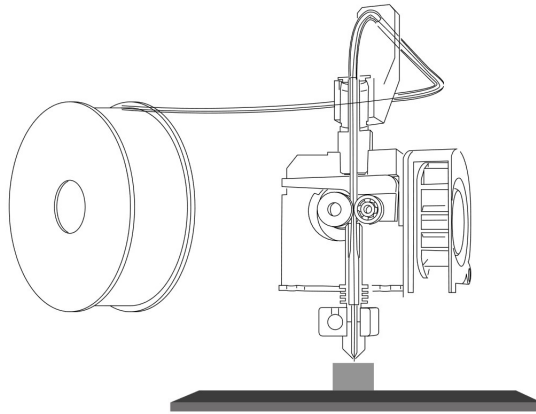


Figure 4.6: Schematic representation of the FDM technology [23]

4.2.2 The eight stages in additive manufacture

According to Gibson, Rosen and Stucker [44], any product development process that involves additive manufacturing technologies can be summarized in eight main steps.

1. CAD: starting from an idea, the first step is to create a 3D solid model of a product. One of the possible method to perform this step is by Computer Aided Design (CAD) system.
2. STL conversion: to use an AM technology, the CAD model has to be described in terms of geometry. STL (name derived from STereoLithography) file approximates the solid with a surface composed by triangles and deletes any construction history.
3. STL to AM machine: before 3D printing, the user can move, rotate and, scale his/her STL file. Furthermore, it is also possible to combine multiple files and build them all at the same time.
4. Machine setup: different materials and parts require ad hoc machine setup. This includes several parameters, such as: speed, supports,

temperature, etc.

5. **Build:** additive manufacturing is a layer-based production technology. It means that the STL file has to be sliced in consecutive vertical layers. The new file (called G-code) include all the necessary instructions for the machine to create the model autonomously.
6. **Remove:** in some case, the output is not ready to be used, but requires that the user separates it from a build plate and cleans the excess material.
7. **Post-processing:** during this step, the user cleans carefully the part. It can involve manual abrasive finishing, chemical treatments, coating and painting.
8. **Application:** finally, the part is ready to be used.

4.2.3 Flexible parts

The hand exoskeleton is composed by several flexible parts. For them, I decided to use, as filament, the NinjaFlex with diameter of 1.75mm because it is a nontoxic TPU that combines elevate strength (tensile ultimate strength 26MPa tested with ASTM D638 method), hardness (85 Shore A tested with the ASTM D2240 method) and elongation (65% elongation at yield and 660% at break tested with ASTM D638 method) [83].

The initial step is to create an STL file of each part designed with the CAD system. Inventor is able to convert the model into the new file. Before performing this step is necessary to set the correct options: binary format for a reduced file dimension, millimeter as unit for a correct scale, and high quality for the best resolution. Considering for example the index finger of the exoskeleton, starting from the model showed in Figure 4.7, I obtained the STL file of the Figure 4.8.

To obtain flexible parts I used the Witbox from BQ. This printer requires as input a G-code file that specifies all the process parameters, such as: the temperature of the nozzle, the height of each layer, the path and the speed of the print head. For this, I used Ultimaker Cura [110]. It is a slicing software that, as the name suggests, slices an STL model in vertical layers and establishes the best path that the print head has to follow to obtain the desired object. I decided to adopt this software for several reasons. Firstly, it is fully compatible with the Witbox. Secondly, it allows defining, saving and reusing customized materials with their properties. Thirdly, it is possible to create different printing settings. The combination of the last two

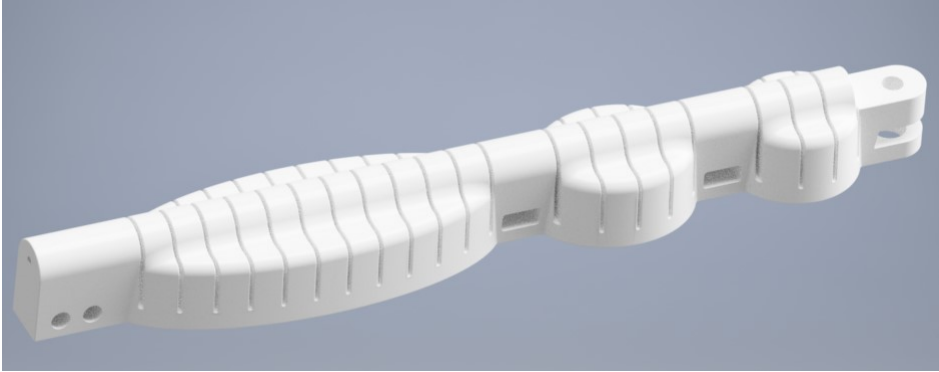


Figure 4.7: CAD file for the index finger

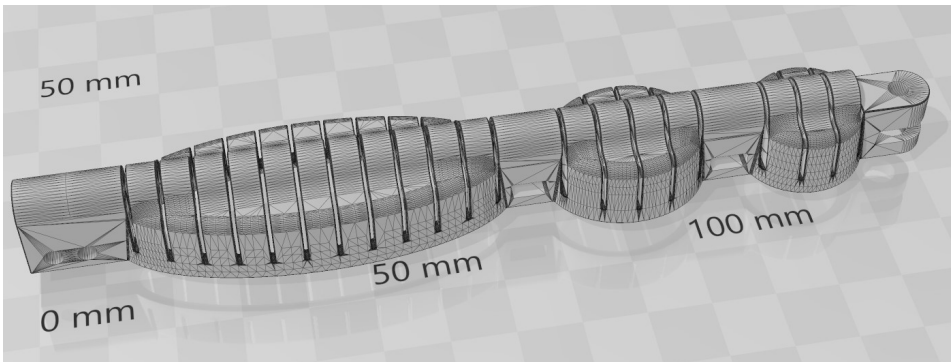


Figure 4.8: STL file for the index finger

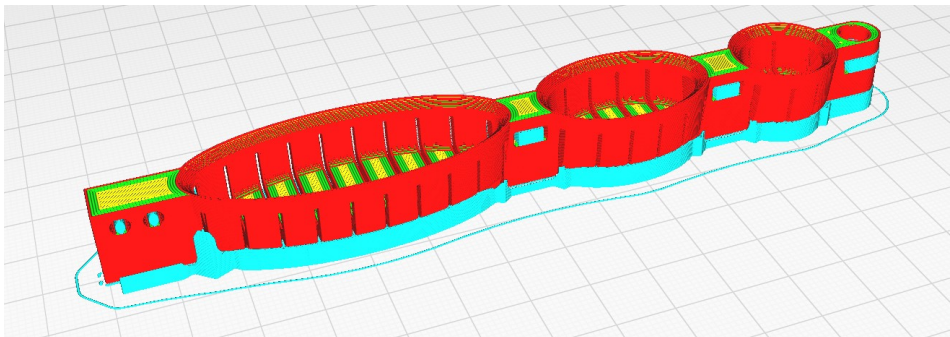


Figure 4.9: Preview of FDM result for the index finger using Ultimaker Cura. The color scheme represents: (cyan) the support material, (red) the shell, (yellow) the top/bottom lines, and (green) the inner walls.

features has been very useful in the phase of tuning the parameters of the machine to obtain a correct product. Finally, it is a very versatile software

that allows to change easily almost all parameters of the AM process.

One of the most important aspect to keep into consideration during this step is the model orientation. FDM technology requires that each new layer is supported by the previous one. Usually, overhangs below 45° are printed with no problems. This angle can be different with different materials. However, when the model has bigger overhangs the slicing software adds support material. Changing the orientation of the model allows reducing support material, which means lower cost and time.

Defining the correct orientation of the flexible models (especially for the fingers) has been particularly challenging. Removing TPU support from the real part is not as simple as with rigid polymers, due to its flexibility. It is difficult to break and tends to leave some residues. Moreover, we need to consider that this component is placed on the hand of a patient. If the inner surface is not as smooth as possible, due to the support left-over, it can cause discomfort during the usage. The orientation showed in Figure 4.8 combined with the parameters reported in Table 4.2 is the one that minimizes the support and produced the best results in terms of surface finishing, resistance and printing time.

Table 4.2 summarizes the main parameters set in Cura for printing flexible models using NinjaFlex.

Table 4.2: *NinjaFlex print settings defined in Ultimaker Cura*

Quality	<i>Layer height</i>	0.2 mm
Shell	<i>Wall thickness</i>	1.5 mm
	<i>Top/Bottom thickness</i>	1.5 mm
Infill	<i>Density</i>	90%
	<i>Pattern</i>	Lines
	<i>Overlap percentage</i>	20%
Material	<i>Printing temperature</i>	235°C
	<i>Retraction</i>	No
Speed	<i>Print speed</i>	30 mm/s
Cooling	<i>Fan speed</i>	100%
Support	<i>Overhang angle</i>	60°
	<i>Pattern</i>	Grid
	<i>Density</i>	30%
Build	<i>Plate adhesion</i>	Skirt

Usually, with rigid material, printing multiple parts at the same time is a convenient solution. If there are more than one part on the building plate, in Cura it is possible to specify if print all the models at the same time or one after the other. However, I noticed that in both cases I had one

problem with TPU. In the first case, due to the material flexibility, there were more bubbles on each model and strings between them. In the second, the print head or its wires tend to collide with completed parts blocking it and translating the building plate. For these reasons, I decided to print one component per time. Even though it required more time and calibrations, it resulted in better outputs.

I started each print by calibrating the building plate manually and adding some spray adhesive to achieve a good adhesion between the first layer and the build plate. Furthermore, I decided to start with a skirt. The machine prints a few loops of material around the model. It ensured me that the flow of the filament was right and the plate was correctly calibrated.

Looking at Table 4.2, it is possible to notice that I decided to disable the retraction of the filament during the process. When it is enabled, the extruder pull the filament back for a predefined length to avoid the material strain and form blobs or strings. While with rigid materials it improves the quality of the final result, with TPU I noticed an opposite behaviour. For this I disabled the material retraction.

One problem encountered during the AM process of TPU was due to the fact that it is an hygroscopic material [83]. This means that it absorbs moisture from the environment. This modifies its mechanical and chemical properties, causing several difficulties throughout the 3D printing process. In the web and literature there are several evidence about this topic and suggest to dry the reel before printing [117]. Removing the moisture and storing the filament in a dry and closed container with some silica gel packs for 3D filament used as desiccant helped to preserve the properties of the TPU.

A further aspect that initially caused difficulties was the feeding mechanism. The Witbox uses Bowden tube to feed the filament into the melt zone. Sometimes the drive gear inside the print head could not overpass the friction caused by the tube and, at the same time, unwrap the coil. This resulted in under-extrusion. I solved this problem removing the tube and unwrap the needed material from the spool before starting the printing process to minimize the resistance.

I followed the same steps for 3D printing also the thimbles and the lock of each finger. Figure 4.10 shows their CAD model (a, d), the STL mesh (b, e) and the output from Cura (c, f). Table 4.3 summarizes the time and quantity of material needed to print each model. Approximately, it takes 14 hours and 20 minutes for producing all the models. Considering the weight of the filament (almost 96g) and the current price of the NinjaFlex with a diameter of 1.75mm of 39.90 €/kg purchased from [1], it results in

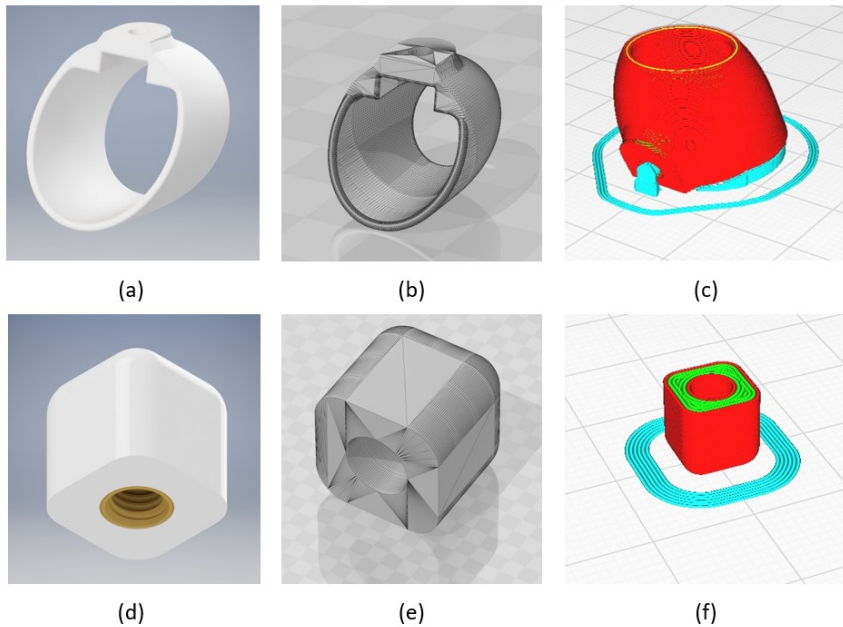


Figure 4.10: CAD, STL and Gcode of the thimble (a, b, c) and lock (d, e, f) flexible parts

a material cost of €3.83. Even though we need to take into account that the resulting time is less than the real one (due to the calibration and setup time needed for the process and for the machine) and amount of money is not the global cost of the process, they highlight the capabilities of the process in a view of fully customized product.

Table 4.3: Time and quantity of NinjaFlex needed to print flexible parts. Global time: 14:13[h:mm], global material weight: 96[g] and length: 31.13[m]

		Thumb	Index	Middle	Ring	Little	Total
Finger	<i>time [h:mm]</i>	1:55	2:46	2:48	2:45	2:11	12:25
	<i>weight [g]</i>	13	18	18	18	14	81
	<i>length [m]</i>	4.21	6.01	6.09	5.96	4.75	27.02
Thimble	<i>time [h:mm]</i>	0:23	0:19	0:18	0:18	0:17	1:35
	<i>weight [g]</i>	2	2	2	2	2	10
	<i>length [m]</i>	0.78	0.65	0.65	0.61	0.57	3.26
Lock	<i>time [h:mm]</i>	0:04					0:20
	<i>weight [g]</i>	1					5
	<i>length [m]</i>	0.17					0.85

4.2.4 Rigid parts

For building the rigid structure that supports the actuators, the rings used to fix the flexible parts to the patient's finger and the connectors between the Bowden tube and the flexible finger I used ABS. It is a thermoplastic polymer commonly used in AM for creating rigid parts. However, ABS demands particular care during the FDM process. It requires an heated and closed chamber to avoid part shrinking and, because it produces fumes and odor while printing, a air-filtration system or a well ventilated area is needed. For these reasons, the Witbox is not adapt to print this material. Indeed, I used a Stratasys uPrint SE Plus [103], based on FDM technology, with its ABSplus™ [102]. The datasheet of the filament reports a tensile strength at yield of 31MPa and an tensile elongation at break of 6% (tested with the ASTM D638 method).

I found the uPrint SE Plus more reliable than the Witbox. For this reason, I was able to print all the rigid components in one step. It works coupled with Catalyst Ex software that slices the models, defines supports and controls the progress of the process. In Catalyst Ex it is not possible to set the infill percentage. But there are only three options with increasing amount of material: low-density, high-density, solid. I set the infill type to be solid: it results in a longer process but in a more resistant output. The following steps regard the orientation and the positioning of the models on the print plate. Usually, the proposed orientation and position was correct to obtain an optimal result.

A further advantage of this machine regards the support. As I emphasized in the previous subsection about flexible parts, the post-processing of the output of the AM and particularly removing support material needs time. The uPrint SE plus uses the SR-30 as support material, which is water-soluble. After the process was over, I left the new components in a circulation tank full of support-removal solution for a few hours to remove all the excess material.

4.3 Actuation

HANDY can work in two different configurations: push-pull, that control both flexion and extension movements, and pull only, that controls only extension but does not obstacle voluntary movement of the patient. The latter requires a resistant thin wire that supports the repetitive forces applied during several rehabilitative sessions. Fishing line seemed to meet these requirements. Originally, it was tested a nylon (PA) monofilament line. However, it presented plastic deformation and a discrete elongation. To

reduce these undesired behaviours, it has been decided to use a braided line: the Spectra® Extreme Braid with a diameter of 0.44mm. It allows to pull till 70lb (approximately 30kg) and the manufacturer declares that it, compared to nylon monofilament, has 24% less stretch, is 4 times stronger and 5 times smaller for the load [53].

Initially, one extremity of the braided line was fixed directly to the movable rank of the T-16P linear actuator. However, we noticed that to completely extend fingers it was necessary to pull the wire for about 45-50mm. We decided to take advantage from the 100mm stroke available in the T-16P and modify the setup to ideally double the mechanical advantage. I take inspiration from the movable pulleys.

