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DESIGN, DEVELOPMENT AND CLINICAL VALIDATION OF A PASSIVE UPPER LIMB EXOSKELETON

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ABSTRACT

Cerebral palsy is the most common cause of disability in childhood, therefore, this project seeks a solution to help improve the quality of life of all those children who suffer the consequences of this set of motor and postural disorders.

The development of a passive upper limb exoskeleton, whose mission is to provide support during rehabilitation to all those users who have reduced mobility in the upper limbs, is the main line of work of this project. The exoskeleton is a mechanism with 4 degrees of freedom and a system of assistance and resistance to support the user.

The functionality of the mechanism, giving freedom to the patient in performing the main movements of the shoulder and elbow, was tested through two clinical stages of evaluation. The first phase made it possible to detect design errors whose changes led the patient to feel comfortable during the use of the exoskeleton in a spatial range adapted to his or her reach. With the second period of clinical analysis, it was possible to validate the mechanism as a functional device using the AMPS scale.

RESUMEN

La parálisis cerebral es la causa de discapacidad más frecuente en niños, por ello, el presente proyecto busca una solución que ayude a mejorar la calidad de vida de todos aquellos niños que sufren las consecuencias de dicho conjunto de trastornos motores y posturales.

El desarrollo de un exoesqueleto pasivo de miembro superior, cuya misión es dar soporte durante la rehabilitación a todos aquellos usuarios que tengan movilidad reducida en las extremidades superiores, es la línea de trabajo principal de este proyecto. El exoesqueleto es un mecanismo de 4 grados de libertad y un sistema de asistencia y resistencia para el apoyo al usuario.

La funcionalidad del mecanismo, dar libertad al paciente en la realización de los movimientos principales de hombro y codo, fue testada mediante dos etapas clínicas de evaluación. La primera fase permitió detectar errores de diseño cuyos cambios llevaron al paciente a sentirse cómodo durante el uso del exoesqueleto en un rango espacial adaptado a su alcance. Con el segundo periodo de análisis clínico, fue posible la validación mediante la escala AMPS de el mecanismo como un dispositivo funcional.

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1 INTRODUCTION

1.1 Objectives, Goals and Scope

Approximately, a range of 1 to 4 out of 1000 kids in the world suffer from Cerebral Palsy (CP), a neurologic condition caused by a brain injury that produces loss or impairment of motor function [1] [4].

Children with CP disability have neurologic damage in parts of the brain that affect muscle tone, gross and fine motor functions, balance, control, reflexes, and posture. Swallowing and feeding difficulties, speech impairment, and poor facial muscle tone can also be expressed. All these signs, limit children in their daily life, preventing them from optimally performing activities such as walking, writing, brushing teeth, buttoning shirts, tying shoes, and eating by themselves.

The main objective of the present project is to improve quality life of children from 6 to 14 with CP, in a way that they can perform daily activities and interact with the environment with as little help as possible.

Movements facilities around the environment, make easier children's social interaction, the engine of cognitive development. Kids need to learn how to make friends, negotiation and compromise human values, how to solve problems and how to accept people is different to them out of so many things they need to acquire. To be able to do that, they need to totally feel freedom, feel sure of themselves, and feel that nothing can stop them on the task of knowing the world.

Essentially, the project's contribution to CP is in the physical sphere. The main goal in this schema is the development of an exoskeleton, a device which helps in enhancing and improving children's physical abilities to help them in their environment's interactions that let them live a full life. An evolution of a previous design prototype will be presented for using during rehabilitation sessions with physiotherapists.

The function of the exoskeleton is to facilitate joint movement and support the weight of the arm so that children can gain muscle tone and precision in psychomotor skills through an assistance-resistance mechanism. The idea is that children repeat a series of exercises with the device on, so that they gain confidence and muscle strength in order to be able to perform the same exercises without a physical assistance once therapy is completed.

In addition, it will seek to design a model of not very large dimensions, low cost and easy usability, so that any clinic or physiotherapy and rehabilitation institute can afford to have the exoskeleton in its facilities to contribute to physical and therefore cognitive children development.

Exoskeletons promise a better future for CP. Contributing to a better physical development of children with CP will not only promote better cognitive development but also the inclusion and happiness of these children.

1.2 Technology Impact on Biomedicine

Technology lineal growth has been changing in the last decades leading to an exponential growth curve. This is happening due to constant increase of processors capacity, technology price decrease in relation with what offer to us and because of the easy interchange of information since internet appearance.

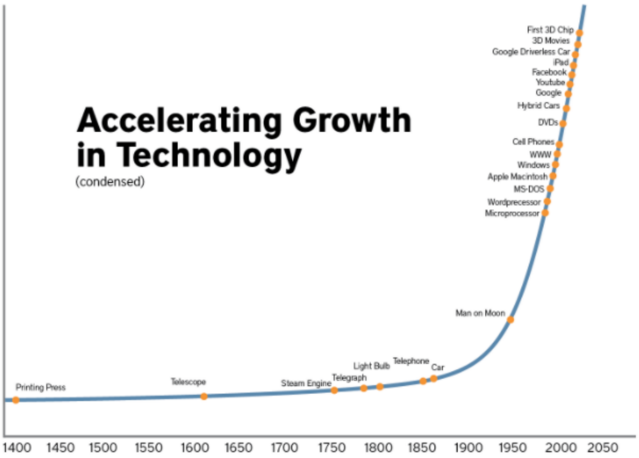


Figure 1: Accelerating Growth in Technology Curve [2][4]

Of course, health field has also been affected by this exponential graph. Technology evolution has contributed to the development of new medical equipment that has allowed make faster and precise diagnostics. At the same time, it has been possible faster interchanging of patient medical records thanks to hospital information systems (HIS).

As early as 1963, Dereck John de Solla Price spoke of exponential growth of scientific literature. He was the father of scientometrics (quantitative analysis of scientific production) which is the basic of Artificial Intelligence (AI) in medicine.

AI has allowed analysing data from clinical trials to test treatments effectivity and to perform experiment's and devices contribution's validations. These make easier to achieve biomedical goal: promise a better and a more comfortable future for patients.

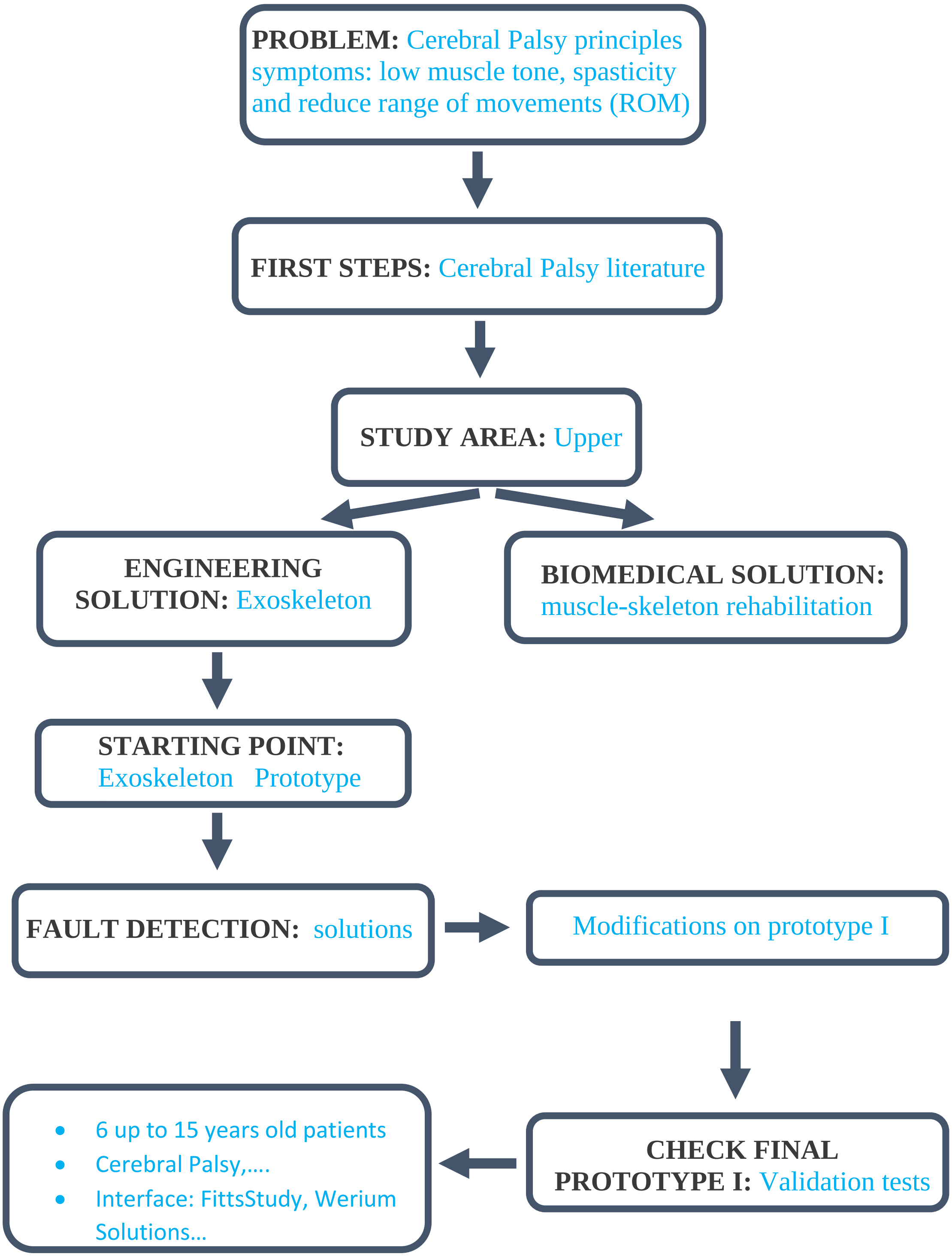
Technology evolution and being able of accessing to medical knowledge from all above the world, let human being to be in constant development of mechanisms that make CP children’s life easier. Furthermore, every time, people is creating new manufacturing ways that reduce costs per unit, what leads to faster device’s improvements at each time to personalise products and adapt them to patient requirements.

The birth of 3D printing has also meant a great advance for prostheses’ and orthose’s field. Being able of creating cheap models and prototypes allows engineers detect errors and make necessary modifications before mechanisms reaches patients. The technology hidden behind 3D printers, allows to obtain complete exoskeletons in just 48 hours, allowing a quick arrival to the patient. In addition, the low printing time allows the exoskeletons to grow up as children do; 3D printers allow adapt orthoses to new patient’s requirements depending on how their physical’s characteristics evolution.

Children with CP can now improve their motor skills thanks to the easy development and adaptation of different mechanisms to their qualities. The support of the exoskeletons during work sessions in physiotherapy clinics is a supplement for physical rehabilitation. This project wants to continue collaborating with CP, providing new solutions and ideas that can help these children improving their quality of life by gaining independence and being able to fend for themselves.

1.3 Methodology

In this section, the steps that were taken, in order to develop an exoskeleton for using during rehabilitation sessions with children with CP, are shown through a workflow scheme:



The starting point was an exoskeleton design by A. Cortellucci (1) with five degrees of freedom. The first task was analysing it for extracting functional or design mistakes.

Once errors and improvements needed were clearly defined, the design process took place to perform changes for reaching a functional exoskeleton. For this step, reading previously lot of literature about exoskeletons and upper limb characteristics was needed.

After redesigned stage, to probe modification's effectivity, the complete prototype was taken to reality out of the computer by 3D printers. This step was essential to appreciate if changes make the exoskeleton functional and if it fits the human body.

The most important goal of this project is that the exoskeleton can be useful for patients with CP and help them in rehabilitation sessions rather than being a hindrance. To corroborate that this happens, once the design stage was completed, an evaluation and validation process began. Participants were patients with not only CP, but also with different disabilities that leads them to the same state as children with CP: low muscle tone, spasticity, and reduce ROM of upper limb.

Validations were performed at *IRF La Salle* institute. First clinical stage stablished during the last 15 minutes of the rehabilitation sessions that patients had with their physiotherapists and evaluations consisted on patient's interactions with a touchable screen where FittsStudy interface had been installed, when they had the exoskeleton attached. Exercises at this first stage were based on reaching targets along horizontal axis.

Second clinical stage objective was the same at first clinical stage; testing if the exoskeleton is functional; but this time, way and interface of interaction were different. Direct contact was replaced by indirect contact thanks to Werium sensors and Werium Solutions video games.

Statistical analysis will be performed on session's data for extracting information about children's evolution during exoskeleton sessions and for obtaining information about exoskeleton contributions comparing attaching mechanism data with no attached mechanism data.

1.4 Project structure

Although in the previous section it has been explained how the different steps were carried out to give life to this project, the structure and organization that this report follows will be explained below to give details of each and every one of the key points of the project.

To fully understand the functionalities that the exoskeleton must provide, an introduction about CP will be made in chapter 2. First, signs and symptoms produced by CP disability are going to be mentioned. Moreover, in order to understand movement's handicaps these children face to, a brief explanation of the normal movements of the 3 arm joints will be defined on this same section for later justification about which movements are supported by the exoskeleton and why.

There will be also a brief introduction about the most well-known exoskeletons on last section of chapter 2. Initially a classification of different exoskeleton types will be included and finally the chapter will focus on upper limb devices.

Before starting with the design and modifications step, the requirements that the mechanisms must meet; indicated by the physiotherapists; will be explained in detail. Physiotherapists, project partners, are the ones who perfectly know children limits and therefore the most indicated people to decide which movements need to be assisted.

The design phase will begin with an exhaustive explanation of the original exoskeleton from which the project starts. The errors detected and the improvement process to solve and remove them will be included on chapter 3 after exoskeleton's requirements.

Once the design phase has been completed, validation phase will be explained on chapter 4. The objectives of these tests, the number of participants, the characteristics and handicaps of each of them, ages and other information considered significant for the study, will be included. In addition, visual and numeric evaluations will be perform from data obtained from FittsStudy and Werium Solutions interfaces in order to quantitatively assess the help that the exoskeleton offers during rehabilitation.

Finally, the results of the studies as well as the conclusions about the help that the exoskeleton provides during children rehabilitation will be exposed on chapter number 5.

2 THEORETICAL FRAMEWORK AND STATE OF ART

CP is the most common motor disability in childhood. Last studies reported by Aspace (Non-profit entity for Cerebral Palsy Care in Spain), reveals that approximately 2 out of 1000 kids in Spain suffer from this disorder, that leads to a total of 120.000 people in the country with CP [3][4]. This disorder is produced by a cerebral injury that affects body position and mobility, restricting day to day activities, being bound with intellectual and sensitive disorders in most of the cases.

Cerebral injuries responsible of the disease, are related to non-progressive disorders that take place before cerebral development reaches the end, what means that is an irreversible neurological injury that does not change throughout life although displayed symptoms may get better or worst. This cerebral injury can occur during the gestational phase or the first three years of age. Injuries also affects Central Neural System in charge of processing external and intern information.

Attention, language, perception, memory and reasoning can be affected depending on the type, the place, the moment, the number… of injuries presented. So, some people live with CP in an imperceptible way and some others need others help to get through daily life.

There are many frequent consequences of suffer from CP (see Figure 2):

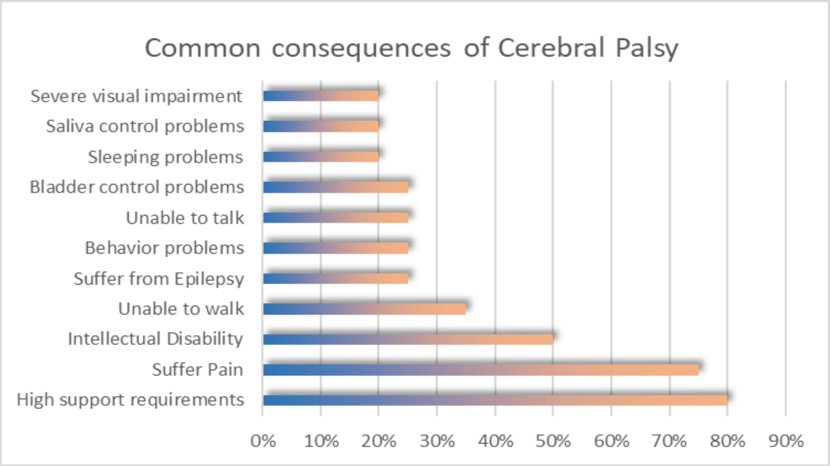


Figure 2: Common Consequences of Cerebral Palsy [4][4]

2.1 Classification of Cerebral Palsy

There are many ways of classifying CP types. Attending to the fact that the disorder difficult message transmission from brain to muscles, Eric Denhoff, pioneer in treating children diseases, defines in 1951 four CP types [5][4]:

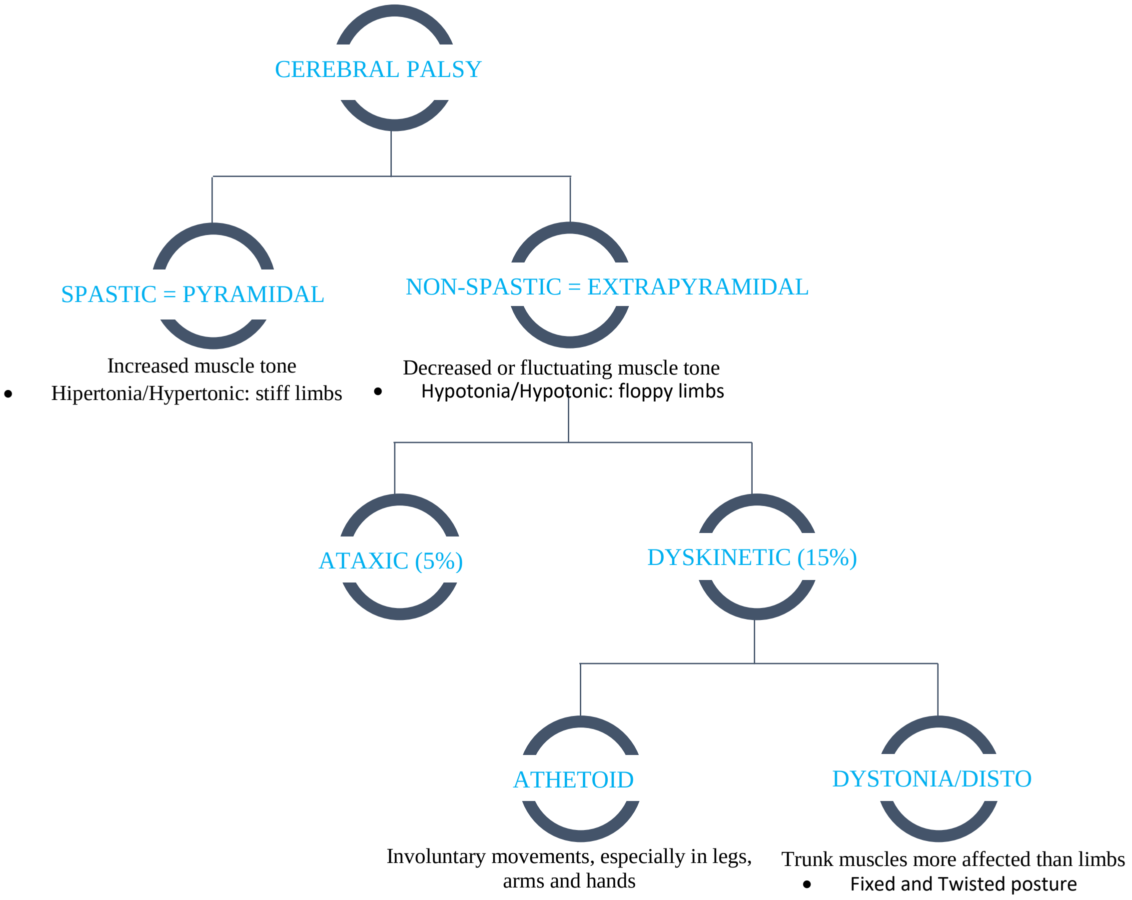
- Spastic: spasticity means rigidity. Head, arms and legs muscles are the most affected in this type of disorder, they become stretched and weakened. Presented when nerve cells from cerebral cortex do not perform in a correct way their functions. It takes approximately the 70% of cases of Cerebral Palsy.