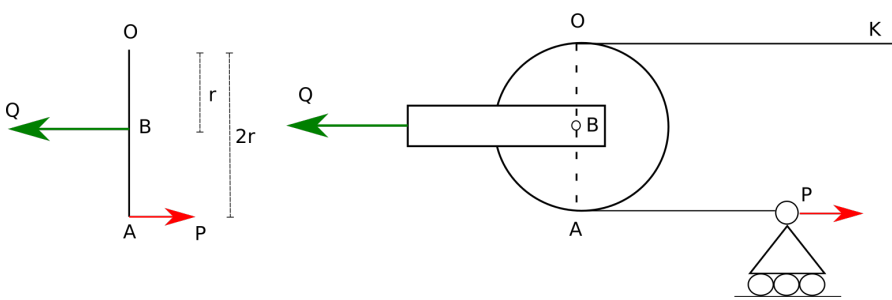


Figure 4.11: Schematic representation of a movable pulley

Figure 4.11 displays the principle behind it. A pulley is a simple machine with a grooved wheel that wraps a rope and rotate around a shaft. In a movable configuration, it is one extremity of the rope that is anchored (point K) and the pulley moves (rotates around B and translate). The load (resistant force Q) is applied to the shaft (B), while the pulling force (effort force P) is applied to one extremity of the pulley (A). It is assailable to a second type lever, where the resistance (Q) is applied in the middle, the fulcrum is situated on one extremity (point O) of the lever and the load is applied to the other one (point A). Ideally, considering inextensible rope and negligible frictions, the mechanical advantage of this setup would be equal to two. This at the expense of the double stroke that the rank must travel. In this layout I used a guitar tuning peg as anchorage for the braided line to regulate the initial tension of the braided line. To obtain the setup in HANDY, I used two pieces of Spectra® Extreme Braid line. One tied to the extremity of the Finger, passing through the Bowden outer cable, and fixed to the shaft of the pulley. The other one is tied to the travelling block of the linear actuator, pass around the pulley and anchored to the guitar tuning peg.

4.4 Electronic circuit

The purpose of the electronic of HANDY, designed at the TNE Lab, is to set and verify the position of each linear actuator. Furthermore, it can return the amount of current absorbed by each motor to perceive the reaction force due to the spasticity of the patient's hand; and the thermal state of each h-bridge.

The core of the PCB are the five LMD18200 H-Bridges from Texas Instruments. It is an integrated circuit that delivers up to 3A of continuous current to a DC motor and control its speed and direction using pulse width modulation (PWM) signals based on sign and magnitude [60]. The principle is highlighted in Figure 4.12. The state of one digital pin specifies the direction of the motor and the speed is proportional to the the duty cycle of the signal.

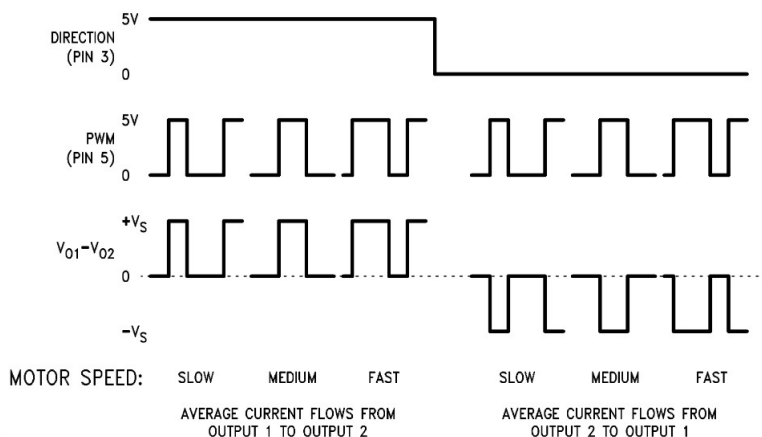


Figure 4.12: Schematic representation of sign/magnitude PWM signals [60]

Considering the number of pins required to control the five actuators, check current and temperature values, and creating a communication with a PC; I decided to use an Arduino Mega 2560 Rev3 as microcontroller [7].

To optimize the space and obtain a more stable connection, reducing the number of jumper wires, it has been designed using KiCAD and then realized a printed circuit board (PCB) based on the schematic of the Arduino Mega 2560 to be connected directly on the latter. Table 4.4 lists the electronic components, all based on through hole technology, needed to complete the PCB. Figure 4.13 shows the footprint and the 3D rendering of the PCB.

Table 4.4: List of electronic components for the PCB

Component	Quantity	Description
LMD18200	5	3A_55V_H-Bridge
2.7k	5	Resistor of 2.7kΩ, for current sense
10nF	10	Capacitor of 10nF
Conn_1x05_Male	5	Connector strip with 5 PinHeaders with a 2.54mm step, to connect the actuators
XT60PW-M	1	Connector XT60 male, for the 12V power supply
Conn_1x08	6	Connector strip with 8 Sockets with a 2.54mm step, to connect the Arduino Mega board
1000μF	1	Electrolytic capacitor of 1000μF100V

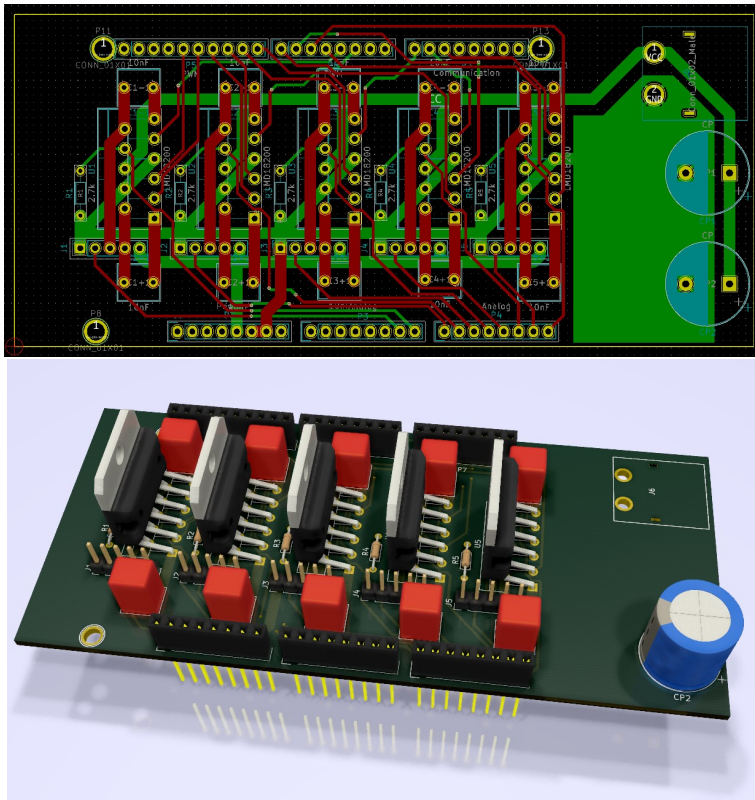


Figure 4.13: Footprint and 3D render of the control board

The Actuonix T16-P actuators require an input voltage of 12V and maximum 1A each. For this reason, the PCB has a XT60 connector for the LiPo battery in parallel to a decoupling electrolytic capacitor. To guarantee a sufficient working time to perform several rehabilitation exercises, a

rechargeable 3s LiPo (lithium polymer) battery with 11.1V, 5000mA and 50C has been purchased.

The current sense output provided by each h-bridge requires a resistor. It was added a $2.7k\Omega$ resistor according to the datasheet [60] and the linearity has been verified using weights. For measures under 1Kg I used precision stainless steel weights, for higher values I used a set of ankle weights. For the latters, I used the mean weight of each element based on 10 measurements. A power supply provided 12V to the linear actuators. Each motor was controlled by a h-bridge that was tested singularly. A wire passing into a Bowden tube connected the actuator to a suspended calibrated weight. Using serial communication, PC sent the command to pull the wire and saved the output values of current sense received during the movement. The same speed was used for all loads. The graph in Figure 4.14 displays the results of the test and the related linear regression.

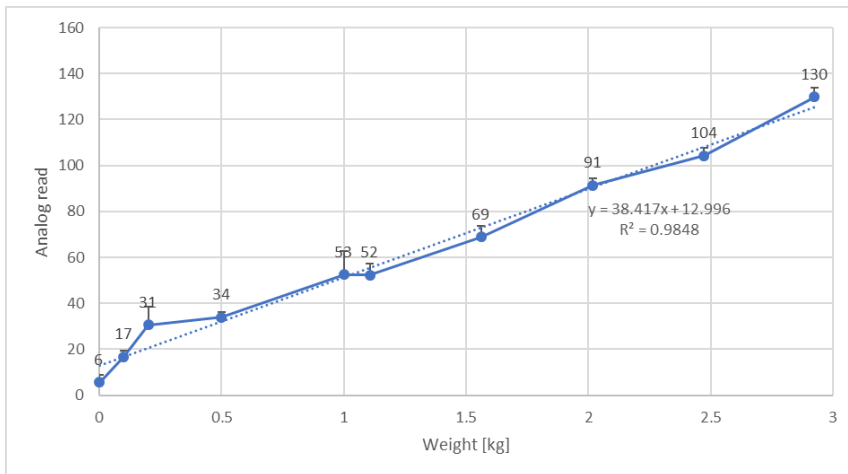


Figure 4.14: Linear regression between the analog current sense output and the resistant weight

One of the main requirements of HANDY is its portability. This means that the communication between the exoskeleton and the computer needs to be wireless. To achieve this, it was examined pros and cons of two different solutions.

1. Adding a Wireless module and connect it to the wireless network of the patient home or hospital. It is the fastest solution and requires only one component, with a limited amount of space and cost. However, I found that it was the less reliable solution in my case. The communication between PC and the exoskeleton needs a fast and stable

connection, and it does not happen so frequently. Moreover, the internet module needs to have a constant IP address. It requires, at the patient's home, a personalized configuration of his/her router and, in clinic, an IP for each active exoskeleton present.

2. Adding an Ethernet module and connect it to a portable and dedicated router. It requires more space and add some weight to the global system. However, the wired connection between the module and the router ensure a more stable and strong network. It allows to assign a fix IP address to the module, and create an internal network independent from the environment infrastructure.

Considered the pros and cons of each solution, I decided to adopt the second one. To limit the negative aspect due to the router size, I choose the *TL-WR902AC* router purchased from *tp-link* considering its compactness (74x67x22mm) and performances [30]. It uses a wired connection by a flat Ethernet cable to the Ethernet module and wireless to the PC.

To obtain a more stable connection I assigned a static IP to the Ethernet module and the PC, and I removed the WPA security protocol and the relative password. However, to limit the access to the reserved network, I adopted a MAC filter. Only the devices I registered can connect to the router and communicate using the private network, in this case the PC and the Ethernet module of the exoskeleton.

To provide 5V voltage input to the Arduino Mega, the PCB, the Ethernet board and the router, a 15W DC/DC converted step down has been used. It converts 12V power supply from the LiPo battery into 5V/3A output.

4.5 Control

Arduino and the PC application need to exchange data in both directions. PC provides instructions to Arduino and the latter supplies information about actuators and the circuit. The linear actuators in HANDY require direction and speed (derived from the polarity and amount of input voltage) and provides the current position of the travelling block. Furthermore, it was necessary a fast, reliable and simple control strategy, so I decided to use a closed-loop proportional control. Figure 4.5 shows a schematic diagram of this approach.

Initially, the controller (P) receives as input the desired position of the moving block of the actuator ($R(s)$) and its actual position as feedback from the internal potentiometer ($Y(s)$). Based on these two values, the it computes the error ($E(s)$) and sends to the system the direction and speed

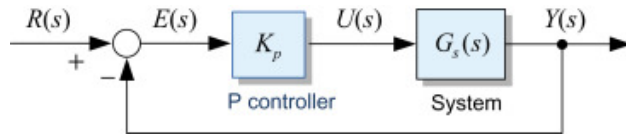


Figure 4.15: Schematic representation of the closed-loop proportional control [95]

needed to reduce the error. However, the error could never reach the value zero, causing unstable behaviour which results in noise of the real actuator. To avoid this, I set a small error interval instead of an absolute value.

The next step was deciding which communication protocol to use between HANDY and a personal computer. The first solution implemented was serial communication. However, it is wired and could provide at maximum a transmission frequency of 2 Hz without generating errors. Looking for a faster and wireless technology I decided to adopt User Datagram Protocol (UDP). Both PC and Arduino support the UDP communication protocol. Furthermore, more than two devices can be connected to the same private network generated by the exoskeleton's router, unlike it would happen with Bluetooth for example.

The TL-WR902AC router included in HANDY creates a private WiFi network. I assigned to the PC and Arduino a static Internet Protocol (IP) address each. The IP defines the format of the packets that are sent and received among end systems and router. When one end system has to transmit one piece of information to another one, it splits the data into packets, adds header bytes and send it to the recipient, that reassembles the data into the original message. UDP is a transport-layer protocol. It is the one that deals with adding header bytes and converting from data into packets on the sending side and from packets into the original data on the receiving side. UDP is also known to be connectionless, because it sends the packets with no handshake before. For this reason it can be considered less reliable than other protocols like Transmission Control Protocol (TCP) but it is simpler and faster [66].

I performed some test only related to communication between my application and Arduino. Sending data in loop and using Wireshark (version 3.0.1) as network protocol analyzer software, I established that the fastest transmission rate without generating errors for the application messages sent among PC and Arduino was 40 Hz. However, during the whole test and the development of the application, I have never lost a single package. Moreover, I implemented a further control using two checksum variables, as will be explained in the next paragraphs, computed on the message con-

tent that allows me to verify the correctness of the message and its transmission and ask it again in case of error. In the worst case, at 40 Hz, even though the protocol would lose a message, I would receive it after 0.025s. Considering the compatibility with both Arduino and the PC, the transmission rate and the reliability, in my case, I decided to use UDP.

Before continuing the analysis of the communication protocol, for each element or variable involved into the process, I want to list their nomenclature and briefly explain their meaning.

- **Pc:** means current position of one actuator. In this variable, Arduino stores the value read from the position potentiometer of the motor: a number comprised between 0 and 1023 (10 bits are needed).
- **Pd:** means desired position for one actuator. This value (from 0 to 1023) is sent from PC to Arduino to provide the new motor's destination and backward to confirm the correctness of the command.
- **Ec:** means cumulative error. This variable stores in 16 bits the cumulative difference between the desired and current position of a motor. It is used by PC to understand whether a motor is blocked or not and generate a related warning. Actually, it is a rolling average computed from an array of errors defined as the module of the difference between Pd and Pc.
- **C:** means current. It represent (in 10 bits) the value received from the sense current output of the h-bridge, related to the amount of current absorbed by the specific actuator.
- **T:** means temperature. It is a 8 bits boolean variable (can be only true or false) used to flag if the temperature sensor into the h-bridge reaches dangerous threshold.
- **B_Cks:** means big checksum. Checksum is a variable used to verify the correctness of a message. In this case, it is one byte (8 bits), placed at the end of the BB computed by a binary sum of all bytes included in the message.
- **S_Cks:** means small checksum. Similarly to the B_Cks, it is one byte variable placed at the end of the SB to check if the message is exact.
- **Pwm:** means pulse width modulation. It indicates the speed required from PC for one motor, because the pwm value generated by Arduino is proportional to the motor's speed. It requires only 8 bits because Arduino needs a number from 0 to 255.

- **BB:** means big buffer. It is the array used by Arduino to store and send to PC all the data related to the five actuators. It requires 243 bit that become 31 byte. It includes arrays of five elements of Pc, Pd, Ec, C, T (for each motors) plus the B_Cks.
- **SB:** means small buffer. It is an array of 98 bits (that become 13 bytes) that includes arrays of five elements of Pd and Pwm plus the S_Cks. It is generated by the PC and sent to Arduino when the user, a therapist for instance, establishes a new position and speed for the actuators.

The names BB (big buffer) and SB (small buffer) are related to their size. I prefer to use this nomenclature and avoid input/output considering that it could be confusing while analysing the communication between PC and Arduino.

To obtain a fast communication, it is necessary to keep the message as short as possible. Each variables (Pd, Pc, Ec, C, T, Pwm) occupies a memory slot that is a multiple of one byte. However, the possible values need, in most cases, a less bits. For example, one value of Pd in memory requires 2 bytes (16 bits) but it can be only a number between 0 and 1023 (10 bits), 6 bits are meaningless. I decided to generate BB and SB using bitwise operations. It allows me to move from 45 to 31 byte in BB and from 16 to 13 bytes in SB.

Figure 4.16 depicts the communication protocol from the point of view of the personal computer. It starts from the idle state and check continuously whether there is a new message or not or it is time to ask to Arduino the current state of actuators. The message can be an output from Arduino or an input. There are two types of input: a beat or a new instruction from the user. A beat is a short message (*0) sent repeatedly (with a frequency equal to $40Hz$) from PC to Arduino with a dual aim: to tell to Arduino that the PC is connected and to request a new BB. A new instruction is represented by the SB. The PC converts the arrays of Pd and Pwm values defined by the user into an array of 12 bytes, then computes the S_Cks byte and creates the SB array. Now the beat or the new SB can be sent to Arduino. On the other hand, output from Arduino can be: the request of the last instructions or the current BB. Arduino can ask to PC to send the last SB (sending *9) for example if the message is damaged. When it receives a new BB, firstly, PC computes and checks the B_Cks. Then transforms the array into the related variables: Pc, Pd, Ec, C and T. If an error emerges while analyzing the checksum or the values of the variables, it flags a warning and sends the related message to Arduino; otherwise displays the values on screen and saves them in files.

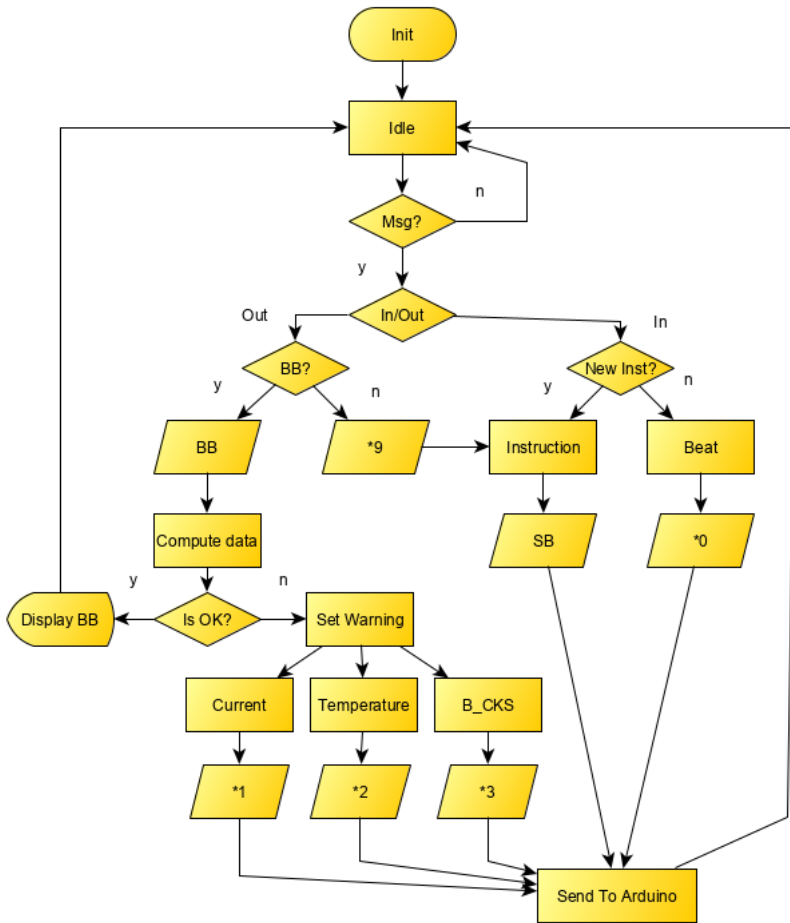


Figure 4.16: Flow chart that describes the PC workflow

Figure 4.17 exemplifies the Arduino’s workflow. It monitors continuously if there is a new message from the PC. If no, it reads all the values from the analog and digital pins and updates the related variables. This way it is ready to build the new BB when receives the request from PC. On the other hand, it performs the required actions related to the PC message. If it receives a SB with new a instruction firstly verifies its exactness using checksum. If it is correct, transform the array into the values of Pd and Pwm and then sends them to the actuators; otherwise request again the message sending *9. If Arduino receives *0, it is a beat request. Arduino "knows" that the PC is connected and is ready to receive the state of all actuators. It assembles the arrays of Pd, Pc, Ec, C, and T of each motor into

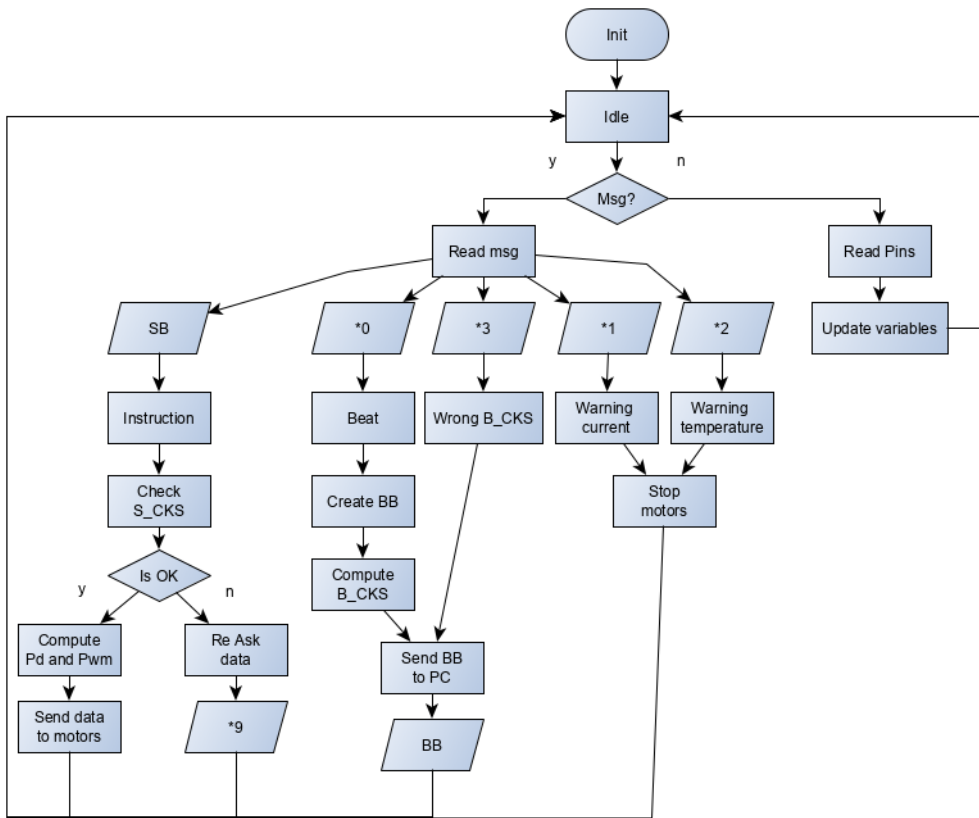


Figure 4.17: Flow chart that describes the Arduino workflow

BB, appends the computed B_Cks to the array and send it to the computer. *3 means that an error during the last transmission occurred: the B_Cks computed by the PC does not correspond to the one appended by Arduino. The latter sends again the BB. If Arduino receives *1 or *2, PC is reporting a warning due to the current amount (possibly related to a block of an actuator) or thermal condition of the h-bridges. If one motor signals a current warning, the PC has already alerted the user and Arduino, to not harm the patient, push the actuator back in a more relaxed position for the patient finger. Similarly, if there is a thermal warning the exoskeleton should push all the actuators back, so that the patient is free to remove the device without any resistance. Actually, during the development process and all tests, it has never been reached the thermal threshold (145°C [60]) in any h-bridge; considering the limited amount of current required by each actuator (1A [57]) with respect to the maximum supported by the integrated

circuit (3A [60]).

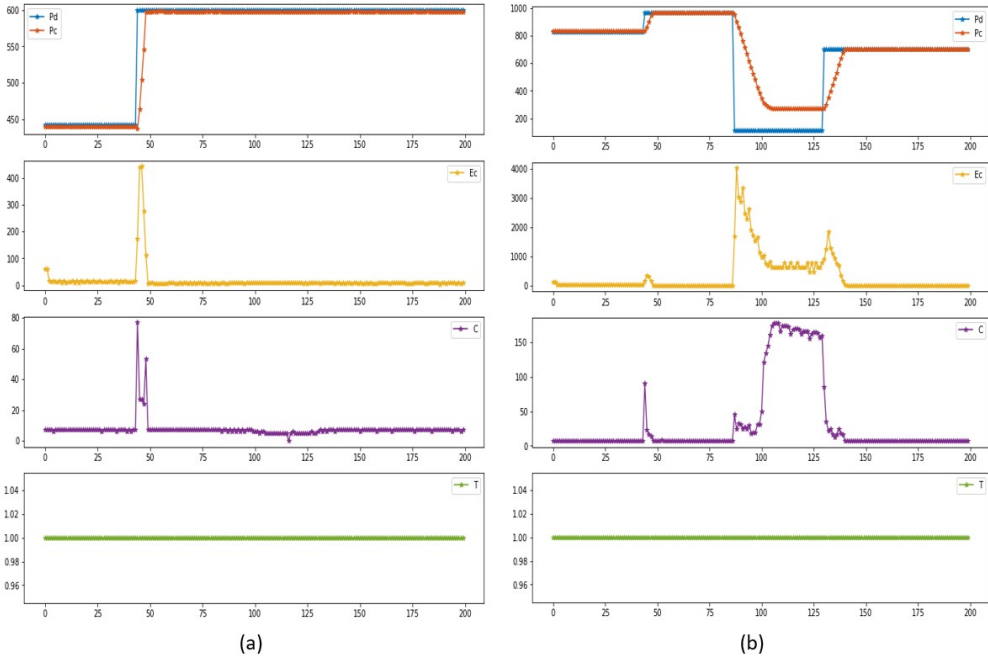


Figure 4.18: *HANDY's controller output for one linear actuator, in two different resistance conditions: low (a) and high (b) load. Pd (■) identifies the desired position of the actuator while Pc (■) its real current position. Ec (■) identifies the cumulative error in time between Pd and Pc. C (■) gives an idea about the amount of current drained from the actuator. T (■) is used to flag if the temperature of the board is reaching the maximum threshold: if equal to 1 it means that the circuit is in its normal condition.*

Figure 4.18 displays two examples of output data from BB of two actuators when the motor try to reach the desired position when no (a) and a high (b) load is applied. All data have been saved at 40Hz. The graphs in the first row highlight the trend of the desired position Pd (■) and the current position Pc (■) measured by the potentiometer of the actuator. The values range from 0 to 1023: 0 corresponds to the actuator's position of the maximum pulling while 1023 corresponds to the resting position. The second row reports the cumulative error Ec (■). The third the current index C (■) obtained from the h-bridge. The last row displays the thermal state T (■) of the h-bridge. It can only be 1, in normal conditions, or 0, when it exceeds the thermal limit.

In the first case (column a), the actuator, indicatively at frame 40, moves from a pulling situation (position 430) to a more resting one (600). Only 5

frames are needed to reach its destination. The value of E_c increases only because of the calculation method and return equal to 0 in a few frames, indicating that the actuator reached its destination. C rises during the motion transient and reaches almost 80 a start. T is always equal to 1 meaning that the integrated circuit works correctly.

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

4.6 The final assembly

The result of this long development process is a portable, lightweight, comfortable and customizable hand exoskeleton that would bring hand rehabilitation at patients' home. Inspired by this idea, I decided to call it HANDY. In the English language, the word "handy" means: useful, convenient, skilful, and accessible [31].

HANDY is the union of multiple components. Figure 4.6 is a photograph of the device. To better examine all its constitutive elements, I created a CAD 3D assembly (rendered in Figure 4.20) using Inventor. Based on this model, Figure 4.21 shows the drawing of the system with balloon annotations to identify each element. As itemized in Table 4.5, it includes the hand exoskeleton, electronic elements, structural parts, actuators, and safety components. The table lists the item number that matches the related balloon annotation in the drawing, its quantity presents in the assembly, its name, if it has been created by additive manufacture (and if so, if it is rigid or flexible) and a brief description of the component.

Items 1-5 are the assemblies of the exoskeleton's Fingers. They are the core of the system and need to be worn by a patient. I called them like the human fingers, but with capital letters. Each Finger has different sizes, but it is constituted by the same parts. For this reason and because they are composed by both rigid and flexible elements, for the AM column the item remands to Table 4.1 that describes the Index.

The Glove, item 6, is a hand tutor that allows to fix the Fingers on the

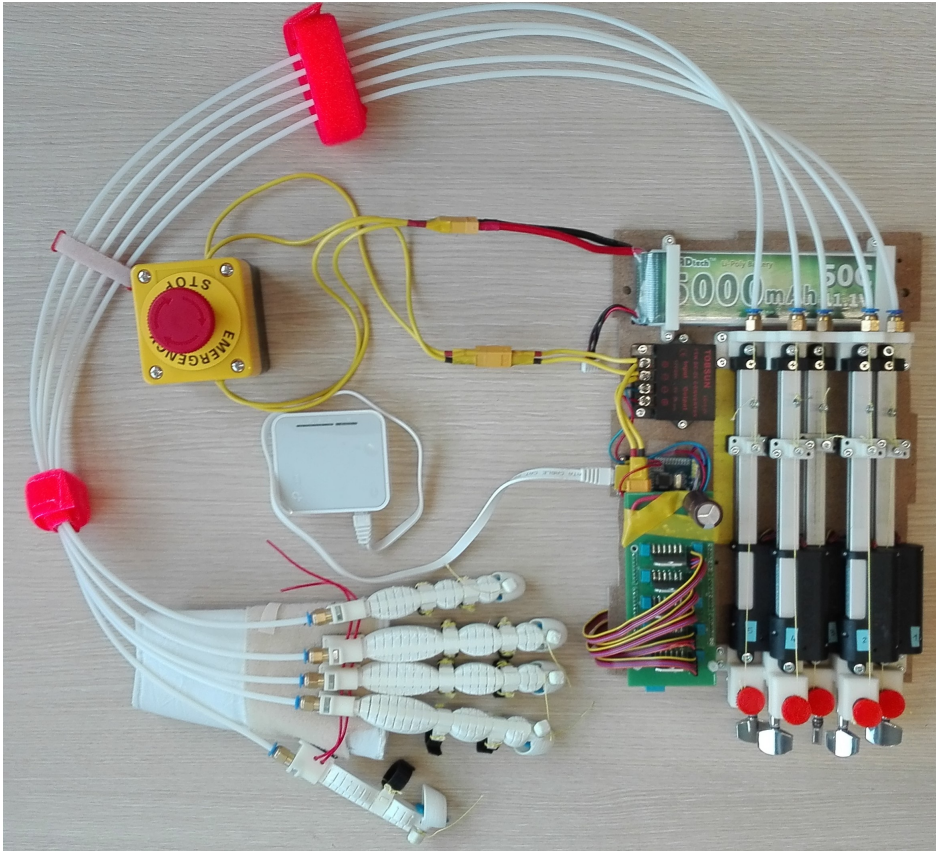


Figure 4.19: *HANDY assembled*

dorsal side of the patient’s hand and keep them in place (Figure 4.22). I sewed it combining three layers of different materials: Velcro (beige), cotton (white) and plastazote (blue). Velcro is the most external element. It is used to close the tutor and to attach the Fingers allowing different placements for different hands’ sizes. The most internal element is in Plastazote®. It is an orthopedic thermoplastic material widely used in healthcare [121]. I inserted this layer to obtain a non-toxic, breathable and lightweight element to reduce skin irritations. However, it is not very stretch-resistant. To prevent it from breaking, I used a cotton-layer between Velcro and Plastazote. It is not rigid as Velcro, allowing the Glove to adapt to the hand shape; and more durable than Plastazote, allowing the user to wear the tutor without destroy it.

There are five linear actuators (item 21) that are used to pull a wire tied to each Finger’s Thimble moving a prismatic element (item 20: Prism).

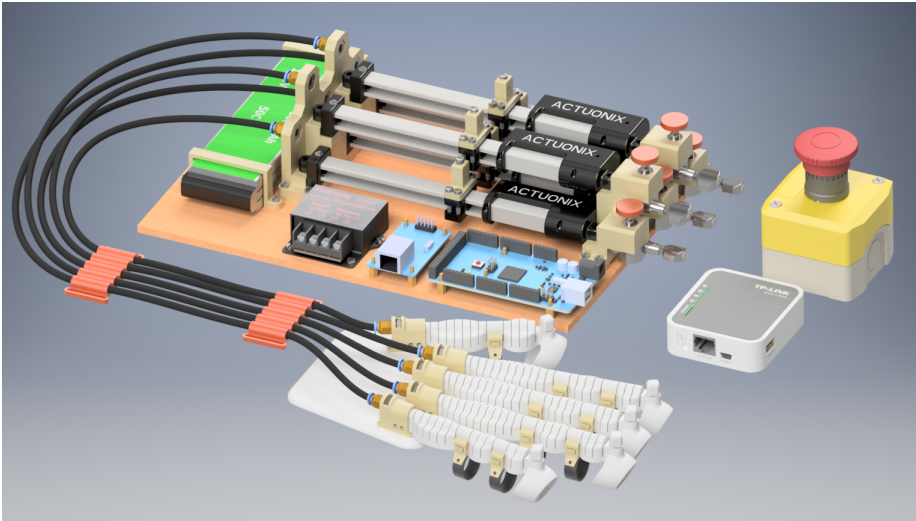


Figure 4.20: Rendering of the global CAD model of HANDY

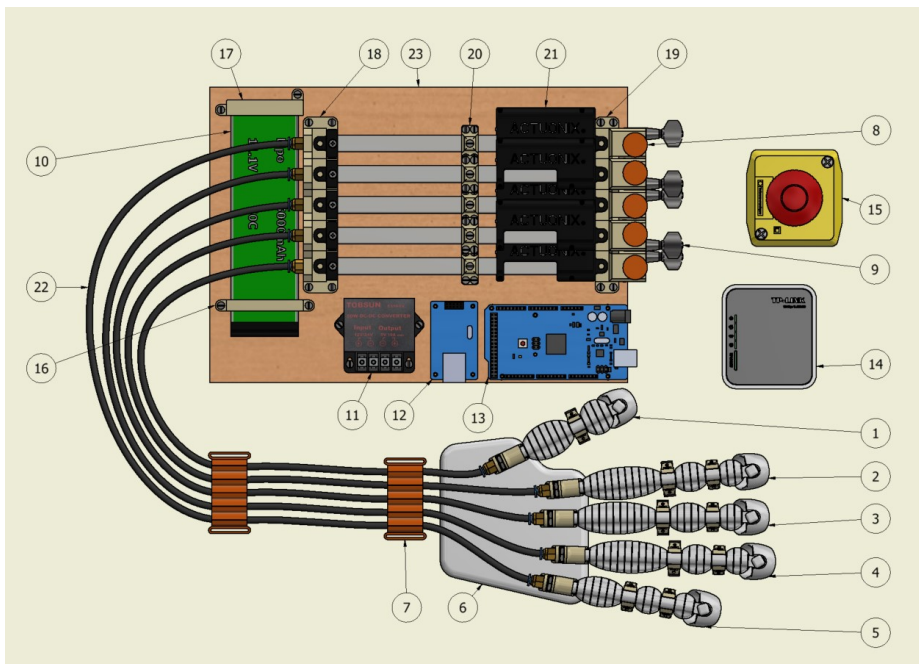


Figure 4.21: Top view of all components of HANDY with balloon annotations

The wire runs into a Bowden tube (item 22) that allows a remote actuation. It reduce the weight on the patient's hand increasing notably the comfort of the device. BaseA and BaseB (item 18 and 19 respectively) have been

Chapter 4. HANDY

Table 4.5: BOM of HANDY related to Figure 4.21. For simplifying the drawing and the list, I removed the balloon annotation for screws and nuts

Item	Qty	Part name	AM	Description
1	1	Thumb	4.1	Assembly for the thumb finger
2	1	Index	4.1	Assembly for the index finger
3	1	Middle	4.1	Assembly for the middle finger
4	1	Ring	4.1	Assembly for the ring finger
5	1	Little	4.1	Assembly for the little finger
6	1	Glove		Representation of the hand tutor made with fabric, Velcro and plastazote
7	2	Band	F	Flexible band used to keep the Bowden tubes in place and fasten them to the patient's arm using a strip of Velcro
8	5	Cap	F	Flexible cap placed on the top of the GuitarPeg to avoid that the wire came out
9	5	GuitarPeg		Guitar tuning peg used to regulate the wire tension
10	1	LiPo		LiPo battery 11.1V 5000mA 50C
11	1	DC_Conv		15W DC converter from 12V to 5V-3A
12	1	Ethernet		Ethernet module
13	1	Control board		Arduino Mega 2560 and the PCB used to control the system
14	1	TL-WR902AC		TP-Link Router
15	1	EmergencyBt		Emergency stop mushroom push-button
16	1	LipoFixI	R	Rigid straight fixing element for the LiPo
17	1	LipoFixL	R	Rigid L-shaped fixing element for the LiPo
18	1	BaseA	R	Rigid element to fix actuators and Bowden tubes
19	1	BaseB	R	Rigid element to fix actuators and GuitarPegs
20	5	Prism	R	Prismatic element moved by the actuator
21	5	T16-P		Actuonix T16-P mini actuator with feedback
22	5	Bowden		Bowden tube with wire
23	1	Structure		Structure used to group all components

designed to fix the actuators to the Structure in a space as limited as possible and to avoid collisions between their pieces. I want to highlight that for all mechanical connections that involve 3D printed parts and screws, I put a threatened brass insert into the part and then tightened the screw. This ensured me a more reliable connection.