- Dyskinetic: Characterized by slow, uncoordinated and unvoluntary movements. Lasts ones get worst with emotions and fatigue, better with rest and disappear with sleeping. People with this type of disorder deals with muscles that change every time from relaxed to rigid and vice versa. This people also have communications problems due to the difficulty to control breathing, vocal chords and tongue. This type of disorder is presented when the injury affects the centre of the brain.

- Ataxic: Produced by a cerebellum injury. People with this disorder struggles to get balance. Depending on the injury scope, walking could be possible although in an unstable way.

- Mixed: More than one brain structure gets affected. A combination of different symptoms will be manifested.

In order to reach a better understanding of this classification, a schema is shown below:



There are many involuntary movements derived from non-spastic CP [6][4]:

- Athetosis: slow and writhing movements that are often repetitive, sinuous and rhythmic.
- Chorea: irregular movements, not rhythmic or repetitive.
- Choreoathetoid: combination of the two previous cases.
- Dystonia: involuntary movements accompanied by an abnormal and sustained posture.

Topographical classification describes body parts affected. Prefixes and root words are combined to yield topographical distribution. To understand what each word refers to, it is essential to understand that *paresis* means weakness and *plegia* or *plegic* means paralyzed [7][4]:

- Monoplegia/monoparesis: Just one limb is affected.
- Diplegia/diparesis: Lower limbs more affected than upper limbs.
- Hemiplegia/hemiparesis: Just right or left body side is affected.
- Paraplegia/paraparesis: Lower limbs get affected.
- Triplegia/triparesis: Three libs are affected.
- Tetraplegia/tetraparesis: Upper and lower limbs are affected, but three of them are more affected than the fourth one.
- Quadriplegia/quadriparesis: All four limbs are involved.
- Pentaplegia/pentaparesis: Furthermore than upper and lower limbs affected, neck or head paralysis is present.

Depending on the severity level of the CP, another classification can be made [5][4]:

- Mild CP: People can perform daily activities by its own although some physical alteration is presented. They can move without assistance.
- Moderate CP: People have some difficulties to perform daily activities, so they need support such as: braces, medications and adaptative technology.
- Severe CP: People is not able of performing daily activities by its own.

- No CP: People present CP signs but the impairment was acquired after brain development and is classified as traumatic brain injury or encephalopathy.

Gross Motor Function Classification System (GMFCS) is a universal classification system that defines five levels depending on the gross motor function performance. It helps to determine surgeries, treatments, therapies and assistive technology selections [8][4].

The higher the level, the more degree of severity:

- GMFCS Level I: walks without limitations.
- GMFCS Level II: walks with limitation. Limitations are related with walking long distances and balancing. Jump or run are not possible options. They may require the assistance of mobility devices when learning to walk.
- GMFCS Level III: walks with adaptative equipment assistance. Wheeled equipment is needed outdoors and hand-held assistance indoors. Can sit on their own or with limited external support. They have some independence in standing movements.
- GMFCS Level IV: power mobility assistance is needed to self-mobility. Sitting actions are usually supported.
- GMFCS Level V: head and trunk control limitations. They need assisted technology, physical assistance and powered or manual wheelchair.

As it was said before, the ability to move is not the only thing that is impaired, cognitive and sensitive disorders are also presented [9][4]:

- More than the third part of children with CP find out problems to make words and talk easily.

- Attention, concentration, memory and information processing issues lead to learning problems.

- Cognitive deficit or delay can be manifested.

- Due to force strength difference between right and left eye muscles, children usually present squint. Also, lack of coordination between both eyes, make difficult distances calculation, 3D reconstruction and body-space relation.

- Hearing loss is not usual but can be presented if auditory nerve is affected.

2.1.1 General Signs and Symptoms

In this section, only physical symptoms and signs suffered by children with CP will be exposed since the project's mission is to provide individual's physical assistance through an exoskeleton designed for rehabilitation tasks. Physical characteristics can be described by the following eight clinical signs [10][4]:

- Muscle tone: ability of muscles to work together by maintaining proper resistance; some muscles contract when others must be relaxed. Improper muscle tone takes place when muscles do not coordinate. Most common abnormal muscle tones in CP are: hypotonia, hypertonia, muscle spasms, fixed joints, abnormal neck, truncal tone and clonus.

- Movement, coordination and control: some signs appear under stress and disappear with sleeping. It is common to experience different impaired muscle control types in opposite limbs. There are different types: spastic movements, athetoid or dyskinetic movements, ataxic movements, mixed movements and gait disturbances. Gait disturbances are control impairments affecting the way a child walks: in-toeing, out-toeing, limping, toe walking, etc.

- Reflex: hyperreflexia are excessive reflex responses that cause twitching and spasticity. Underdeveloped or lacking postural and protective reflexes are warning signs or abnormal development. Some of the most common primitive reflexes that persists: asymmetrical tonic reflex, symmetrical tonic neck reflex, spinal gallant reflexes, tonic labyrinthine reflex, etc.

- Posture: usually, posture expected to be symmetrical. Asymmetrical postures are prominent in instances of CP. Some of the postural responses that children with CP may not develop are: traction, landau reflex, parachute response, head righting and trunk righting.

- Balance: inability to sit, crawl or walk because of balance ability affected, can be a sign of CP. Some signs to examine when a child is making balance actions that may indicate CP impairments are: requiring both hands for support, for sitting or for standing, having difficulty balancing when not using hands, unsteady when walking, difficulty making quick movements, needing hands for activities that require balance and walking with abnormal gait.

- Gross motor function: impaired gross motor functions lead to limited capability of walking, running, jumping, maintaining balance, etc. and delay gross motor functions means that physical skills are developed later than expected.

- Fine motor function: executing precise movements involve combinations of mental and physical skills. A good fine motor function leads to perform some activities such as: grasping small objects, holding objects between thumb and forefinger, setting objects down gently, using crayons or turning pages of a book. Impaired or delay fine motor skills are possible indicators of CP that make difficult performing the previously listed tasks.

- Oral motor skills: difficulty in using lips, tongue and jaw indicate impaired oral motor function. Examples of this impairment are problems while breathing, articulating or voicing. Apraxia and dysarthria are common speech impairments in CP. Drooling, another sign of CP, means that mouth and face muscles are not able of control coordination.

2.1.2 Cerebral Palsy Treatments

Children with regular growth, stretch their muscles and tendons while performing daily routines, making them growth at the same time as bones. Nevertheless, children with CP suffer from spasticity, that keep off muscles from growing at the same velocity as bones, which causes difficulties when performing movements.

CP disorder can not be cured but specific treatments can be applied to get better movements, to develop communication skills, to stimulate intellectual development and to stablish social relationships. There are 4 types of treatments: physical therapy, occupational therapy, compensatory education and speech therapy. Active and positive attitude from patients, families and professionals are essential to take benefits from treatments.

Focusing on physical therapy due to the exoskeleton would help during rehabilitation sessions, two objectives are going to be pursued along this project: avoid muscular atrophy because of disuse and avoid contractures caused because the muscles are fixed in a rigid and abnormal position.

There are 6 different methods to perform physical therapy [11][4]:

- Le Métayer method: motor difficulties are treated depending on the pathology level, stimulating and teaching the kid how to control and perform volunteer movements.

- Rhythmic movements and primitive reflexes therapy: Easy and funny for children. Based on repeating rhythmic exercises that involves the whole body. On the floor, the child have to imitate usual baby movements in growth phase. Through sensitive stimulation, primitive brain areas are activated connecting to other areas more developed.

- PETO Method - Conductive Education: altered or not well-developed functions, can not be recover because of neural plasticity but can be reorganised by learning since nervous system can readapt and replace the altered functions.

- Bobath method: for central brain disorders. The brain has the capacity of being reorganised, this means that, the healthy brain areas assume or compensate functions that has to be performed by injured brain areas. This method tries to support middle-side affected in order to adapt its movements to the middle-side not affected, or to reduce non-healthy side influence on the healthy one.

- Vöjta method: with this treatment, children are positioned in determined positions. Then, specific points are stimulated and resistance is apply to unchained movements. This leads to the appearance of common activities from first year of life such us crawling, turning and walking

- Threasuit method: developed in Rusia to deal with negative effects spacemen suffer from due to long trips without gravity. It is a soft, dynamic and proprioceptive orthosis consisting of a hood, a two-piece suit, knee pads and shoe straps linked by a system of elastic bands used to performed specific activities to help children progression.

Each of these physical methods can also be combined with exoskeletons to release the patient of limb body load or to help patient on therapy movements realization.

2.2 Upper limb physioanatomy

As the main objective of this project is to develop an exoskeleton for CP upper limb rehabilitation, in this section, only arm physioanatomy will be explained. Some of the bones and muscles that give structure and movement to the upper limb are going to be listed because by knowing physical anatomy's interactions, main motion of the arm joints will be understood and that is necessary to understand what is wrong in the daily activities' performed by children with CP for being able of giving a solution through an exoskeleton.

Before explaining motion, degrees of freedom and anatomy from each upper limb joints, it is important to know the three basic human body planes orientation to understand pretty well how movements can be performed (see Figure 3):

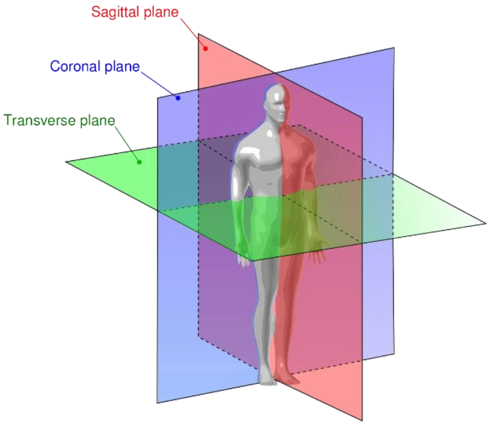


Figure 3: Body human Being Planes [12][4]

Each upper limb skeleton is made up of 32 bones that give structure and support to muscles and other tissues: two bones join the extremity to the trunk (clavicle and scapula or shoulder blade), one bone made the arm (humerus), two bones give life to the forearm (radius and ulna) and 27 bones create the hand (carpals, metacarpals and phalanges) (see Figure4):

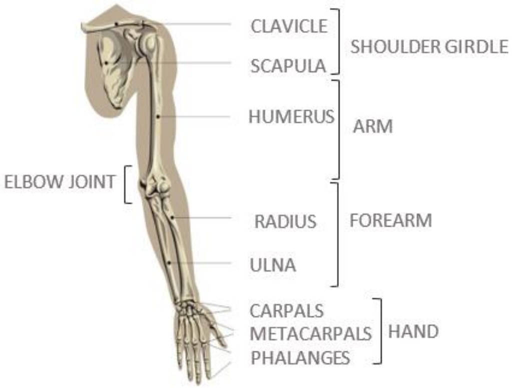


Figure 4: Principle arm's bones [13][4]

- SHOULDER:

Shoulder joint, also called glenohumeral joint, is in the proximal part of the upper limb. It is a ball in socket synovial; the humeral head rotates like a swivel over the glenoid socket of the scapula, which means it has a wide range of movement, being therefore the most mobile joint in the body and also the most instable one [14][4].