The linear actuators demand 12V and 5A as power input. To satisfy this requirements a Lithium polymer (LiPo) (item 10) has been used. It also powers all the electronic boards (items 12 and 13) and the router (item 14) through a DC-converter (item 11). As can be noticed, between the LiPo battery and all other electrical elements there is a mushroom push-

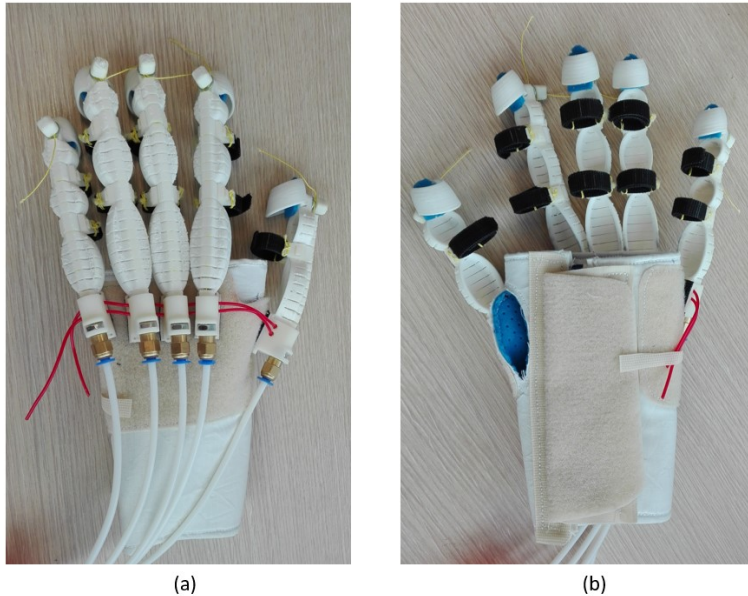


Figure 4.22: *Dorsal (a) and palmar (b) view of the Glove. It is visible the plastazote in blue inside the tutor and the thimbles*

button (item 15). It is used as security element to stop the device in case of emergency or malfunctioning.

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

HANDY needs to be portable to be easily carried or to allows patient to perform rehabilitation exercises while s/he is moving. To achieve this result, it is fixed to the internal frame of a small backpack, as shown in Figure 4.23 (b). The most important aspect is that it must be comfortable to wear and move for a patient. The backpack is padded and has a ventilated back, as can be seen in Figure 4.23 (a). It has also a hip belt to keep it in place while unloading the actuators' force.

Considering all components, the size of the base Structure (item 23) is 210x297mm (equal to A4 paper size) and HANDY's global weight is about 3.7kg composed as shown in Table 4.6. Only 190g are on the patient's hand,

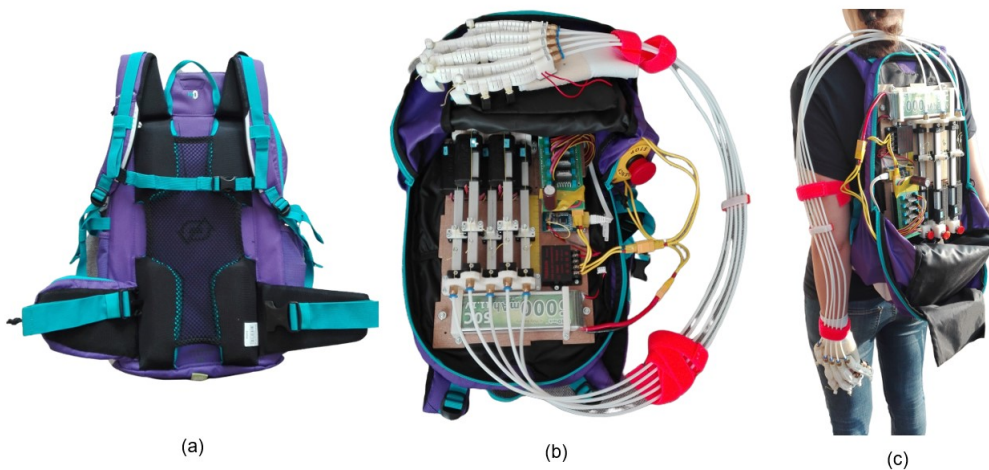


Figure 4.23: *HANDY is fixed to the internal frame of a backpack. (a) shows its aerated and padded back side. HANDY’s components are placed into the backpack with only the emergency push-button in the side pocket, to be accessible in case of emergency (b). (c) displays HANDY when worn by a user*

value notably below the threshold of 250g suggested by therapists and less than numerous prototypes proposed by the literature.

Table 4.6: *Weight subdivision in the HANDY’s sub-assemblies*

Item	Weight [kg]
Tutor	0.02
Fingers	0.17
Actuation	2.70
Backpack	1.00
Total	3.70

CHAPTER 5

MAIA

This chapter describes the development of a virtual assistant, named MAIA, starting from the needs of medical personnel and patients to the final 3D model. The main feature that characterises MAIA is its capability to interact with users using speech due to the integration with some artificial intelligent capabilities related to natural language processing.

5.1 From needs to final 3D model

5.1.1 Users' needs

Nowadays, more and more researches about post-stroke rehabilitation that combines mechatronic devices with serious games or interactive applications based on virtual reality [73] to reduce the therapy abandon rate caused by exercise monotony. However, some patients still experience difficulties in interaction with personal computers. Furthermore, both patients and therapists pointed me out that common reinforcement systems (based on numeric scores) usually appear half-hearted and not very motivating. They would prefer a more friendly element capable to provide encouragement messages. On the other hand, medical experts and bioengineers from Villa

Beretta rehabilitation centre highlighted that sometimes they need to solve simple problems such as providing the exercise's instructions or the wrong positioning of a device by phone or personally going to the patient's house. These operations are time-consuming. Based on these concepts, was born the idea of creating a new virtual assistant that would be the linking point between therapists and patients, especially to bring hand rehabilitation to the patient's home.

Before starting the development of a virtual assistant, it was necessary to understand if patients would appreciate it. So, an informal focus group has been arranged with therapists and patients with mild symptoms to discuss this innovative idea. However, we noticed that some patients had little knowledge about information technology and would have been difficult to explain the concept of a virtual assistant without any example of 3D virtual objects. For this reason, we decided to involve, for this qualitative study, 12 patients (aged 82.3 ± 9.4) who was previously recruited to test a virtual reality rehabilitative application related to the users' interaction with virtual objects. We took advantage of this previous experience with virtual objects to explain the aim of the focus group and ask them to fill in a qualitative questionnaire about their willingness to interact with a virtual assistant, what actions would be considered useful, and their favourite physical appearance for a virtual character.

As shown in Figure 5.1, the majority of them (92%) would like a virtual assistant and would prefer to interact with it more naturally and immediately such as using speech.

The next step was understanding what kind of actions the assistant should perform. However, we need to keep in mind that rehabilitation is a therapy and it is only the medical personnel who have to evaluate and decide about the disease progress. Excluded the possibility of modifying the therapeutic settings, other actions both patients and therapist seemed interested in were that it could give instructions about the exercise, do some demonstrations, assist the user with the application settings (for instance while moving among pages and exercises) and others such as provide encouragement and feedback about the execution. The graph in Figure 5.2 summarises them.

Once it was decided what actions the virtual assistant should do, the next stage was what physical appearance it should have. I decided to proceed by categories. The first regarded the main classes of character (such as humans, animals, cartoon, science fiction, etc.). As shown in Figure 5.3, the majority preferred science fiction characters followed by cartoon and objects. Interesting was the low statistic obtained by the "human" class. In

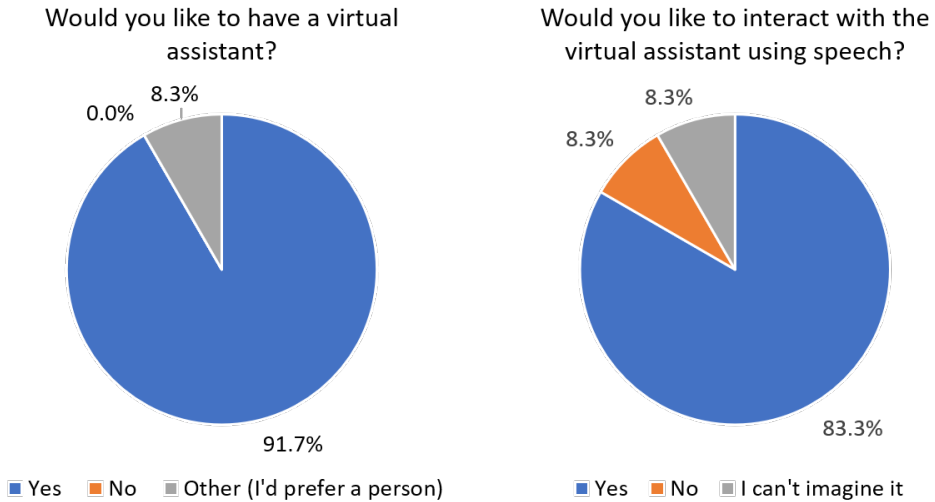


Figure 5.1: Willingness to have and to speak with a virtual assistant

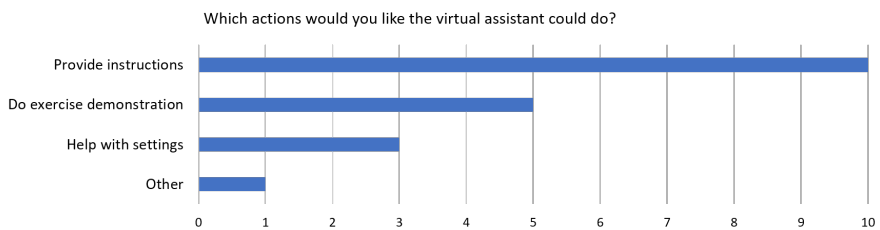


Figure 5.2: Desired support requirements for the assistant

literature are present several studies about the aspect and the behaviour of virtual assistants (especially considering the rapid spread of chatbots in recent years). There are numerous conflicting opinions, but they tend to agree that a virtual assistant should behave with some human-like characteristics but it also must not deceive the user (it must be clear that it is an artificial element) [106]. Therapists and bioengineers from Villa Beretta also did not prefer the "human" class for the assistant, because seen as a misleading or replacing element.

Continuing with the look of the virtual assistant, the other elements to evaluate were its age, gender, novelty and size. The bar graphs in Figure 5.4 reveal that the majority of users prefer a virtual assistant with a young appearance. The gender is unconcerned for the plurality of users. None of them would have an already known character, but they prefer a new one. Finally, about the size, there is not a clear preponderance, with small and

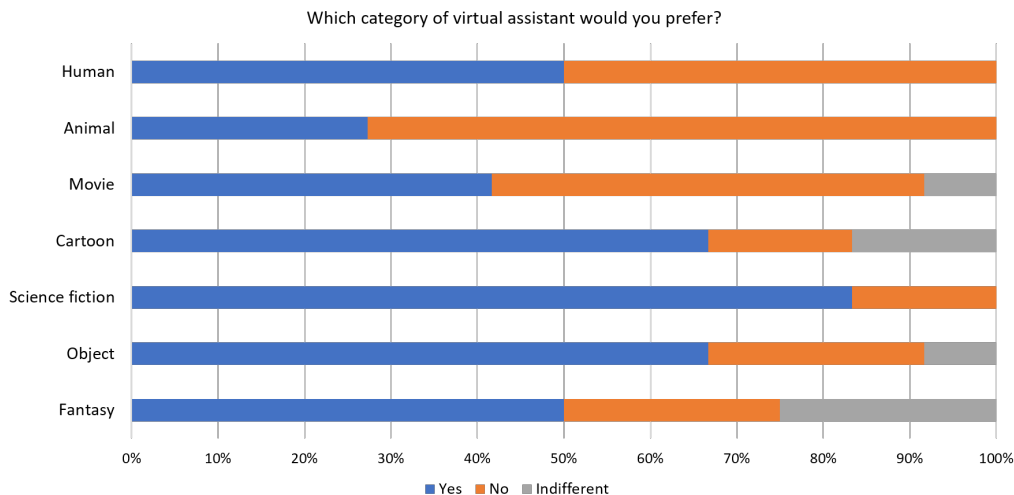


Figure 5.3: Preferences about character class

indifferent tied for first. However, therapists highlighted that the assistant should not have a distracting nor invasive element in the virtual scene. For this reason and considering the results of the questionnaire, we were inclined to choose the "small" size.

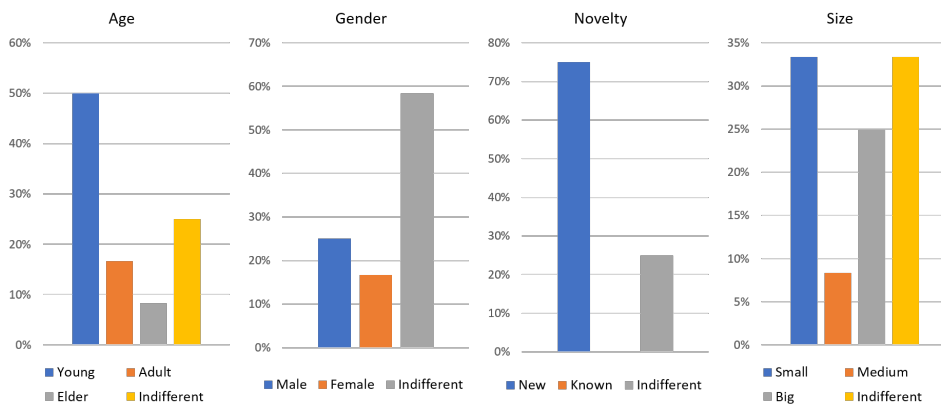


Figure 5.4: Preferences about character aspect

5.1.2 Creating MAIA

Starting from the outcomes of the questionnaires about the physical aspect of the virtual assistant, I drew some concepts of the character. The one

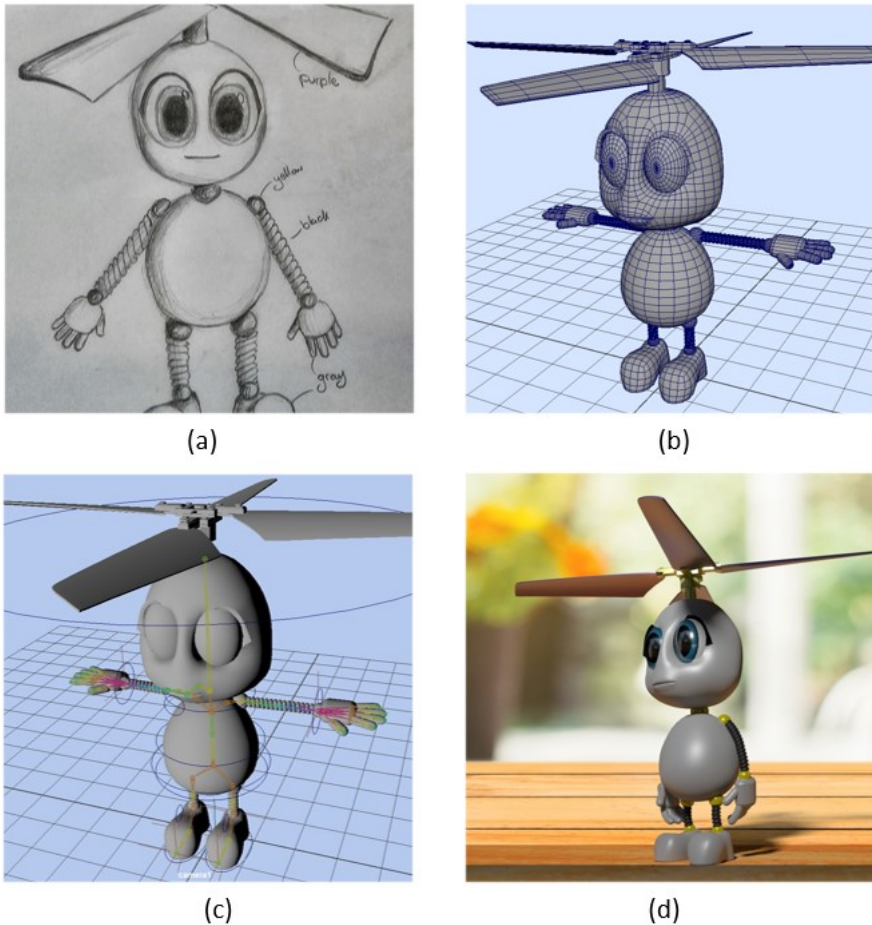


Figure 5.5: Milestones in creating MAIA: (a) is the drawing derived from users' needs and used as starting point, (b) shows the mesh of all polygons that constitute the model, in (c) it has been added the forward and inverse kinematic controllers (respectively the skeleton and the circular handles), and (d) represents a render of the final 3D model using the Arnold plug-in

that therapists and bio-engineers preferred is the one shown in Figure 5.5 (a). It responds to all needs highlighted in the questionnaires. Furthermore, its small size makes it non-invasive; the big eyes and rounded body give it a friendly look, and if the legs and arms give it a humanoid aspect, the helicopter blades permit to freely move it around all the screen.