Shoulder joint has three degrees of freedom that let guide the arm along the three human body planes. First degree of freedom is related with adduction and abduction movements, second degree of freedom is referred to flexion and extension movements, and last degree of freedom let perform external and internal rotation.

To better understanding of shoulder degrees of freedom, ranges of motion and movements description will be include next:

- Abduction and adduction: movements away and toward midline in coronal plane. Abduction movement bring the arm laterally away from the body reaching 180 degrees of amplitude while adduction movement bring the arm laterally toward the body reaching just 45 degrees of amplitude [15][4] (see Figure 5):

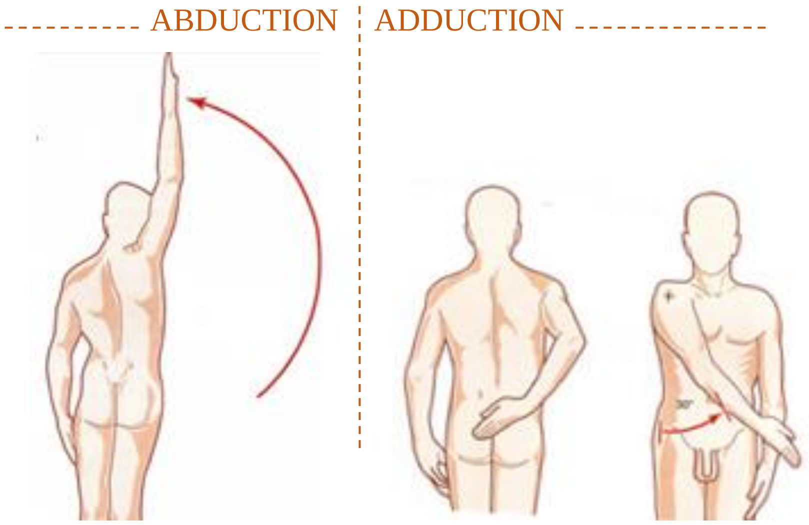


Figure 5: Shoulder abduction and adduction [15][4]

- Flexion and extension: backwards and forwards movements on sagittal plane. Flexion brings the arm forward with a maximum amplitude of 180 grades, and extension brings the arm backwards with a maximum amplitude of 50 grades [15][4] (see Figure 6):

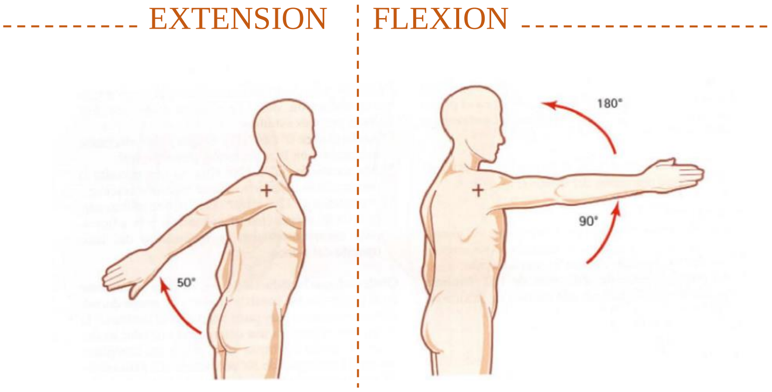


Figure 6: Shoulder Flexion and extension [15][4]

There are also flexion and extension movements on transversal plane. Flexion this time means moving the arm to a closer chest position and can achieve 140 grades of amplitude, while extension means moving the arm away from the chest until 30 grades of amplitude on horizontal plane [16][4] (see Figure 7):

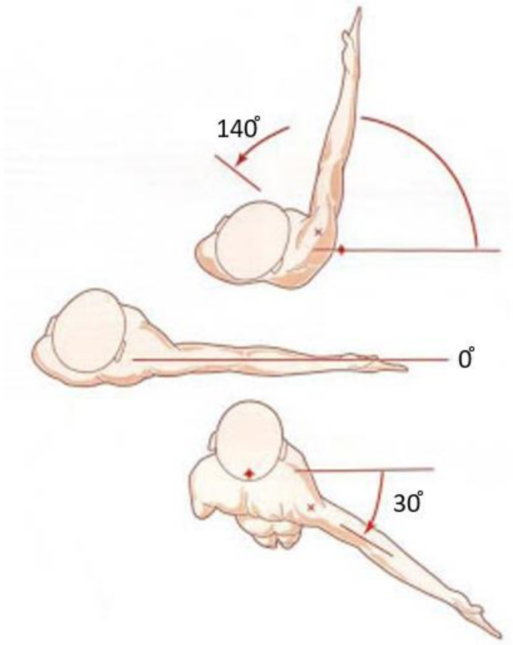


Figure 7: Shoulder flexion and extension on transversal plane [16][4]:

- Medial and lateral rotation: approaching and getting away on transversal plane. The shoulder joint is able of performing two more movements: intern and external rotation. Medial or internal rotation place the arm closer to the chest taking up to 110 degrees of movement amplitude (when elbow is bent and humerus alongside lateral trunk). Lateral or external rotation place the arm farther away from the chest with 80 degrees of movement amplitude (when elbow is bent and humerus alongside lateral trunk) [17][4] (see Figure 8):

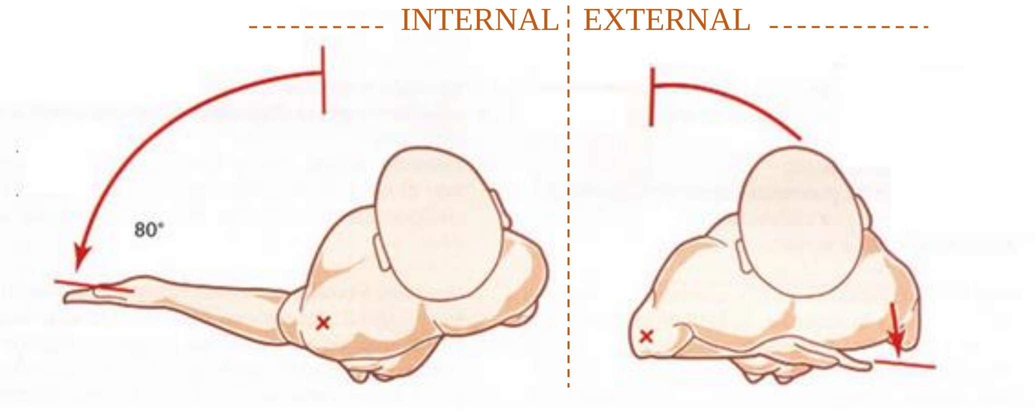


Figure 8: Internal and external shoulder rotation [17][4]

- Circumduction: the combination of the movements performed around each of the axes (vectors representing the direction of the plane each of the three human body planes), give rise to the circumduction movement, a movement represented by a cone whose vertex coincides with the centre of the scapulohumeral joint [18][4] (see Figure 9).

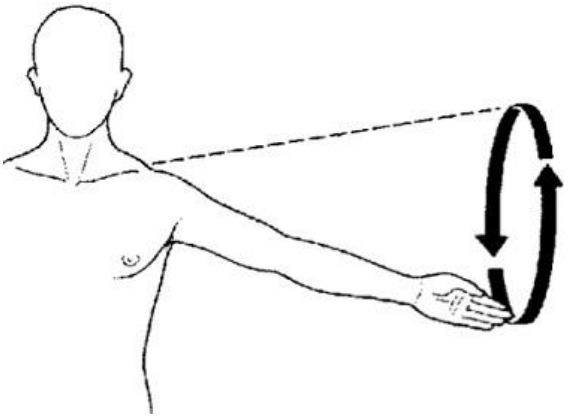


Figure 9: Shoulder circumduction [18][4]

Muscles responsible of performing arm movements by coworking with bones are shown below [19][4] (see Figure 10 and 11):

- Abduction: deltoid and supraspinatus
- Adduction: pectoralis major, teres major and latissimus dorsi
- Flexion: deltoid, pectoralis major and biceps
- Extension: deltoid, teres major, latissimus dorsi and triceps
- External rotation: infraspinatus and teres minor
- Internal rotation: subscapularis, pectoralis major, latissimus dorsi and teres mayor

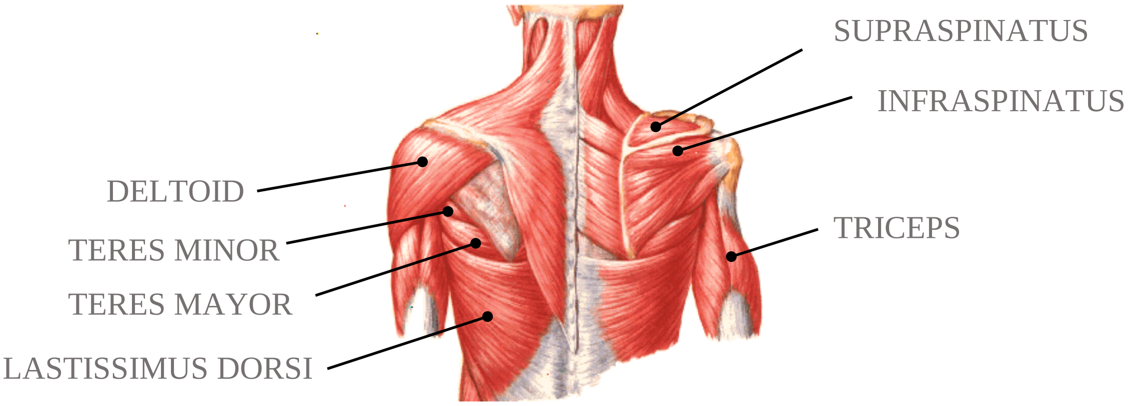


Figure 10: Back shoulder muscles [13][4]

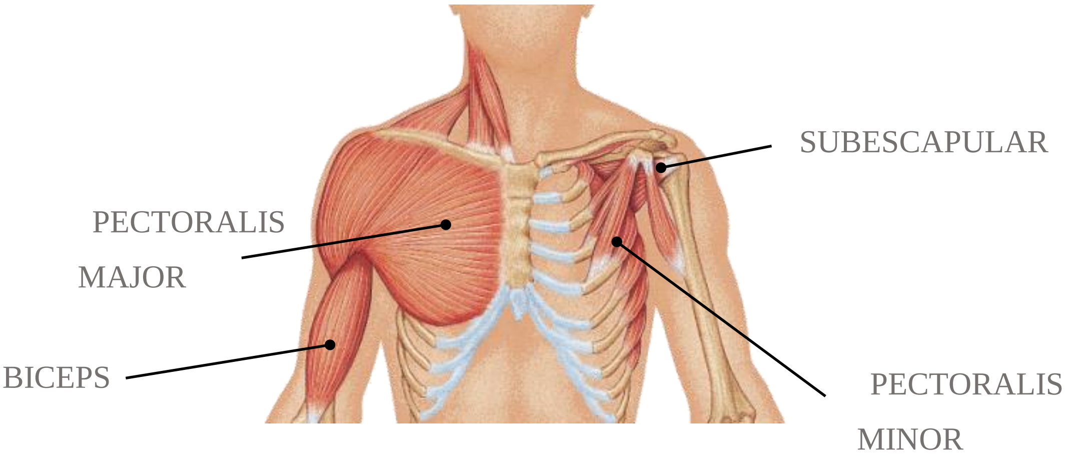


Figure 11: Chest shoulder muscles [13][4]

- ELBOW:

Two degrees of freedom characterised this arm joint. First degree of freedom is related to flexion and extension movements, and second degree of freedom is referred to prono-supination. To better understanding of how movements are performed, next a briefly explanation is included:

- Flexion and extension: approaching and moving away the forearm from the upper arm on sagittal plane. On these movements performance elbow angle change from 0 grades to 150 grades[20][4] (see Figure 12):

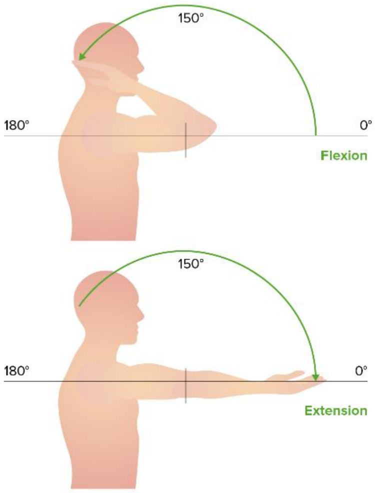


Figure 12: Elbow flexion and extension [20][4]

- Pronation and supination: hand palm looking down is called pronation and hand palm looking up is called supination. Amplitude between both movements reaches 75 to 90 degrees on sagittal plane [20][4] (see Figure 13):

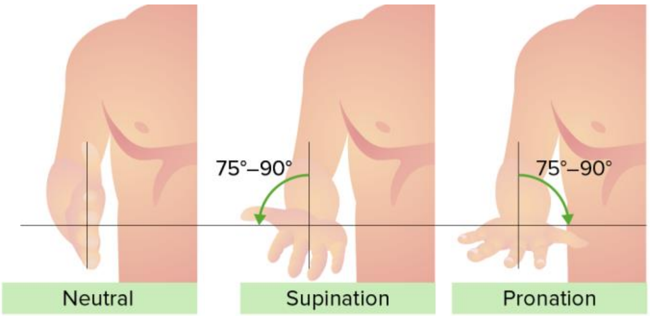


Figure 13: Forearm pronation and supination [20][4]

The elbow joint is formed by the humerus-ulnar and humerus-radial joints. The muscles that cover this joint are responsible of the flexion, extension, pronation and supination of the forearm. Some of those muscles also work performing wrist movements (see Figure 14):

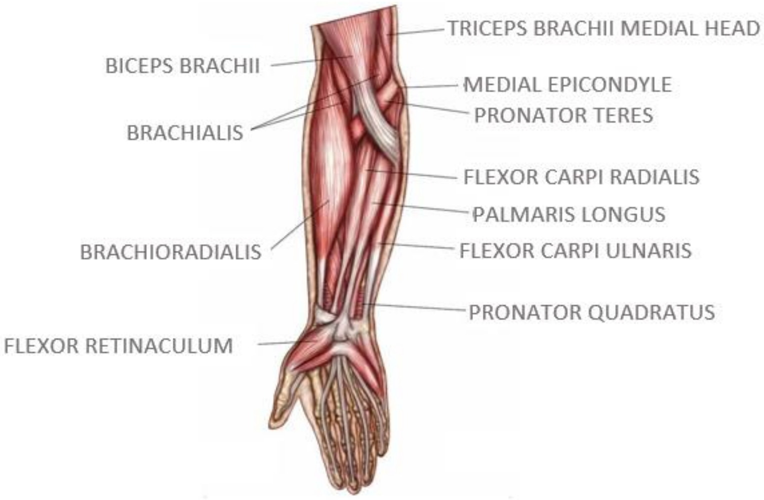


Figure 14: Forearm muscles [13][4]

- WRIST AND HAND:

Wrist joint is the last joint of the arm, connects the forearm with the hand. Abduction and adduction are performed on transversal plane and flexion and extension on sagittal plane as it is shown on the following images [21][4] (see Figure 15):

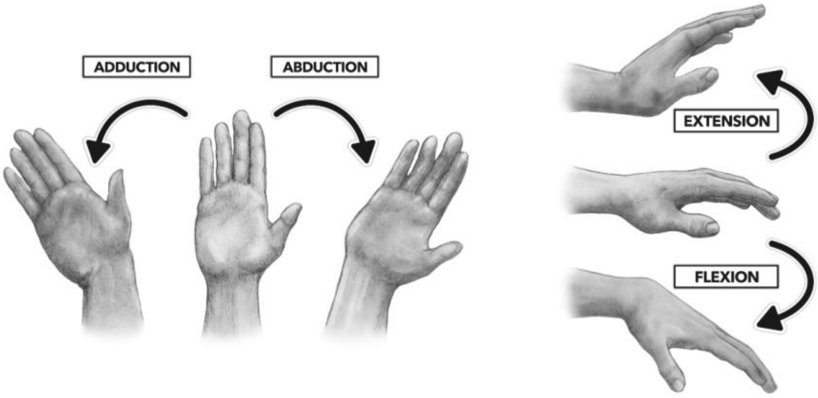


Figure 15: Wrist movements: abduction, adduction, flexion and extension [21][4]

2.2.1 Upper Limb Disorders

Approximately, 83% of children with CP suffer from upper limb disorder. Some of the most common disorders in CP affecting the upper limb will be shown below [22][2]:

- Shoulder adduction with internal rotation contracture: characterized by glenohumeral internal rotation contracture (see Figure 16).

Figure 16: By default shoulder internal rotation [23][4]

- Forearm-pronation deformity and elbow flexion contracture (see Figure 17 and 18).

Figure 17: By default forearm pronation [23][4]

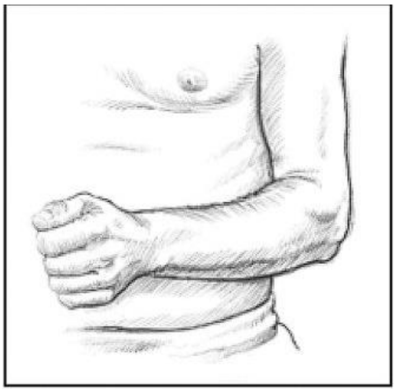


Figure 18: By default elbow flexion contracture [23][4]

- Wrist-flexion with pronation: wrist is typically flexed and in ulnar deviation. Associated with weak wrist extension and pronation of the forearm (see Figure 19).

Figure 19: By default wrist flexion on pronation position [23][4]

- Thumb in palm with clasp hand (see Figure 20).

Figure 20: By default thumb in palm [23][4]

All this position deformities usually appear together (see Figure 21):

Figure 21: Common arm position at Cerebral Palsy [23][4]

It is so important to understand which is the common posture for children with CP to be able of developing an exoskeleton that remove this position as normal and make the arm stays in repose as it should be if no CP disorders was present.

Once the major physical alterations caused by the disease are known, it is necessary to know the different types of exoskeletons; its functions and characteristics; developed so far, as well as its contributions or limitations.

2.3 Exoskeletons

2.3.1 Definition and Classification

An exoskeleton is an assistive technology that help to increase, maintain, or improve functional capabilities of individuals with a disability or impairment. These devices are rigid external covers that work in tandem with the user.

There are a huge number of different exoskeletons, and classification can be made through different categories [24][2]:

- Paying attention to the fact of being powered:
  - Passive: No energy is required for controlling the exoskeleton but elastic elements such as springs are used for supporting body weights.
  - Active: use energy supplies for controlling sensors and actuators. Energy comes from engine devices.
- Many types of technology can supply power to the exoskeleton. Depending on the type of actuators we can classify exoskeletons in:
  - Electric/ Robotic (55%): use electric servos and batteries.
  - Hydraulic (20%): use hydraulic actuators that are more powerful than electric ones, but they need combustion engines or hydrogen fuel cells so they are less portable.
  - Fully mechanical (13%): passive exoskeletons.
  - Others (13%): pneumatics, shape memory alloys…
- Depending on how much rigid the structure is, we can classify exoskeletons in:
  - Hard/classic exoskeletons: rigid structures and optional actuators. They can provide lot of power.

  - Soft exoskeletons: made of soft materials. Power is applied to the body via compliant actuators such as air muscles or cables. These ones are more comfortable, but power supplied Is lower.