Considering its role of virtual assistant in the medical field, that it can interact with humans using natural language (as will be described thoroughly in the next section), and the need to use a simple and short name, I decided

to call it MAIA (Medical Artificial Intelligent Assistant).

To create an interactive 3D virtual assistant, I needed an advanced software for 3D modelling, animation, simulation, and rendering. In my opinion, Autodesk Maya® [13] one of the most complete and advanced software in this field. For this reason, I decided to use its version 2019 for the whole creation of my assistant.

The first step in 3D character creation is modelling. I modeled each constitutive part of the character (Figure 5.5 (b)). Each component in MAIA is created using polygonal meshes. A polygon mesh is a 3D object composed by vertices, edges and faces. As can be seen in Figure 5.5 (b), I used four-side faces (called quadrilaterals or quads) to realise the polygon meshes that compose the global 3D model. An important aspect to keep into account during modelling is the pose of the humanoid object. The pose I used during the modelling process (with the arms stretched horizontally) is called T-pose and it is widely used in 3D modelling because it facilitates considerably the following rigging step.

The second step is rigging: the creation of Forward Kinematic (FK) and Inverse Kinematic (IK) controllers (also called skeletons and IK handles respectively) of the 3D model, binding skins to the skeleton, and setting up constraints. FK consists of a skeleton composed of bones and joints inside of the 3D meshes. In 5.5 (c) bones are highlighted and the color ramp represents their hierarchy. In Maya, the skeleton follows a hierarchical organization: children elements are influenced by the rotations of the parent. The root joint is the pelvis node. A move of the pelvis results in a rigid translation of the whole skeleton, a rotation of the wrist joint results in the rigid rotation of only its children bones: metacarpals and phalanges of all fingers. Due to the humanoid aspect of MAIA, its skeleton resembles a schematic representation of the human one. Only limbs require a different structure. Arms and legs of the virtual assistant are represented like long rubber springs. To obtain the correct deformation, each requires a chain of bones. This way they have multiple rotation joints that confer a uniform deformation along with the spring. FK follows the parent-child relation. However, sometimes the inverse behaviour results more convenient. For this reason, I added IK controllers. IK allows to automatically rotate parent joints of the skeleton moving a handle placed at the end of the kinematic chain. Furthermore, they are more accessible than single bones during the making-animations process. In 5.5 (c) the IK handles are the blue circles around the 3D model. For instance: raising the IK handle placed at the extremity of the foot, the knee and ankle joints rotate and the foot moves upwards.

However, till now the skeleton and IK handles are not connected to the polygon meshes. To bind the 3D model to the skeleton is needed a further step: skinning. MAIA's parts required two different types of skinning: rigid and smooth skinning. The main difference between the two methods is how the polygon meshes deform based on the skeleton's rotations. With rigid skinning, each vertex is influenced by only one joint. It results in a rigid deformation effect. I used this method with all the parts of MAYA that should not deform: the eyes and the helicopter blades are rigidly bonded to the head joint. On the other hand, smooth skinning creates articulate deformations by enabling several joints to influence the same vertices. The amount of influence of each joint on a vertex usually vary with the distance between the two, but it can be modified, and adapted to each specific case, changing the binding parameters. However, the default method in the smooth bind, based on the closest distance between the polygons and joints, generates optimal results with a model composed of a unique mesh. MAIA, instead, has been created combining several polygon meshes. Autodesk Maya® has a specific option in the smooth skinning to tackle these cases: geodesic voxel. It consists in representing the global model using voxels (the amount of 3D space occupied by an object) and calculating the binding weights based on the geodesic distance between joints and voxelized meshes [11]. I used this method for all other parts of the 3D model. The resolution of the voxels has been chosen as a trade-off between quality and binding time.

The next step in the process of creating MAIA regarded the appearance of the surfaces of the model. In Autodesk Maya®, materials (also called shaders) include several attributes that allow defining colour, transparency, roughness, reflections, etc. Autodesk Maya® provides a dedicated panel, called Hypershade, to create and define materials. One main parameter to take into account for the choice of a material type is the specular highlight. It influences how the light reflects on a surface. Shiny and wet objects are inclined to have strong and hard-edged specular highlight instead, matte objects are likely to have diffuse and soft-edged specular highlights [35]. In MAIA, I used three types of materials. Lambert: is a shader for matte surfaces, without any specular highlight. I decided to use it for the limbs of the model. Phong: is for glossy surfaces, with hard specular highlights and reflective properties. I used Phong for the joints' surfaces (neck, shoulders, wrists, hip and, ankles) and the eyes. Blinn: is a shader with soft specular highlights and reflections, particularly effective in simulating metallic surfaces, but it also is the most computationally expensive among the three. It has been used for all other metallic parts of the robot.

Because I defined all polygonal meshes in the way that to each mesh corresponds a unique material, this process does not require to manually paint the materials on specific portions of the model, but to each mesh was assigned the related shader. This methodology required more complex skinning but allowed an automatic and more precise shaders assignment.

The following stage involved the creation of some animations to permit the 3D assistant to behave more naturally. There are several different techniques to create animations. The one I used is called Keyframe animation. It lets transform scene elements over time using markers called keys. In my case, I set the orientation of some joints and moved the IK handles to obtain the desired position of the 3D virtual assistant at specific time instants. Particularly, I created some animation such as the idle, walk, fly, talk, and right (it shows the OK sign with the hand) or wrong (it moves his head sadly) decision, used to provide feedback to patients during active exercises, as described in the next chapter. In this method, it is not necessary to set manually each frame. The software will compute the intermediate values interpolating two following frames. Even though in the majority of cases it works correctly and is a great advantage, there are situations where the developer needs to intervene to avoid mistakes. I found very useful the book "The animator's survival kit" by Richard Williams [114]. It describes thoroughly techniques adopted in media and suggestions to design realistic and effective animations focusing particularly on humanoid characters. While it describes keyframe animation, it highlights a case in point about wrong in between automatic frames. Imagine a soft ball falling. The first frame displays a perfectly round ball in the air. In the last frame, the ball is flattened to the ground. Obviously, in any intermediate frame before the contact with the ground, the ball falls due to the gravity but maintains its spherical shape. However, an automatic solution could generate an ovoid (wrong) surface at an intermediate height between the initial position and the floor. One important step that I would highlight for the animation, is the bake. It is not an obligatory step, but I had to do it before exporting the animations to Unity3D [113], the software I used to assemble HANDY and MAIA into a global application. Unity3D allows importing animations from Autodesk Maya® but limited to skeleton's joints. All transformations derived from IK handles are neglected. Baking an animation inheres in automatically defining the keys of each joint based on their position and orientation at each frame of the timeline.

The final step in the 3D computer graphic production of MAIA is rendering. Rendering is the process of generating an image (called render) from the 3D scene considering all elements and parameters previously set

(such as 3D models, materials, lights, shadows, the position of the cameras, background image, and so on). Rendering requires a lot of computational power and time, due to the complexity and a large number of calculations. For this reason, the final render is a compromise between quality and speed. Autodesk Maya® 2019 offers the opportunity to use as rendering library, Arnold by Solid Angle. It is an advanced and powerful tool to generate photo-realistic and physic-based renders [98]. It can be installed with Autodesk Maya® as a plug-in feature and integrated into the 3D scene development pipeline. I prefer do not dwell too much on the rendering topic because of lies outside the aim of this thesis. However, rendering is one of the main phases in 3D computer graphic. A resulting render of MAIA is shown in Figure 5.5 (d).

At the end of the development process of MAIA, it was decided to ask the group of users that initially expressed their preferences about the virtual assistant, described in subsection 5.1.1, their opinion of the final result in a 5-point Likert scale, where 5 means strongly like it and 1 strongly dislike it. Over the 91% of users expressed positive feedback (Figure 5.6), confirming the initial idea and providing a promising starting point for the next improvement.

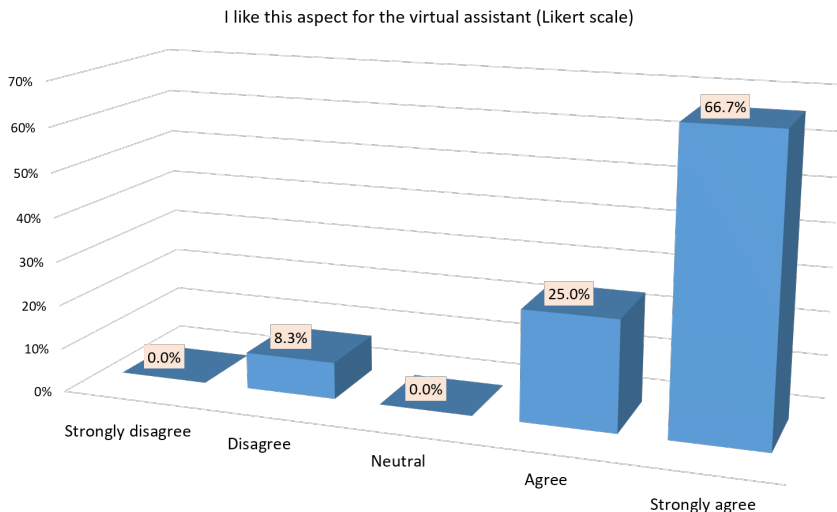


Figure 5.6: Outcome of the Likert scale questionnaire about the physical appearance of MAIA. Over 91% of users appreciated it

5.2 Natural language processing

5.2.1 Definitions and brief history

Human language can be extremely variable and ambiguous. The human brain evolved to think, produce and interpret elaborate and subtlety meanings with language. However, it is difficult to formally enunciate the rules that govern a language. Furthermore, natural language is discrete and compositional. Language is composed by discrete symbols (characters) that, when combined to form words, generate meanings in our head. These abstract representations cannot be deduced by the single letters used to write the word. The compositional aspect of language make the understanding process even more complex. Words form sentences, and the global semantic of a phrase can be larger that the sum of the meanings that compose it. One clear example is sarcasm. It is extremely difficult to define general rules to classify sentences without considering their meaning [46]. Natural Language Processing (NLP) is an interdisciplinary field that aims to understand natural language using a computerized approach. It involves computing science, artificial intelligence, and linguistic.

In literature, there are several definitions of NLP. However, I decided to cite the ones written in the "Deep Learning in Natural Language Processing" book. From a scientific point of view, NLP aims to model the cognitive mechanism hidden behind the production and understanding of human languages. From an engineering outlook, NLP intends to develop applications to promote the interaction between humans and computers using languages [38].

The NLP origins date back to '50s. In 1950, Alan Turing came up with the homonym test to assess if a computer could exhibit an indistinguishable human-like behaviour [107]. Till the 1980s, the main approach was based on the belief that language knowledge is fixed by generic inheritance in our mind. This approach has been called rationalism [38]. This led to several attempts to formalize vocabularies and handwritten rules of natural language and reasoning in computers. Some examples derived from these complex systems of rules are MARGIE, to structure sentences into conceptual ontologies, and ELIZA, to emulate a Rogerian psychotherapist.

In the '90s, a new approach, called empiricism and driven by statistic and data corpora, appeared. It was due mainly to the increased computational power and availability of machine-readable data. In contrast with the previous theory, the empirical one assumes that the human brain requires a variety of sensory input to learn the structure of a language. In the same

years, computer vision combined with artificial intelligence start developing image classifiers and face recognition techniques. These algorithms based on data-intensive machine learning were used also to process natural language. Researchers focus on building statistical models or basic neural networks. They automatically "learn" their parameters based on vast training data by attempting to generalize among different conditions. Examples of these algorithms are Bayesian networks, expectation-maximization, and back-propagation neural networks. This approach leads to far better results and robustness than those created with the rational one [38].

Starting approximately from the 2010s, the deep-learning paradigm drove a new approach. The empiric models, despite their success in numerous applications of NLP, usually require human expertise and effort, especially in the training phase. Deep neural networks are inspired by the human brain and use several layers of neurons to extract higher and higher-level features from input. This enables to obtain an increased level of abstraction compared to the previous statistical approach.

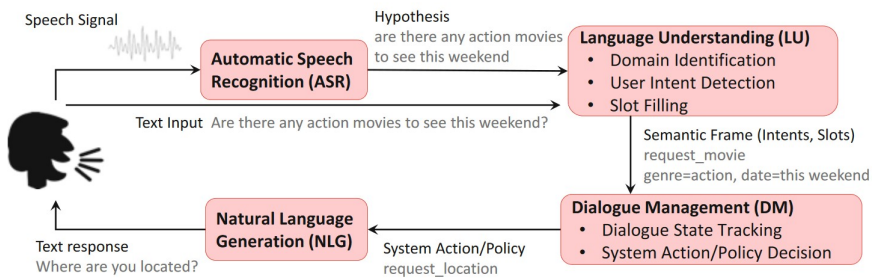


Figure 5.7: Example of natural language processing pipeline, retrieved from [38]

One aspect included in NLP is Automatic Speech Recognition (ASR). It consists in the automatic translation from natural spoken input to written text. Nowadays, deep neural networks combined with the back-propagation algorithm are the basis of all state-of-the-art and major commercial systems for speech recognition (such as Google Assistant, Microsoft Cortana, Apple Siri, Amazon Alexa, and more). On the other hand, the element of a NLP pipeline that deals with the translation of a text-based reply into a synthesized sentence is called Natural Language Generator (NLG). The next core element of NLP are Language Understanding (LU) and Dialog Management (DM). Once the spoken input has been translated into written words, the NLP system has to extract the meaning of the sentence in the context of the conversation. The current techniques are based on an expanded version of empirical methods. They are still based on data-intensive training

with all their advantages but add the increased power given by deep neural networks [38]. In Figure 5.7 is shown an example of NLP pipeline.

5.2.2 Choosing among NLP software

Considering the complexity, the effort and time required to create a NLP system combined with the desired level of reliability and performance, which necessitate a huge data set for the training session and an advanced cyber-architecture, it has been decided to use one of the most advanced systems available on the market. Doing some literature review, I found that the most advanced NLP systems, in 2018, were IBM Watson [55], Microsoft Azure cognitive services [77], Google Cloud [47], and AWS Comprehend [4]. All these platforms include services based on an artificial intelligence designed to build a NLP architecture and a LU model that can be trained directly online. However, they have pros and cons and I decided to compare them in parallel and use the one that satisfied the most the requirements of this thesis.

The first I decided to test was Watson from IBM. It has a friendly online interface that permits to define and train the LU model. I obtained excellent performances in intent predictions during preliminary tests, considering that it was able to discard hesitation sounds treating them as noise. Furthermore, it also supports the Italian language, but with less precise results, in my opinion, regarding the precision compared to the English language. One great advantage offered by Watson is the possibility to design NLG responses based on the dialogue structure. However, I found very complex in designing a dialogue. Interesting suggestions are proposed by Google [49]. Users can say unexpected utterances and get confused or frustrated. We have to pay attention to the way they express concepts or requests. Designing a dialogue requires several iterative tests to verify that the design fit the users' behaviour. Furthermore, the design should follow the Pareto principle (also known as 80/20 rule). It states that approximately 80% of consequences derive from 20% of the causes. In LU, 80% of users follow the most important 20% of possible paths [49]. This means that the most effort is required to design the key user cases, but we need to consider also the less common conversational paths. Watson supports C# language and has a complete software development kit (SDK) for Unity, software used to build the final application, allowing simple integration with the platform. It also can be used for desktop applications, as should be mine. It also provides integration with IBM cognitive services such as text-to-speech (TTS), and speech-to-text (STT). However, the latter does not support the Italian

language, making it necessary to also use the translation service which can add further errors. Furthermore, due to the complexity to foresee the dialogue structure combined with the limited trial period, I had to discard this platform.

The next I took into consideration was the one provided by Google Cloud. It seemed promising to me, considering all the services available including the number of languages and voices available for TTS and STT, and the LU online interface similar to the IBM Watson one. However, I could not use and test the service.

AWS Comprehend was the following NLP system analysed. In 2018, it did not support Italian language either for LU nor TTS. Because it is a fundamental prerequisite for the thesis, it was discarded. However, I have to say that recently it has increased the number of supported languages, including also Italian.

The last NLP platform tested was Microsoft LUIS. Its online interface allows to define all LU properties, train the model and produce it. Applications can request to the cloud service the utterance classification with REST API and obtain a JSON file as output. It supports the Italian language not only for LU but also for STT and TTS. The latter has 75 different voices and 5 neural voices, that improve the realism of the synthesized output. It is part of the Microsoft Azure portal, enabling integration with numerous other cognitive services. Unlike Watson, it does not have a Unity3D SDK but provides one for C# language that can compensate it. Furthermore, I obtained excellent results comparable with the IBM ones.

I decided to test also two LU free systems: Wit.ai recently acquired by Facebook [115], and DialogFlow by Google [48]. However, both are designed more for mobile or web applications rather than desktop. Furthermore, they are not directly integrated with other cognitive services needed for NLP and, in my opinion, prediction results are quite less precise than the other systems. Finally, they lack an online system for monitoring the requests and analysing the performance of the model.

For all these reasons, I decided to use Microsoft LUIS combined with Azure TTS to provide MAIA with NLP capabilities.

5.2.3 Microsoft LUIS environment

After the sign in to the LUIS web portal, it is necessary to create a new application defining its name and culture (the language that the app understands). The next step lies in creating intents. An intent represent an action that the user wants to perform, the aim of the input sentence. Ex-

amples of intents I defined are "StartExercise", called when a user desire to start performing a rehabilitative exercise; "Instruction", for help requests; or "Greeting", to accept and reply to users welcomes. LUIS has also a "None" intent to manage the less common cases. To define an intent, LUIS requires a set of reference utterances that consists of text examples of users' requests with that aim. The "None" intent should include examples of topics that the application does not address.

The other core element, together with intents, are entities. An entity is any data the application is interested in. Defining entities is an optional procedure, but it enables extracting relevant pieces of information contained in the user's request. LUIS allows defining prebuilt entities such as date, ordinal, email address, etc. and custom entities. I defined one custom list entity named "exercise". It itemizes a series of values, and each identifies a specific rehabilitative exercise. Each value is defined with a primary name and some synonyms. I also included "number" and "ordinal" prebuilt entities.

Figure 5.8 shows a screenshot of the LUIS dashboard related to the "StartExercise" intent with some example utterances, some with the "exercise" entity included. It is also visible the prediction score assigned to each example once the model has been trained online. It is between zero and one and indicates the level of confidence LUIS has for prediction result of an utterance.

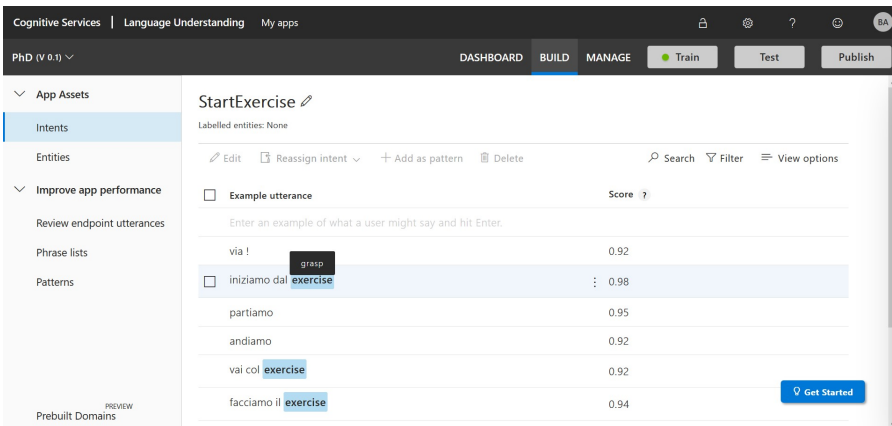


Figure 5.8: Screenshot of the LUIS dashboard to build an intent

After the build process, the app needs to be trained. Here, LUIS computes all prediction scores and generate an internal model that can be tested, directly in the same online interface, with some users' utterances. If the results are satisfying, the application can be published. It generates an end-

point URL that allows client app to send utterances to the service using REpresentational State Transfer (REST) Application Programming Interface (API) and obtain a JavaScript Object Notation (JSON) file that specifies information about the main intent, entities (if present), and sentiment analysis (if desired). The latter integrates "Text Analytics" service and express, with a number between zero and one, the sentiment of the data (positive is closer to one and negative closer to zero). LUIS also provides "spelling correction" and "speech priming" services. However, I did not need and include them in my application.

Figure 5.9 displays an example of the output, in the JSON format, generated by LUIS after a sent utterance. Line 2 indicates the input query received from the client app. Based on this sentence, LUIS compute the intent with the highest prediction score ("StartExercise" at line 5) and provide also the value of the score ("0.709" at line 8). If present, LUIS lists the entities identified in the utterance specifying the type ("number" and "exercise" respectively at lines 12 and 15) and value ("dieci" [ten] and "grasp", lines 13 and 17). At line 50 there is confidence score, in this case, equal to 0.575 (almost neutral sentiment). Each entity is further specified as shown in Figure 5.9 (b) with additional data that can be useful for the client application.

```

1  {}
2  "query": "facciamo dieci ripetizioni di grasp",
3  "prediction": {
4    "normalizedQuery": "facciamo dieci ripetizioni di grasp",
5    "topIntent": "StartExercise",
6    "intents": {
7      "StartExercise": {
8        "score": 0.709018767
9      }
10   },
11   "entities": {
12     "number": [
13       "dieci"
14     ],
15     "exercise": [
16       [
17         "grasp"
18       ]
19     ],
20     "$instance": [ ... ]
21   },
22   "sentiment": {
23     "score": 0.5753274
24   }
25 }

```

```

21  "number": [
22    {
23      "type": "builtin.number",
24      "text": "dieci",
25      "startIndex": 9,
26      "length": 5,
27      "modelTypeId": 2,
28      "modelType": "Prebuilt Entity Extractor",
29      "recognitionSources": [
30        "model"
31      ]
32    }
33  ],
34  "exercise": [
35    {
36      "type": "exercise",
37      "text": "grasp",
38      "startIndex": 30,
39      "length": 5,
40      "modelTypeId": 5,
41      "modelType": "List Entity Extractor",
42      "recognitionSources": [
43        "model"
44      ]
45    }
46  ]
47 }

```

(a) (b)

Figure 5.9: Example of LUIS output in the JSON format where the main intent, entities and sentiment analysis are present (a) with the detail of each entity (b)

5.2.4 Integration between LUIS and Unity

Once the LUIS online model was built, it was necessary to integrate it into the global desktop application dedicated to the thesis. To develop the project, I decided to use Unity. It is a cross-platform 3D engine and development environment [113]. It can be used to develop both 2D and 3D games and applications for a large variety of platforms and accepts, as development languages, C# and JavaScript. Unity uses the term "scene" to indicate the container of all elements that interact to realize the final application. Making a comparison with the world of video games, the environment for which unity was born, a scene can correspond to a level. It includes, for instance, menus, lights, objects, characters, and scripts.

The goal of the interaction is that the user activates the virtual assistant with a short and easy-to-remember keyword and then pronounce his/her request. The system converts the utterance into a valid input for LUIS. The latter classifies the query and outputs back to Unity the main intent and entities. Unity based on the results, performs the related actions, including some animations and synthesized replies from MAIA. However, the development process was not as simple as its concept.

The prerequisite for the speech interaction between user and PC was the presence of a microphone. I used the one integrated with the personal computer, but it can also be an external device. For this reason, I created a class that verifies the presence of this device when the application is running and prevents errors if it is not connected. To develop the interaction between Microsoft LUIS and Unity, I have written scripts that exploit some classes defined in the `UnityEngine.Windows.Speech` API. Particularly, I found very useful `KeywordRecognizer` (KR) and `DictationRecognizer` (DR). KR allows to define some keywords and the microphone keeps always waiting for listening to these words and fires an event when one is detected. On the other hand, DR takes possession of the microphone and records everything that is said for a specific period of time (usually a few seconds). I combined these two classes because, even though it requires that the user activates the recording system each time s/he has a request, it prevents to record and send to LUIS each utterance that would produce unwanted behaviours of the virtual assistant and costs for LUIS.

Figure 5.10 shows an example of this interaction in a Unity 3D scene where the user greets the virtual assistant that replies. I also reported below the screenshot some log messages to better explain the process.

The activation word for the KR needs to be short and simple to pronounce and remember. So, I decided to use the name of the virtual as-



Figure 5.10: Example of speech interaction between MAIA and user

sistant, MAIA. Each time the microphone detects this keyword, the KR's script fires an event called "OnPhraseRecognised". If the input has a confidence level at least medium (to limit errors) and it coincides with the keyword "maia", the virtual assistant change its position, a callout appears in the graphical interface (to give a feedback to the user), and then activate the DR. However, because KR and DR can not be active at the same time and it is not sufficient to stop or dispose KR, firstly I shut down the "PhraseRecognitionSystem" class, that sits underneath both, and then restart it with the activation of the DR class. This can be seen also in the first three log messages in Figure 5.10.

DR class listen to the input and try to convert it from voice to text. It

has four events: DictationHypothesis is triggered when the DR changes its hypothesis for the current utterance, DictationResult indicates that a phrase has been recognized with a specified confidence level, DictationComplete is fired when the session completes and DictationError when there is an error. When DictationResult is fired, if the confidence level is at least medium, the output text is sent to another class created to convert the query into a valid input for LUIS. In Figure 5.10 at line 4 is visible the user's utterance (buongiorno [good morning]) and the confidence level (high) of the DR's hypothesis.

Once DR outputs the string variable, using a web request the class sends to LUIS the formatted query and wait for the reply into an asynchronous function (to avoid a blocking algorithm). With a try-catch code, it tries to analyse the JSON output received from LUIS, otherwise, it manages exceptions in the catch block. Log message number 6 in Figure 5.10 shows this step, where LUIS has identified correctly that the input is a greeting with the 93.5% of probability. Then, the KR class is restarted to be ready for the next request.

Based on the main intent obtained, Unity executes specific functions. For instance, MAIA can reply and the answer is written into the graphical callout and synthesised, performs animations, provide assistance, shows instructions, etc. Figure 5.11 summarises the main steps involved in this cyclical process.

A separate discussion should be made regarding TTS capabilities. Microsoft Azure Speech services include also TTS, that converts text into human-like synthesized speech. It is available in more than 75 standard and 5 neural voices. Compared to the standard ones, neural voices use deep neural networks to improve intonation and pattern of stress. Precisely, they do prosody prediction and voice synthesis at the same time, obtaining a more natural and fluid voice [78]. I used an Italian female neural voice, named "ElsaNeural", for MAIA.

Unlike STT and LU, that are in real-time, TTS could introduce latency in the application. Furthermore, cognitive services have fees based on the number of requests. If a user often asks an answer for the same intent (for instance confirmation of an action), the system probably would send the same audio file more than once, increasing uselessly the costs. For these reasons, instead of sending a new request to Azure with the textual reply of the virtual assistant, I decided to build a Python script that allows me to type a sentence, synthesize it with the "ElsaNeural" neural voice and save the output in an audio file. So that, I could create arrays of possible replies for MAIA classified for intent, and import them in Unity. Here, suitable

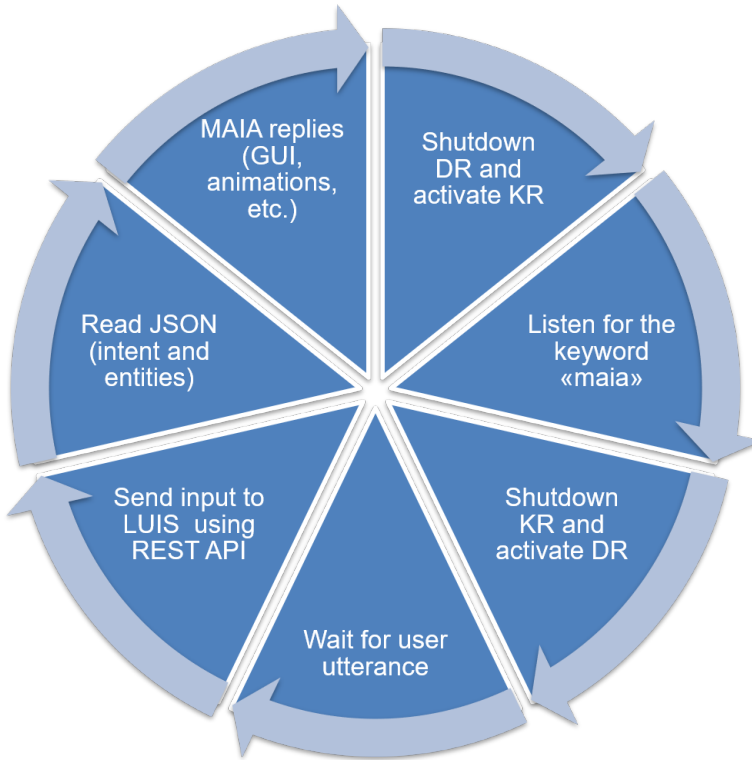


Figure 5.11: Summary image for the cyclical interaction process between user and MAIA

audio is chosen and played. This approach indeed limits the number of MAIA's possible answer, but it eliminates the service's cost (or reduce it notably) and improves the speed of the reply and the system. Moreover, the array can be enriched with new answers with almost no effort.

A further aspect to consider when creating a virtual assistant is its personality. In literature are present numerous researches about human-computer interaction related to the acceptance and the design of virtual or robotic social companions [34,36,39,40,65,67,71,101]. I found also very interesting an article published in The New York Times by Clive Thompson [106] titled "May A.I. help you?". He describes the new attitude humans have towards machines and conversational agents. If in the '80s emerged the point-and-click interface, nowadays million people tell Google Assistant, Microsoft Cortana, Amazon Alexa or Apple Siri to perform actions such as play music or even tell a joke. In opposition to what happened in the '50s, when A.I. programmers desired to pass the Turing test [107], now none of this software is aiming to deceive us. People want authenticity and trust.

Elderly may find very appealing the natural interaction with a virtual assistant compared with input devices like mouse and keyboard. Furthermore, they are available at all hours, can reply happily to repeated questions, and do not need to be paid.

CHAPTER 6

Global application and validation

This chapter illustrates the global application of the cognitive and motor rehabilitation system that permit to combine HANDY and MAIA with passive and active exercises. Then, it describes methods and results of the preliminary evaluation of the system with post-stroke patients.

6.1 The application

The following stage of the development process of the rehabilitative system for the hand consists in the creation of a global desktop application that allows patients performing rehabilitative passive and active exercises with HANDY, and therapists to define the therapy and monitor their results.

Figure 6.1 represents a schematic view of the structure of the application. It wants to be a compromise between functionalities and straightforward graphical user interface (GUI). For this reason, I kept a minimal and parametric design that enables the customization of the application with minimal effort (for instance adding new exercises).

The main menu (Figure 6.2) is dedicated to logging in. Both therapists and patients have to authenticate them before using the system, considering that the application could threat personal and sensitive information. Cur-

rently, because are not used real users' data, both usernames and passwords are stored into a local SQL database built with the SQLite library version 3.27.1. It is an open-source library to create small, fast, and self-contained SQL databases [99]. Even though it has not the security requirements that a commercial application would have, it was useful to communicate the concept to medical professionals.

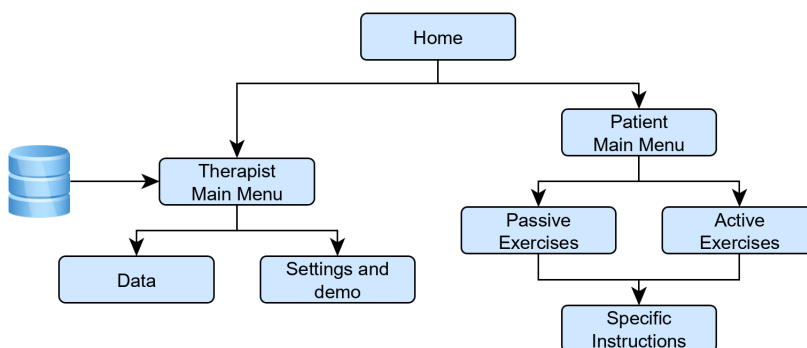


Figure 6.1: Application diagram



Figure 6.2: Main menu of the rehabilitative application

6.1.1 For therapists

On the therapists' side of the application, they can perform multiple actions. Firstly, they can manage patients' database creating a new entry, or

modifying an existing one (as exemplified in Figure 6.3). A unique identification number is automatically assigned to every new entry. Together with medical experts from Villa Beretta rehabilitation centre, I defined the most relevant fields required to identify a patient and his/her disease. In addition to classical personal data such as name, date of birth, etc. there are specific fields related to the disease such as the type of pathology, the side of the affected limb, the MAS score, etc.

Paziente ID: 0005

Nome <input style="width: 90%;" type="text" value="Enter text..."/>	Patologia <input style="width: 90%;" type="text" value="Enter text..."/>
Cognome <input style="width: 90%;" type="text" value="Enter text..."/>	Sotto-patologia <input style="width: 90%;" type="text" value="Enter text..."/>
Genere <input style="width: 90%;" type="text" value="M / F"/>	Arto interessato <input style="width: 90%;" type="text" value="Dx / Sx"/>
Data di nascita <input style="width: 90%;" type="text" value="gg/mm/aaaa"/>	Note <input style="width: 90%;" type="text" value="Enter text..."/>
Modified Ashworth Scale <input style="width: 90%;" type="text" value="0 / 1 / 1+ / 2 / 3 / 4"/>	

Figure 6.3: Scene dedicated to manage patient's database

Secondly, they can assist patients in executing continuous passive motion rehabilitative exercises for the hand. It can prevent and/or reduce tendon retraction, spasticity and oedema [21]. Examples of movements for the hand are:

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

the thumb and the index finger, the thumb and the middle finger, etc.