- Depending on the part of the body they are going to adjust to, we can find:
  - Upper limb exoskeletons: provide support to arms: shoulder, elbow and wrist.
  - Lower limb exoskeletons: provide support to legs: hip, knee and ankles.
  - Full body exoskeletons: provide support to arms, legs and trunk.
- For last, According to the functionality they play, exoskeleton could be use on:
  - Industry field: support for works mostly on lumbar area and arms. They are mainly used to carry large amounts of weight to avoid injury
  - Rehabilitation and physiotherapy field: to help people with disabilities to perform daily activities.

2.3.2 Upper Limb Exoskeleton

The objective of the project is to design a passive and mechanical exoskeleton for using in upper limb therapy and rehabilitation sessions, made of light and inexpensive materials.

It is important to develop an exoskeleton for rehabilitation sessions because there are many limitations of conventional arm and hand therapy as many shown below [25][4]:

- Severity prevents practice.
- Difficult to keep patients motivated.
- Limited number of repetitions.
- Therapy limited by availability of therapists.

- Unclear feedback regarding progress and performance.
- Changing needs of patients.

Focusing on the importance of designing and exoskeleton adaptable to the arm, a brief resume and an exploration about the differents upper limb exosketon that are used nowdays, are going to be made.

Beginning with the currently best known exoskeletons for upper limb rehabilitation, Hocoma brand has two devices developed for this purpose: Armeo Power and Armeo Spring [26][4]:

Armeo power (see Figure 22) is world’s first robotic arm exoskeleton for integrated arm and hand therapy for severely impaired patients. It is a highly advanced arm and hand rehabilitation device for early-stage patients even before they develop active movement. Some benefits provided by Armeo Power are shown below [27][4]:

- Highly Intensive Early Arm Rehabilitation
- Assist-As-Needed Movement Guidance: when patients cannot carry out a movement or exercise, sensors and algorithms are able to recognize it and assists the patient to reach the goal.
- Arm Weight Support in an Extensive 3D Workspace: the device has 6 degrees of freedom that allow training in an extensive 3D workspace.
- Motivating Exercises: it has an extensive library of game-like exercises to train core movement patterns that are commonly used in activities of daily living.
- Increased Therapy Efficiency: improve therapy efficiency by reducing the therapist’s physical effort.
- Objective Assessments: The ArmeoPower precisely records how patients perform during their therapy sessions and how much support they need.
- Hand Function Training

Figure 22: Armeo Power [26][4]

The Armeo Power counts with an extra hand module named ManovoPower (see Figure 23) that enables severely impaired patients to relearn hand opening and closing tasks. It allows patients to train reaching and grasping with assist-as-needed support from shoulders to fingers [28][4].

Figure 23: ManovoPower [28][4]

The other Hocoma exoskeleton, Armeo Spring (see Figure 24), is a supportive device use during recovery of arm and hand functions. It is for self-initiated repetitive therapy in an extensive 3D workspace.

As Armeo Power, this other mechanism, provides some therapy advantages [29][4]:

- Self-Initiated Movement Therapy: patients are able of using any remaining motor function thanks to arm weight supported help.
- Simultaneous Arm and Hand Therapy in a 3D Workspace: the 6 degrees of freedom allows simultaneous arm and hand training in an extensive 3D workspace.
- Ergonomic Exoskeleton: ArmeoSpring embraces the whole arm, from shoulder to hand, and counterbalances the weight of the patient’s arm.
- Motivating Exercises and Objective Assessments as Armeo Power
- Increased Therapy Efficiency: The ArmeoSpring enables therapists to deliver higher training efficiency (more hours per day) thanks to self-directed therapy, which may lead to better long-term outcomes.
- There is already a real model for pediatrics

Figure 24: Armeo Spring [26][4]

Armeo Spring also present an extra modeule: ManovoSpring (see Figure 25). Manovo Spring is an instrumented hand orthosis for patients with therapy goals focusing on hand rehabilitation [30][4].

Figure 25: ManovoSpring module [30][4]

Working with ArmeoSpring and ArmeoPower means working without direct contact with game-like Augmented Performance Feedback exercises, something that let the user interact with the environment in a comfortable range space.

Continuing with come other devices developed for arm assistance, there exists many more robotic exoskeletons for rehabilitation such as Caden-7, L-Exos, ARMin III, WREX or T-REX.

- Caden-7 (see Figure 26) was developed at the University of Washington, Seattle, and it is a robotic cable-actuated anthropomorphic exoskeleton with 7-DOFs for neuro-rehabilitation. Some advantages provided by this mechanism are: low inertia, negligible backlash, high stiffness links, mechanical stops, emergency switches and driven pulleys that make possible to distantly locate the actuators reducing the torques on the robot framework [31][2].

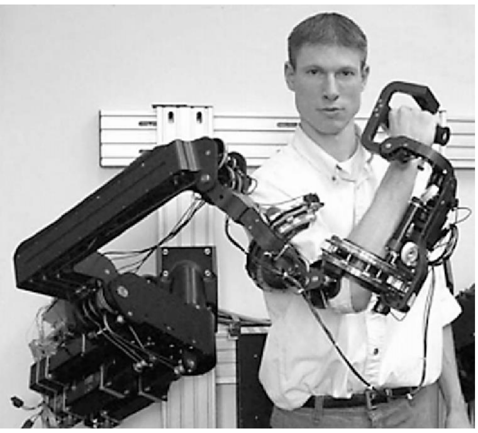


Figure 26: CADEN-7 exoskeleton [31][2]

- L-Exos or Light Exoskeleton (see Figure 27) is an active robotic device, that can provide active guidance during the execution of some exercise and gravity support for the weight arm. The exoskeleton has four actuated Degrees of Freedom (DoFs) with anthropomorphic kinematics, so that active assistance can be provided for shoulder abduction/adduction, flexion-extension, internal/external rotation and for elbow extension/flexion, and one passive DoF, corresponding to the wrist prono-supination [32][2].

Figure 27: L-exos device [32][2]

- ARMin III (see Figure 28) is a symmetric robot that can be support left and right arm. It is equipped with six motors moving the shoulder joint in three DoF, the elbow joint, lower arm pro/supination and wrist flexion/extension [33][2].

Figure 28: ARMin III exoskeleton [33, 34][2]

- The WREX (see Figure 29) stands for Wildmington Robotic Exoskeleton and is made of lightweight plastic, metal, and rubber bands. Elastic bands are used to negate the effects of gravity allowing people with neuromuscular weakness to move their arm in 3 dimensions. It can be attached to a child's wheelchair or to a jacket for kids who can walk. This one is the prototype model from which this project starts [35][2].

Figure 29: WREX exoskeleton [35][2]

- T-WREX (see Figure 30) is an adult-sized version on WREX. This exoskeleton is a five DOF system that passively and partially counterbalances the weight of the arm using elastic bands that includes sensors devices [32][2].

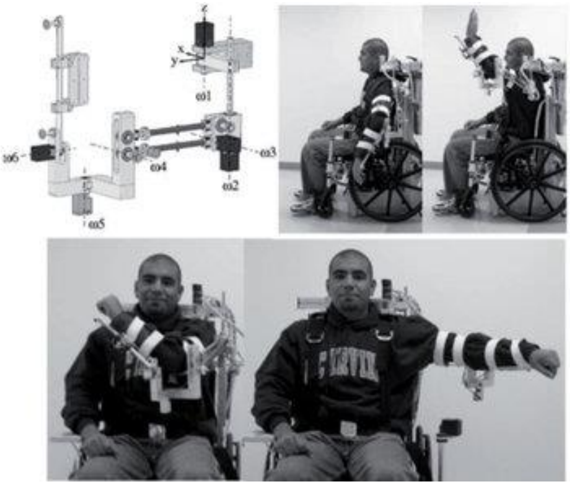


Figure 30: T-WREX exoskeleton [32][2]

From all exoskeleton reviewed, just the last two ones are mechanical devices without electric movement initation. It is difficult to find out purely mechanical mechanisms for rehabilitation thus electronic components and small electric engines generate an input force to the system that allows the patient's arm to move with little effort. However, these electronic components also have disadvantages as they increase device’s price.

The goal of this project is to evolve a prototype similar to the WREX, which works through elastic bands and without needing electric engines. It would be taken to reality through 3D manufacturing to achieve a low-cost device that anyone with upper limb mobility problems can have within reach of their needs.

2.3.3 Usability and Functionality Assesments Validation

Any device validation is important for the product to be accepted by society. Validations give information about the effectiveness or contribution of the product to the users. In medicine, validations are critical measures of the benefit that the use of the device will bring to the patient. Any medical device has to go hand in hand with bringing benefits to patients.

There are many types of mechanism's validations: validations of comfortability, functionality, usability, ergonomics, etc. To know if the exoskeleton designed, help children with Cerebral Palsy during rehabilitation sessions, it is necessary to perform a validation about the effectiveness or progression of children with and without the exoskeleton.

Most of the validations obtain test results based on making the patient repeat a series of exercises. Quantitative data can come from sensors, measurement software or different variables such as execution time or patient sensations.

Looking at upper limb assistive devices, some such as WOTAS, a mechanism to reduce tremor, use the data obtained from different gyroscopes to see the reduction of involuntary movements. Others such as APPARATUS, measure usability after repeating 3 types of exercise 10 times using 2 types of instruments: Tele-healthcare Satisfaction Questionnaire - Wearable Technology '(TSQ-WT) and the system usability scale (SUS) [36][4]. The validation of the LIGHTarm exoskeleton is carried out from 4 tests (grap, grip, pinch and gross), in which through the use of 3 IMUS the execution of the Action Research Arm Test (ARAT) [37][4] and the SUS questionnaire determine the evolution of the patient.

In most industrial exoskeletons, whose main objective is the lifting of large loads, EMG signals are used to see how the work of the muscle is reduced, something that could also be used for rehabilitation in CP but with another purpose, test if after using the exoskeleton the muscle has more energy than before.

SUS questionnaire and ARAT Test will be explained below.

SUS is a reliable tool for measuring usability. It allows you to evaluate any type of product or service. It consists of a 10 items questionnaire with five response options for respondents; from Strongly (4) agree to Strongly disagree (0). It is very easy to administer to patients, can be used on small samples and it's efectivelly diferenciating between usable and unusable devices [36][4].