As can be seen in Figure 6.4, the caregiver set the desired exercise from the drop-down menu at the top of the GUI (in this case the Grasp). On the left side, s/he can set, using sliders, the range of motion (ROM) of the fingers, the number of repetitions and the speed of the movement. Once all parameters have been defined and HANDY is correctly mounted on the patient's damaged limb and connected to the application, the therapist can start the exercise. The connection between HANDY and the application starts immediately and in a completely automatic way. HANDY has a dedicated router that generates a stable, wireless and private network. To both PC and the device have been assigned a static IP address on the network that allows them to communicate without manual intervention on the application. The figure also shows input data from HANDY related to the desired position, current position, average position error, the current absorbed and temperature status of each linear actuator.

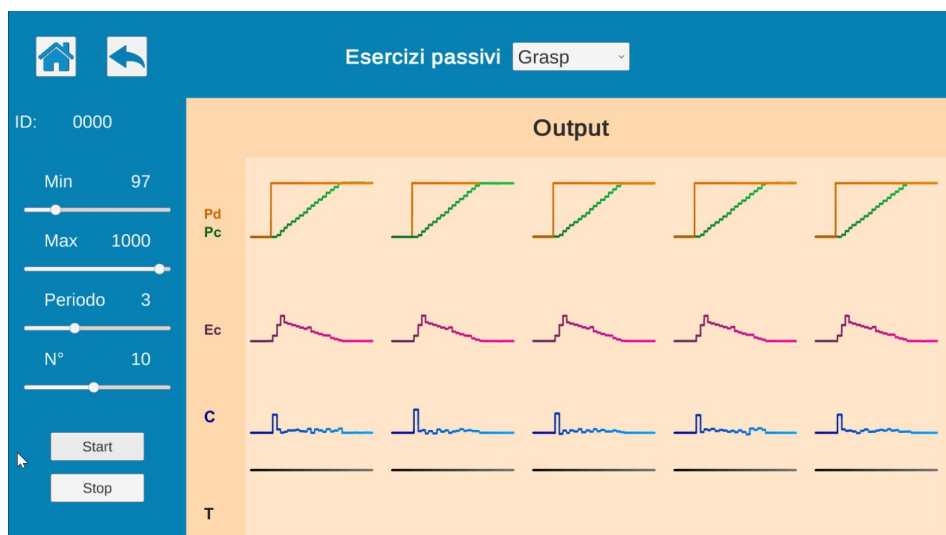


Figure 6.4: Scene with standard therapeutic exercises

The application provides therapists with the freedom to customize rehabilitative movements. It could happen that a patient cannot move one specific finger, or the ROM is not equal among all fingers, or the therapist wants to measure the patient's ROM during the assessment phase. The scene showed in Figure 6.5 has been developed to suit all these cases. It allows defining for each finger, from left to right, if it is moved by the device, its minimum and maximum value of ROM, the speed of the movement, and

the number of repetition. Lastly, s/he can set the time interval between the two following repetitions and start the exercise.

In both scenes, all data acquired from HANDY plus data about patient's ID, exercise type, date, starting time, and global duration time are saved into a textual file. It can be retrieved and elaborated by the application to show progress and historical schedule of each patient.

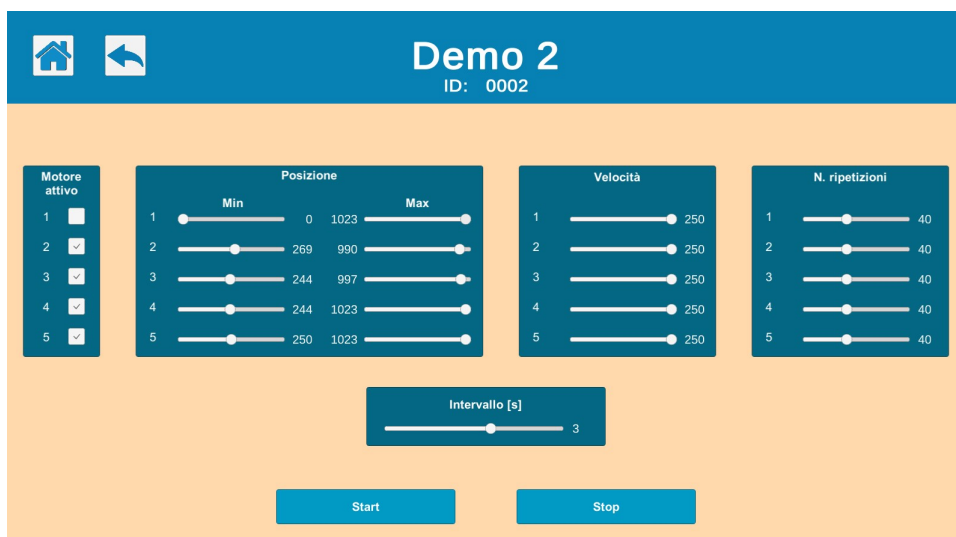


Figure 6.5: Scene with customizable exercises

6.1.2 For patients

This rehabilitative system aims to bring post-stroke hand rehabilitation at the patient's home and face the therapy abandon rate. One cause of the issue is mainly difficulties related to standard user interfaces such as keyboard and mouse devices. For this reason, I decided to supplement standard input devices with two more natural ones: the Leap Motion Controller (LMC) and voice input, with MAIA.

The LMC is a small device that enables hand tracking and gesture recognition. It is possible due to the combination of two CCD cameras that detect light emitted by three infrared LEDs and an internal model based on the anatomy of the human hand. To use the device with a personal computer, it has to be connected to the PC via USB cable and put the hand over the controller. It detects the hand with a tracking speed up to 200Hz in a 150° field of view [15] and generates its virtual representation on the screen. In Figure 6.6 it is possible to observe an example of desktop application de-

signed for the Leap Motion Controller (notice the virtual robotic model of the human hand on the screen that mimics the real posture) and, on the right, an exploded view of the device.



Figure 6.6: *Principle and structure of the Leap Motion Controller [111]*

Currently, LMC can be integrated with Unity using a dedicated SDK called Orion version 4.4.0. In recent years, the software development kit has focused more and more on virtual reality and head-mounted displays (such as the Oculus Rift and the HTC Vive) to bring hand presence in immersive virtual environments. However, it improved the robustness and the hand tracking precision and kept the desktop version.

I decided to use a Leap Motion Controller into my application to provide patients with a more natural way of interaction with the application, and therapists an instrument to obtain visual and quantitative feedback of patient's range of movement during rehabilitative exercises. It brings a notable advantage for therapists compared to the traditional rehabilitative process. Currently, therapists assess patients' conditions (such as range of motion, spasticity, etc) at the beginning of the therapy and periodically (every few months). The application exploits the LMC to continuously measure and store in files the angular ROM of the fingers. This, combined with the data from HANDY (current drain, actuator' stroke and speed, etc.), increases the amount of data therapists could use to evaluate the patients' signs of progress.

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

- passive: involves repetitive specific rehabilitative hand movements

(such as Grasp, Pinch, etc.) performed by HANDY. Even though this type of exercise is the less rousing, it is fundamental for people with severe symptoms (motor or cognitive) and, helps therapists to schedule standard therapy and monitor patient's progresses.

- active: consists again in rehabilitative movements but, unlike the previous type, it is the patient themselves who control the position of each actuator in HANDY with their unaffected limb using the LMC.
- ADL-based: aims to involve both cognitive and motor functionalities that have been damaged by stroke. They are task-oriented exercises inspired to activities of daily living (ADL) such as cooking. This type of exercise is the most engaging among the three.

Figure 6.7 shows the scene dedicated to passive exercises. Similarly to the therapist's version of the scene (Figure 6.4), the exercise is defined in the drop-down menu at the top of the page and the parameters can be modified using the sliders on the left side. However, this time all data captured by HANDY are not displayed (but saved anyway). In their place, the LMC generate a virtual schematic avatar that mimics the position of the hand during the rehabilitative movement. Furthermore, it estimates and shows the angular ROM of each phalanx. The implementation of this visual feedback is inspired by post-stroke mirror therapy. In standard mirror therapy, a patient is asked to perform the same movement with both hands. However, s/he sees a mirror reflection of the healthy upper limb instead of the affected limb. Mirror therapy has been found to generate a positive effect on motor functionalities in post-stroke patients [105].

To satisfy the patients' desire to see their hand move again and allow them to control finger extension, only when their therapist agrees, they can use the LMC to control HANDY and the affected limb with the unaffected one (Figure 6.8). Post-stroke patients usually have contralateral hemiplegia, it means that only one side of the body has been damaged by the disease and they could use the other side to perform symmetric hands movements. The exercise is called active because it is the patients the one who decides what action to perform and when. For this reason, it is not only a motor activity but also cognitive.

In literature, there are pieces of evidence that applications designed for LMC show high usability rating, but the sensor has also some limitations such as high influences of bright light conditions and tracking loss due to self-occlusion of the fingers [15]. Presently, other commercial devices can be used to track fingers' position and orientation, such as the Prime One

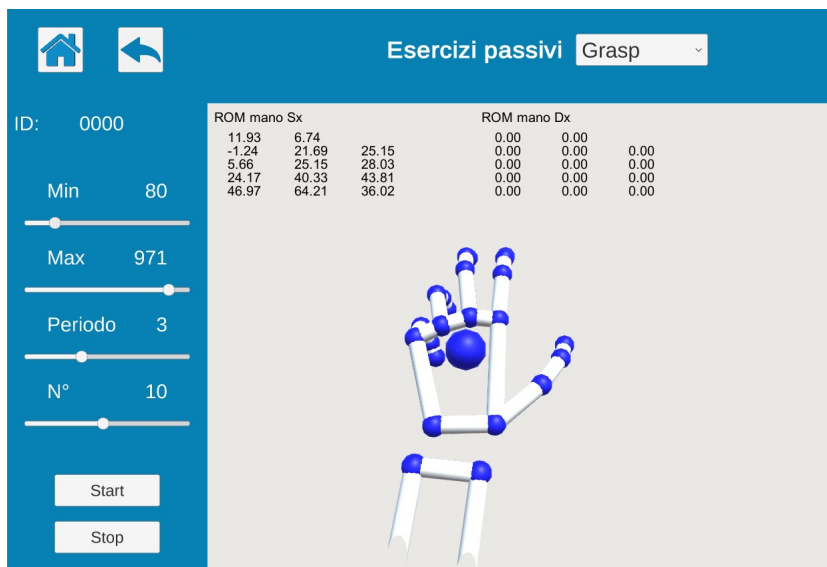


Figure 6.7: Scene designed for passive exercises. While the patient performs the grasp movement, the LMC measures the ROM of the fingers of the left hand

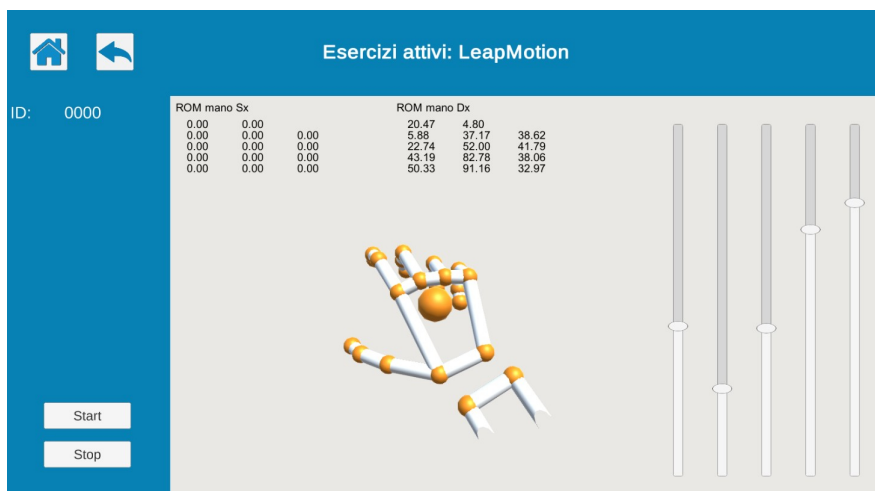


Figure 6.8: Screenshot of the active exercise with the Leap Motion Controller. On the top are listed the angular values of ROM of each joint (from the thumb to the little finger). On the right, the sliders show the actual position of each linear actuator derived from the LMC

Glove by ManusVR. It consists of a wireless data glove that exploits ten flex-sensors and inertial measurement units to compute hands data [74]. Nevertheless, I decided to use the LMC as an additional input device to con-

trol HANDY mainly for three reasons. Firstly, its simple and natural way of interaction that can be easily learnt by post-stroke patients in a few sessions as we could notice during the development of this thesis. Secondly, it suits the requirement of a low-cost device that can be bought directly by the user or by the rehabilitation centre and then lent to the patient in a perspective to perform rehabilitation in a domestic environment. Currently, the LMC can be acquired for €80, while the Prime One Glove costs €2990 [74]. Thirdly, one further advantage of LMC is that it is a non-contact measurement device. User does not have to wear it, as it is necessary for gloves. It would be extremely complex for the patient to wear autonomously the device on their healthy hand with the affected one.

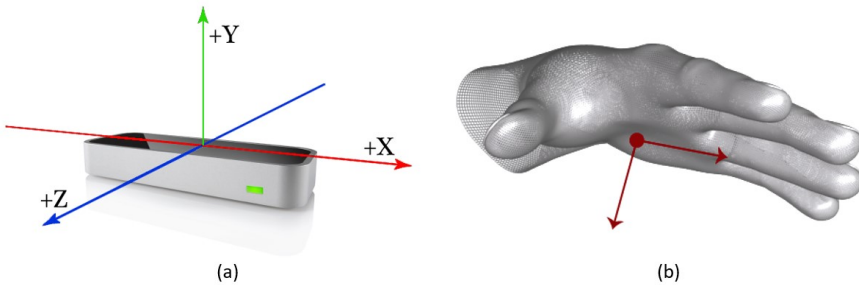


Figure 6.9: Leap Motion Controller coordinate system (a) [68] and palm direction and normal vectors (b) [69]

To define the position of the linear actuator based on the LMC data, I compute the spatial position and orientation of the fingers' bones. The Leap Motion SDK uses a right-handed Cartesian coordinate system with the origin centered at the top of the sensor (Figure 6.9 (a)) [68]. Each finger is defined by four bones: metacarpal, proximal, intermediate, and distal. Each bone can be described by the 3D coordinate of the base joint (the nearest to the wrist), the 3D coordinate of the end of the bone, and a 3D normalized vector for its direction (from the base to the tip). Afterwards, I compute the relative two-dimensional angles of the MCP, PIP, and DIP joints projecting the segments that define bones on the plane identified by the normal direction of the palm (pointing out) and the direction from the palm towards the fingers (Figure 6.9 (b)) [69]. These values can also be seen in Figure 6.7. At the same time, to avoid abnormal configuration of the hand due to possible tracking loss, I adopted multiple precautions. Initially, I did not consider the DIP angle because it was the least reliable among the three. The linear actuators could not overpass the ROM limits defined by

the therapist. The position sent to the actuator is an average value between MCP and PIP computed considering multiple measures of a time interval. In case of tracking loss, HANDY slowly returns in a neutral position of the hand.

Another cause that leads to therapy abandon is the monotony of exercises. There are shreds of evidence in the literature that task-oriented exercises are more effective than repetitive passive ones to improve patients' conditions. For this reason, I implemented a scene based on ADL. One screenshot is visible in Figure 6.10.

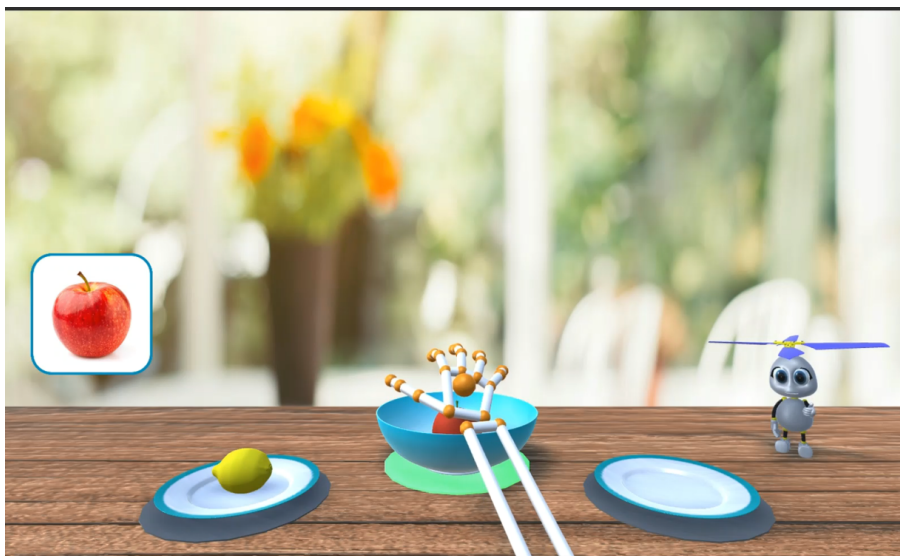


Figure 6.10: *Cognitive and motor exercise based on activities of daily living*

The serious game aims to create a meal following a receipt, training the hand with the Grasp gesture. On the table, there are two plates with one ingredient each and one bowl in the middle. Each time, the user has to put the correct ingredient, highlighted in the image on the left of the scene (an apple in this case), into the bowl. If the answer is correct, two new ingredients are generated, otherwise, the user has to try again with the same ingredients. In both cases, audio and visual feedback (different animations performed by MAIA such as a thumbs up) are played.