The participant's scores for each question are converted to a new number, added together and then multiplied by 2.5 to convert the original scores of 0-40 to 0-100. If the final punctuation is in the range from 0 to 50, means the device is not good, if the score is between 51 and 74, means the device is ok but can be improvable, and a score higher than 70 means it is " a good device".

Although this questionnaire could give lot of information for the continuing evolving the exoskeleton, in the end it will not be carried out because participants clinical trials do not have a high reasoning capacity and are not able to judge clearly due to their young age.

ARAT test consists on 19 items divided into 4 sub-tests (grasp, grip, pinch and gross arm movement) [37][4]. Unlike SUS tool, it is a specific test to measure arm performance, tested for each item by a rated 4 point scale:

- 0: Can perform no part of the test
- 1: Performs test partially
- 2: Completes test, but takes abnormally long or has great difficulty
- 3: Performs test normally

The ARAT validation contains many evaluation tests involving the hands. As the main objective of the exoskeleton is not to support rehabilitation of fine psychomotor tasks involving this part of the body, this validation will not be carried out in this project, as most of the children who have participated in the clinical trials are unable to perform grasping and gripping movements with their hands.

From pyshiotherapists point of view, another important validation is AMPS evaluation. Assesment of Motor and Process Skills (AMPS), is an observation-based assessment used to measure the quality of performance in activities of daily living (AVD). Simultaneous assesment of patient’s ability when performing instrument activities of daily live, and motor and proccessing skills, can be done through this validation technique.

It will be explained later, but as a brief resume, for testing exoskeleton on patient, two clinacal stages were carried out, and after second clinical stage, pythiotherapist performed and AMPS validation over data obteined from one intensive session week.

Further on, in chapter 4, parameters extracted from FittsStudy and Werium Solutions interfaces during testing sessions will be explained, as well as theoric background besides this executables will be detailed. From this data, conclusions will be drawn in order to evaluate exoskeleton functionality.

3 TECHNICAL DEVELOPMENT OF UPPER LIMB EXOSKELETON

3.1 Design Requirements

3.1.1 Functional Requirements

The exoskeleton design must fullfill a list of requierements needed for assisting CP children during rehabilitation exercises. The requirements list has been made from different sources: normal arm movement information, CP movement characteristics studies and feedback from phisiotherapist who work everyday with children with upper limb mobility limitations.

Bearing in mind that the exoskeleton will initially only support movements that include shoulder and elbow participation (hand movement is excluded), the requirements taken into account to design the orthosis are detailed below:

- The mechanism must enable elbow flexo-extension movements
- The mechanism must enable pronato-supination middle-arm movement
- The mechanism must enable shoulder flexion and preventing users from making compensatory movements with the body trunk, something they are used to do in their daily life to reach objectives.
- The mechanism must enable intern and extern shoulder rotation
- Although the exoskeleton will not rehabilitate the hand in a functional way, it must ensure that the hand belongs in a comfortable resting position, avoiding wrist flexion in pronosupination by default, common in patients with CP
- Having a correct posture when being sitted is really important for users to avoid compensating movements, to force the patient adquiring abilities when movieng the arm that are not present due to CP

conditions and to avoid developing extra problemas such as back contractures because of shoulder desalignment. For this reason, the mechanism must allow the user to be seated as follows:

- Straighted head and neck, parallel to the frontal plane
- 90 degrees between thighs and back
- Thighs parallel to the floor
- Elbows close to the body and bent 90 degrees
- Legs slightly open
- Knees at 90 degree angle
- Small gap between seat and knees
- Sole of the foot resting on the ground or on a footrest
- Shoulders relaxed and aligned in the transverse plane, and simetrically positioned in regard to sagital plane

Once the exoskeleton has been developed, it will be necessary to check one by one that all the above requirements are met. In the same way, each modification or improvement will require the consecutive verification of requirements.

3.1.2 Technical requirements

In order to meet the functional requirements discussed in the previous section, it is necessary that the joints and parts of the mechanism meet a series of characteristics:

- Allowance between pieces that altogether stand for principles movements of arm joints, must be ensured so that the user can move the upper limb through the three-dimensional work space without extra effort. These union points, must ensured sufficients allowance to permit movements, and must not exceed a limit for preventing pieces from flexing one on top of the other reaching a huge bending moment. For this to happen, a good dimensioning of holes, screws and nuts is necessary, which means that hole’s diameter have to be 0.5 mm higher than screw’s diameter and pieces that fit inside other must have at least 0.5 mm lower of wide than the space of union. This 0.5 mm are so important in 3D printing.

- All those joining points that structurally do not require the turn of one piece over another, must be fixed avoiding any possible allowance or mismatch that creates bending moments that lead to impossible cilyndrical turns on joints that trully require it. This could be done with two differents union point between 2 parts.

- No part or point of connection should come into contact with the user in a harmful way. All 3D printed parts must be filed and lined with soft materials to promote patient comfort. Screws and nuts will be hidden in the pieces to avoid snagging or chafing.

- The ties that allow the easy adaptation and attachment of the exoskeleton on patients, must be elastic and flexible to allow adaptation to different physical complexions.

- The exoskeleton should be designed using telescopic systems for easy adaptation to children of different ages and sizes.

Focusing now on anthropometric characteristics of children between 6 and 15 years, the exoskeleton must meet the following sizes features:

- Exoskeleton pieces will be designed also for support adult’s arm weight so the mechanism must be able of handle up to 5kg [38][4].

- Total arm length of children from 6 to 15 years old goes from 44,2 cm till 61,1 cm. Exoskeleton pieces which follow arm and forearm length must be designed according to these anthropometric measures [39][4].

3.2 Previous Exoskeleton

Adriana Cortelucci and Lucía Arce were the designers of the previous exoskeleton from where this project starts [40][4]. The exoskeleton designed by them, it is a mechanism of 4 Degrees of Freedom (DoF) pretty much similar to Armeo Spring and let the user perform shoulder internal and external rotation, shoulder flexo-extension, elbow flexo-extension and pronosupination.

The design was composed of 10 different pieces. Four of them; yellow, green, purple and red parts (see Figure 31); let the exoskeleton perform shoulder movements, 2 of them; light and dark blue parts (see Figure 31); represent elbow and shoulder internal and external rotation, another two; orange and gray parts (see Figure 31); let the user carry out pronosupination, bars support the user's arm as well as allowing flexion and extension of the shoulder and elbow thanks to the allowance with the rest of the pieces. The combination of elastic rubbers and lugs, makes it possible to convert the exoskeleton into an active mechanism that serves both for assistance and resistance. All this information is clarify in the following images and tables classifying pieces by color:

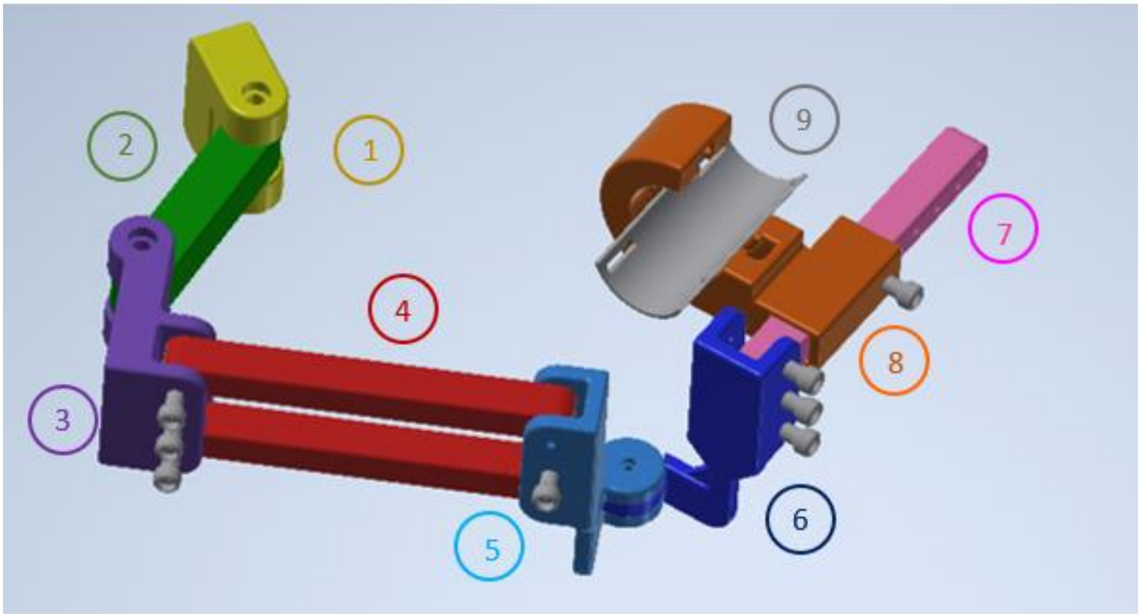


Figure 31: Original exoskeleton with numbered pieces (Autodesk Inventor Professional 2021)

Number ID	Pieces colors	Units	Movement participation and functions
1	Yellow	1	• Attachment to exoskeleton support platform • External and internal shoulder rotation
2	Green	1	• External and internal shoulder rotation
3	Purple	1	• External and internal shoulder rotation • Shoulder flexion and extension
4	Red	2	• Upper arm longitudinal structue
5	Light blue	1	• Elbow flexion and extension • Contribution on external and internal shoulder rotation when elbow is bent
6	Dark blue	1	
7	Pink	1	• Forearm longitudinal Structue
8	Orange	1	• Displacement base pronosupination
9	Gray	1	• Wrist and forearm structural support • Rotating rocker pronosupination

Table 1: Exoskeleton pieces identification

3.3 Previous prototype functional evaluation

Once the exoeskeleton was ready, a stage of testing took part to check if the mechanism met the requirements set in the previous section.

One of the first issue that was perceived, when performing exoskeleton functional testing, was the huge difficulty to make pronatosupination movement. This difficulty is due to the fact that the turn that the forearm must make when it rests on the mooring beam is not a concentric turn to the circle that serves as a guide for the rotation. In order to perform the pronosupination movement with this system, the user would also have to exert a flexion-extension movement to move the rocker along the guide. In addition, the dead weight of the forearm on the rocker, makes the base of it stick on the channel that acts as a guide, opposing resistance and friction to the user.