To put an ingredient into the bowl the user use the LMC. However, it has been developed two different types of control based on two possible patients' conditions. If the patient can not extend the hand and is wearing HANDY, the LMC detects the palm position. When the hand is over a plate and stays there for two seconds HANDY flexes the fingers. When the hand

is over the bowl, HANDY extend the fingers. To provide further visual feedback to the user about the hand position, the flat disk below dishes and bowl change its colour in fluorescent green, as can be seen in Figure 6.10. On the other hand, if the user conditions are less severe and s/he can partially open/close the hand, s/he collects and releases the ingredient based on the LMC grabbing condition. When the user closes fingers, the distance between two or more fingertips decrease and the device identifies a grab gesture. On the contrary, opening the hand signifies the end of a grab.



Figure 6.11: Screenshot of instructions about how correctly connect the LMC to PC explained by MAIA

In any moment patient can ask pieces of information or assistance to the virtual assistant MAIA. For simple requests, a reply obtained with the NLP algorithm can be sufficient. But for more complicated explanations, such as exercise instructions or assistance with input devices, the application reproduces the most appropriate videos or images about the topic among those specifically created and included into the application asset, and the 3D virtual assistant clarifies the concept combining animations and synthesized voice obtained by NLG and TTS. Figure 6.11 shows MAIA that illustrates how to correctly connect the LMC to a personal computer.

6.2 Validation

6.2.1 Protocol

Once the application included all features described in the previous sections, the whole system was presented and tested by the bioengineers and medical professionals from Villa Beretta rehabilitation centre involved in the development of the prototype. They expressed a very positive opinion regarding the system and defined it safe, promising, fit for rehabilitative purpose. They also were intrigued by the system and curious about how their patients would react by using it. They willingly agreed to perform a preliminary qualitative evaluation with post stroke patients.

The test does not aim to quantitatively measure the improvements that patients can obtain with a repeated and constant use of the system; because to have statistically significant data, a large sample and structured protocol are needed. Furthermore, to observe the first results from the medical point of view, a considerable amount of time (months or even years) could be needed. On the other hand, the goal of the observational study is to evaluate the comfort of HANDY and user's willingness to use the device within their rehabilitation program. Even though a clinical trial would be necessary for the future, these are preliminary and fundamental requirements for a rehabilitative device.

With medical professionals, a protocol has been defined to obtain homogeneous results. Patients are recruited voluntarily by therapists, based on their health conditions. Inclusion criteria are adult subjects in post-stroke sub-acute or chronic phase, with limited upper limb ROM. Exclusion criteria are disabling pain; cancer patient; severe deficiency of visual acuity, acoustic perception, and communication; and Modified Ashworth Scale ≥ 3 . One expert from Villa Beretta is always present during the evaluation. Initially, I explain to the patient the device, perform a demonstration and clarify the aim of the session. Then, I help the patient to wear HANDY and ask her/him to freely express any curiosity, doubt, and feeling about the system. Afterwards, s/he performs ten repetitions of two rehabilitative movements (Grasp and Wave) assisted by HANDY that is controlled wireless by the scene with standard exercises from the therapist's side of the application (Figure 6.4), so that both I and the medical expert can monitor the state of the system. After this step, the patient fills in the first questionnaire about comfort and willingness to use HANDY. Then, s/he is asked to do the ADL-based exercise with the LMC. Lastly, s/he fill in the System Usability Scale (SUS) questionnaire.

As declared by the creator of the questionnaire, SUS aims to rapidly measure people's subjective perception of the usability of a system [25]. It is currently considered a standard questionnaire in the literature to evaluate usability cited in more than 8000 articles. It has 10 statements based on a 5-point Likert scale where 1 means "strongly disagree" and 5 "strongly agree" with the statement. User has to assign a score to each. The score contribution of each item ranges from 0 to 4. It alternates positive and negative items to avoid response biases [25]. For the positively worded items, the score contribution is the scale position minus 1. For negatively worded items, the contribution is 5 minus the scale position. The sum of the scores is multiplied by 2.5 to obtain the overall value of SUS in a range of 0 to 100 [25].

However, several times patients and elderly I asked to fill in the SUS questionnaire, in different projects, defined it confusing [9]. Moreover, the SUS gives a global index about the usability of the system but does not provide specific indicators that could be used as input to further improve the system. For this reason, it has been decided to integrate it with the first and more specific questionnaire about HANDY. It uses 5-point Likert scale questions to assess the main features and components of the exoskeleton such as the comfort, the lightness, the aesthetic, the noise, etc. Furthermore, the informal setup of the observational sessions combined with the think-aloud strategy allowed patients to express themselves freely, generating more impressions and suggestions than using just questionnaires.

6.2.2 Results

So far three patients (two male and one female) undergo the validation session (Figure 6.12). One has an ischaemic stroke in chronic stage with left hemiplegia. Also, the second has an ischaemic stroke with left hemiplegia but in a sub-acute phase. The last had a concussion followed by coma that caused right hemiparesis with MAS score equal to 2. This highlights that the system is not only designed for post-stroke but extensible to other diseases that involve the hand, such as concussion.

The first questionnaire has 9 statements specifically defined with caregivers to assess the comfort and the willingness to use HANDY. It is based on a Likert scale from 1 to 5 where 1 means "strongly disagree" and 5 "strongly agree". Similarly as the SUS, also this questionnaire has positive and negative (items 2, 4, 5) statements. To each item corresponds a normalised score from 0 to 4. For the positively worded items, the score contribution is the scale position minus 1. For negatively worded items,



Figure 6.12: Photographs taken during validation sessions with patients wearing HANDY with a enlargement on the hand

the contribution is 5 minus the scale position. The final value is the sum of all contributions. It can range from 0 to 40. Table 6.1 shows the outcome with mean and standard deviation. The statements have been here translated from the original Italian version.

The second questionnaire, filled in at the end of the whole session, is the SUS [24] translated in the Italian language (mother tongue of participants). Table 6.2 summarises the mean and standard deviation values based on the normalised scores obtained.

The outcome from the SUS questionnaires was 72.50 ± 6.61 points out of 100. Using the adjective-based rating of the SUS proposed by Bangor, Kortum, and Miller in their article [16], the system obtained an overall "good" usability result.

6.2.3 Discussion

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

Table 6.1: *HANDY's comfort and willingness to use questionnaire. Mean values ranges from 0 to 4 and negatively worded items have been normalized. HANDY obtained 33.50 / 40*

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

Table 6.2: *SUS questionnaire results. Mean values ranges from 0 to 4 and negatively worded items have been normalized. The system obtain 72.50 / 100*

#	Statement	Likert Scale [1 – 5]	Normal. Mean [0 – 4]	Std. Dev.
1	I think that I would like to use this system frequently	4.67	3.67	0.58
2	I found the system unnecessarily complex	2.00	3.00	0.00
3	I thought the system was easy to use	4.33	3.33	0.58
4	I think that I would need the support of a technical person to be able to use this system	4.33	0.67	0.58
5	I found the various functions in this system were well integrated	4.00	3.00	0.00
6	I thought there was too much inconsistency in this system	1.00	4.00	0.00
7	I would imagine that most people would learn to use this system very quickly	4.33	3.33	0.58
8	I found the system very cumbersome to use	1.00	4.00	0.00
9	I felt very confident using the system	2.67	1.67	0.58
10	I needed to learn a lot of things before I could get going with this system	2,67	2.33	1.53
	Total (sum * 2.5)		72.50	6.61

irrelevant aspect. All of them showed interest and declared that they would use the system very willingly both in the clinic and at home. One user expected a greater ROM of the fingers. It can be understood considering the

only-pull HANDY's configuration adopted during these initial tests combined with the flaccid state of the patient's hand. However, this aspect can be overcome with the other push-pull configuration of HANDY. None has shown signs of pain or discomfort. On the contrary, one user asked the present bioengineer if he could continue using it. Another was very surprised to see her hand move again after 4 months and said that she didn't believe it anymore. All these promising considerations are confirmed by the results of the first questionnaire.

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

It is a preliminary qualitative evaluation of the system, that would surely need a more exhaustive assessment with a higher number of participants. However, the positive first outcomes obtained by the global prototype with patients and also medical professionals seemed promising.

CHAPTER 7

Conclusion and future work

7.1 Conclusion

This thesis describes a cognitive and motor rehabilitation system for the hand designed to assist post-stroke patients during their rehabilitative therapy towards the process of regaining of their autonomy. Improving the hand capabilities permits performing activities of daily living and interact with the environment. The thesis also suggests solutions that could possibly reduce the social, economic and personal burden of stroke.

The system involves several innovative aspects designed keeping in mind the users' needs compared to the literature. Users are both patients and therapists, and both have been actively consulted during the whole development process collaborating with the Villa Beretta rehabilitation centre. These innovations can be classified into the three main aspects of this thesis: the exoskeleton HANDY, the 3D virtual assistant MAIA, and the global application.

The initial research question emerged from the literature review of hand orthosis was connected to the possibility to develop a prototype of exoskeleton that satisfies requirements about comfort, portability, customization and cost. Furthermore, the collaboration with the medical experts and patients

of the Villa Beretta rehabilitation centre through periodic focus groups has allowed emphasizing some aspects often overlooked in the literature during the development of a prototype such as safety and lightness. HANDY includes several features implemented to address these necessities:

- **safety:** although still at a prototype level, HANDY was developed keeping in mind that a rehabilitation device must first of all guarantee the safety of its user. At the firmware level, the control algorithm constantly monitors the force applied to the fingers and the state of the components. At the hardware level, the PCB strongly limits the presence of stray wires and improves the reliability of the system. Besides, the emergency stop button provides a further level of protection for the patient.
- **comfort:** HANDY is extremely lightweight on the hand (only 190g), permitting repetitive rehabilitative exercises without fatigue. Its design avoids mechanical misalignment between the device and fingers. The materials for the glove (such as the Plastazote®) and the flexible components (NinjaFlex®) minimise the skin abrasion. These represent two of the principal causes of discomfort in current rehabilitative devices.
- **portability:** it is ensured by the small backpack that contains all components of HANDY, including a rechargeable power supply. The backpack has a dedicated router used to provide HANDY with a reliable network to control the device wirelessly. The backpack also allows patients with wheelchairs to use the device, fixing it to the back of the wheelchair, without causing any obstacle to the movement.
- **customization:** HANDY is mainly composed of two subassemblies: the drive and control unit and the glove. While the former is standard for each patient, the latter can be designed to fit the individual user's hand. This solution is dictated by the fact that HANDY is designed for home-therapy and therefore used by a single person for a long time. Consequently, it does not require that the single prototype has to be adaptable to several people, but rather that in a short time it will be possible to create a model that is most suitable for the specific patient. This is made possible by the combined use of the automatic design tool, the parametric CAD software and the additive manufacturing technology. With a few hand measurements, the tool generates the input parameters for the CAD software. This modifies all parts of

the assembly and exports them in STL files. At this point, 3D printing allows making them quickly and at limited costs.

- cost: concerning the cost of the prototype, it is currently difficult to estimate what the cost of a final product could be. However, the overall cost of the prototype is around 1000 euros. Some comparable commercial devices significantly exceed this amount and probably if hypothetically HANDY became a final product, the production costs would be further reduced compared to the single prototype. This economic advantage would allow more people to undergo rehabilitation therapy.

Thinking about moving the therapy at the patients' home, during several focus groups with therapists, the idea of creating a virtual element capable of interfacing with the patient in the case of simple requests appeared very interesting: hence MAIA was born. It could be a linking element between medical professionals and patients capable of providing help and encouragement using natural language. More in detail:

- linking element between patients and therapists: from a home therapy perspective, the need arises for an element capable of responding quickly to the patient's basic needs, such as how to connect a sensor or what to do in an exercise. Currently, these needs are usually addressed personally by a therapist, who must solve the problem on the phone or by going to the patient's home. This involves considerable use of time and resources by the medical staff. MAIA includes some of these features so that the patient can receive the necessary information without having to contact the therapist. Although it is not possible to solve all the needs, this innovative solution would result in improvement compared to the state of the art. Furthermore, the set of possible actions could be enriched with little effort in future.
- encouragement: the majority of the forefront solutions that implement rehabilitative exercises use a numerical score to provide feedback to the patient related to their execution of an exercise. Although for some people this can be seen as a challenge to improve, for others it can seem a little apathetic. MAIA has been designed to be a hearty but not invasive companion in the scene. If the patient is autonomous it will provide feedback about the execution without disturbing the execution (with some animations such as the thumbs up pose). On the other hand, if the patient requires more support, it could be more interactive (communicate suggestions or motivational phrases).

- natural language interaction: providing MAIA with some capabilities to respond to patients' needs, it requires to implement an input method. Usually, standard input devices are used such as mouse and keyboard. However, while performing a rehabilitative exercise with the exoskeleton worn on the hand, it could be difficult for a patient to digit his/her request. To overcome this issue, it has been used the speech input. This led to a further aspect to take into account: each action in the application requires a specific input, usually a keyword. Nevertheless, increasing the number of possible actions would result in more and more keywords to remember, a task that could be challenging. Here Natural Language Processing capability is helpful. Only one activation keyword has to be remembered (the name of the assistant: "maia") and then the user states the request as s/he would normally do to another person. It is the task of the NPL system to understand the intent and the entities enclosed in the sentence and to generate a formatted output that the application can manage automatically.

Rehabilitative exercises are the core of the therapy. The developed application has three different levels of exercises: passive, active, and active-cognitive based on activities of daily living. The integration of a rehabilitation device with this software offers several advantages for both therapists and patients:

- customization: stroke symptoms vary among different persons and even the same patient can move through different phases of the disease evolution as highlighted by Brunnstrom [26]. A patient with more severe condition could not be able to perform active movements and passive exercises for fingers extension aimed at reducing hand spasticity can be more effective than active ones. On the other hand, a patient who can move voluntarily, even if partially, the hand will be more attracted to carry out active or cognitive exercises. Moreover, each type of activity can be further customized changing the difficulty of the task tuning some parameters such as the number of repetitions, the amplitude of the movement, etc.
- patient's evolution monitoring: currently, most of the rehabilitative centres distinguish two different phases concerning the rehabilitation of patients: assessment and therapy. The first aims to quantitatively measure the patients' strengths and deficits with functional scales and instrumental exams. It is performed at the beginning of the therapy

and periodically (for instance every few months) to define and adjust the rehabilitation plan. The second includes all the activities that the patient does to improve her/his health conditions. This methodology lacks in terms of treatment adaptability. The global system developed within this thesis harvests data from the exoskeleton and the Leap Motion controller about the range of motion of each finger, the force applied to them, the number of repetition and the speed of each movement, etc. Currently, all these data are associated with the patient's ID and saved locally in text files. These can be used to track the patient's clinical evolution continuously during treatment, and not only in the assessment phase, significantly improving the adaptability of the therapy to the clinical evolution of the subject compared the state of the art. Furthermore, in the future, this could lead to a partial self-adapting system.

- engagement: when a patient has mild to moderate symptoms, especially with home-therapy, if the exercises are considered boring, the user can discontinue the therapy or even abandon it. The global application endeavours to reduce this phenomenon by proposing 2 solutions. The first is to use the Leap Motion to give the patient the possibility to control the exoskeleton naturally. It involves the patient's sense of agency and enhances the power of rehabilitation. The second is combining HANDY with different types of serious games based on activities of daily living or even more inspired to actual games. Here I developed an example grounded on cooking. It uses the Leap Motion Controller as an input device to track the hand position and HANDY, as output, to assist patient performing the grasping movement. It also involves cognitive aspects of rehabilitation increasing further the efficacy of the activity. However, this is only an example of a possible situation. Each rehabilitative movement can be surrounded by a different environment and associated with a different objective (for instance the pinch could be connected to the domino game or a puzzle). Also, it can be created games related more to fun, such as the one I developed during my master's thesis. The goal was to save the Earth from asteroids. The movement of the grasp, controlled by the LMC, activated the cannons of the spacecraft virtually driven by the patient.

Even though the system is still a prototype, the outcomes from the preliminary qualitative evaluation, that are fundamentals, seems very promising. Both patients and therapists showed interests and willingness to use the system. This can have multiple positive repercussions on the burden of

the disease. The patient, with the serious game approach of the application, could be more encouraged to continue the therapy compared to the traditional and passive methods currently used in clinics. Moreover, it could impact also the economical aspect such as the cost for the patient and his/her family of healthcare and time off work, the government costs of healthcare. Finally, home therapy allows medical professionals to address multiple patients' needs and monitor their progress at the same time compared to the individual patients' periodic visit.

7.2 Future work

I think that a clinical quantitative evaluation is needed to assess that a new therapy with the system is safe and effective from the point of view of improving patients' conditions will be necessary. However, it requires a greater number of participants and it would last for a long time. Medical experts from Villa Beretta stated that to observe quantitative improvement in the disease symptoms, months or years of constant use of the device are needed, depending on the severity of the disease.

Another aspect that would be interesting to explore is the integration with Mixed Reality. The system could be easily integrated with this technology that allows interacting with virtual and real objects. It could enhance further the range of possibilities and involve users more, reducing the therapy abandon rate.

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