When using the exoeskeleton, huge noises arise from the mechanisms. The origin of the noise came from pieces 5 and 6 (see figure 31). Every time dead weight is placed on the exoskeleton, the slim profile that descends into the turning circles that enlivens the elbow rotation, undergoes great flexion despite the stiffening rib they carry.

This bending makes the rotating cylinder parts tighten one on the other, thus also hindering the easy and simple rotation of the shoulder when the elbow is bent.

The axis of rotation of part 2 with part 3 is not aligned with the joint axis of part 3 with bars number 4. This axis offset makes it necessary to move part 3 over part 2 with a torque very large, which complicates the movement of the user's upper limb. Remember that a tourque is generated as a consequence of a force exerted at a distance. The smaller the distance of the force to be applied to overcome the pair, the greater the force necessary to give life to that torque. To solve this problem, it will be enough to align the axes of both points of rotation or contact of part 3 on the x axis.

The point of attachment of the exoskeleton to the support is, at the same height as the shoulder. This causes the user to have an unusual shoulder posture when wearing the exoskeleton, causing the shoulders to not be correctly aligned on the frontal plane and not to be symmetrical on sagittal plane. This decompensation will prevent the patient from keeping the back upright, generating decompensation of the musculoskeletal system and user’s trunk compensation to carry out the movements. To avoid user feel uncomfortable and to avoid user’s arm tied to the exoskeleton be on a higher or lower position than the released shoulder, pieces 1,2,3 design will be modified as will be discussed in the next section.

Also, position of pieces 1,2 and 3 will be modified because when using elastic ruber for assiting patient during performance of movements affected by gravity (elbow and shoulder flexo-extension), these pieces suffer from large flection torque moments, that prevent the user from being able to perform movements related to the shoulder.

The prototype shown in the *figure 29* does not include any type of rigid and stable support where the upper part of the arm can rest. In order for the elastic bands attached to the studs to help the user in antigravity movements, a support will be designed to hold the arm at rest and push the upper limb when raising the arm through force induced by elastics bands.

Finally, although the forearm rests on the pronosupination swing, the user's wrist is not assisted at any time. Although at the moment the mission of the exoskeleton is not to functionally help the hand, that the hand remains in a comfortable and usual resting position it is a main objective. To eliminate the default posture that many patients with cerebral palsy have, wrist flexion, a support will be designed for adquiring normal posture on the distal part of the forearm with a wristband.

A summary of the most important faults and those that need to be rectified urgently are collected (see table 3). Also a brief explanation of the solution is going to be taken is added:

Movements or pieces affected	**Issue**	**Solution**
Pronosupination	• Non-concentric rotation of the forearm on rotation guide • Rocker weight on turning channel, generates friction	New concentric turning system
Elbow pieces	• Slim profile that can cause parts to break under dead weight	Profile resizing and reinforcement
Internal/external shoulder rotation	• Shoulder rotation axis and flexion axis not aligned. The force necessary to overcome the torque and perform the rotation is very large.	Alignment of the axis of rotation and the axis of flexion-extension in part 3
Shoulder position	• Union of the exoskeleton to the support at the same height as the shoulder produces decompensation and asymmetry between shoulders	Increased distance between shoulder and bracket attachment
Shoulder Flexion/extension	• The position of the parts 1,2,3 makes the mechanism flex during assistance in antigravity movements • Lack of firm and rigid support for the upper arm	Double union to the support Upper arm support
Flected wrist by default	• Abnormal wrist posture	Support + Wristband

Table 2: Identified issues from original exoskeleton, and solutions proposed for new exoskeleton version

3.4 Design modifications

The purpose of this part is to describe all the design implementations carried out to solve the design problems of the initial exoskeleton, listed in the previous section. Comparative before and after figures will be added to understand the design changes as well as the improvements in functionality.

3.4.1 Shoulder pieces amendments

In order to understand shoulder mechanism changes, a figure will be shown below. This figure contains first shoulder pieces design, from previous prototype, and the final design of these same pieces (1,2 and 3) as well as the extra parts (pieces 1’ and 2’) necessary for a good consolidation of the exoskeleton (see Figure 32):

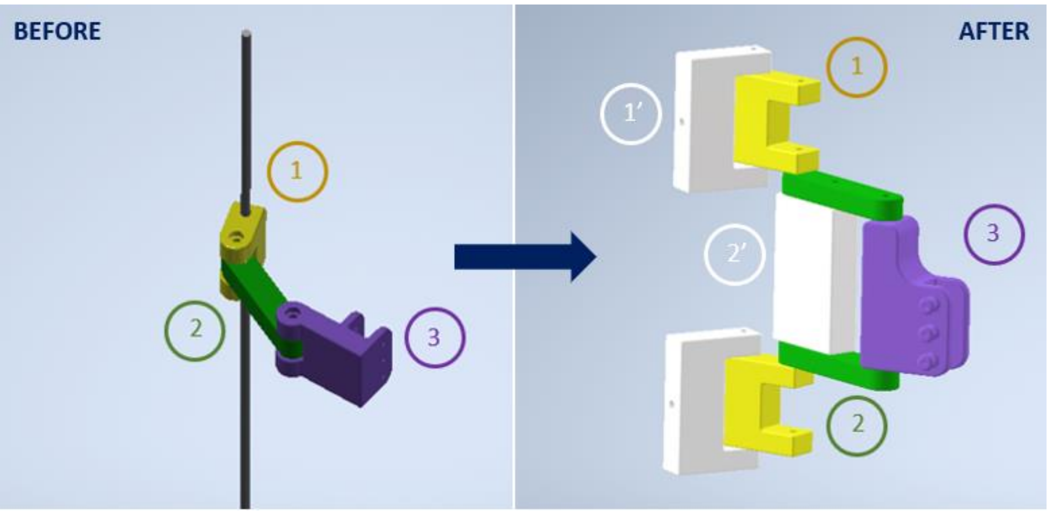


Figure 32: Shoulder mechanism changes (Autodesk Inventor Professional 2021)

Looking at the right side of the figure 30, the beginning of the exoskeleton from which the device is attached to the external platform of support, starts with a new piece called 1’. This extra part, so similar to yellow part 1, has only one function, attaching the functional exoskeleton to the new platform, which details will be explained at the end of this section. The main difference between these new extra pieces or part 1’ (see Figure 32) and previous parts 1, is that there is not a vertical hole that goes through the solid side of the piece because the union with suppport platform will take place in the transversal plane of the piece. For this task, two horizontal holes have been place (see Figure 33).

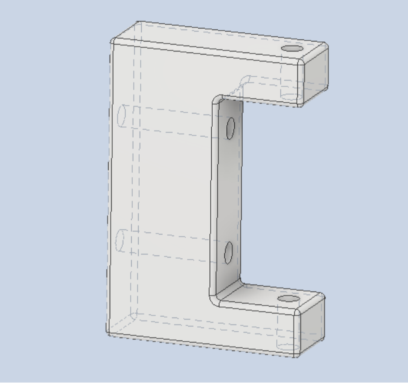


Figure 33: New attaching piece between exoskeleton and external platform with two horizontal tie holes (Autodesk Inventor Professional 2021)

The yellow piece of the exosqueleton (part number 1 on the left side of figure 32), is practically the same as was in the origin, the difference resides on the number of units of this type of pieces. Using 2 pieces instead of just 1, gives rigidity to the exoskeleton at the same time that we erase flexion stages as consequence of using elastic rubber to assist antigravity movemets.As two units of piece type 1 (yellow parts on figure 32) are present on new exoskelton design, 2 units of piece 2 (green parts on figure 32) are needed for providing consistency to the device. Pieces 2 are exactly the same as in the original design except for the inclusion of a new hole. Talking about this extra hole mission, is to provide another point of attaching for extra piece 2’ that gives rigidity to the system and avoids bending stages on green pieces while force from elastic rubbers and weight from user’s arm is applied.

Piece 2’, the white one between green pieces (see figure 32), is just a rectangular block with two holes through which it fix with green pieces for give them consistency and avoiding reaching limits of breakage.

Piece number 3 has suffer from drastic modifications. One of these modifications is aligning shoulder rotation axis and shoulder flexion/extension axis. To better understanding, the axis for shoulder rotation must be in the proyection of piece 4 axis, erasing distance between shoulder rotation axis and piece 4 along flexo-extension holes axis (see Figure 34).

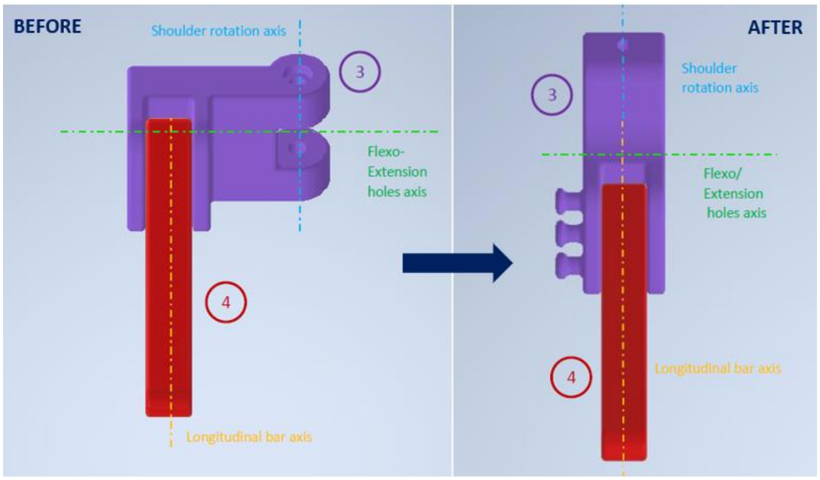


Figure 34: Part 3 modifications (Autodesk Inventor Professional 2021)

Axis alignment modification is so important for reducing user's force when performing internal and external shoulder rotation movement. What happened with the original exoskeleton was that when doing for example external roation for reaching close objects, the user needed to perform huge effort for being able of movimieng pieces 1,2 and 3 due to the short distance between shoulder rotation axis and longitudinal axis. This short distance becomes an impediment when performing rotational movements because it creates a difference between the actual movement of the shoulder and the movement that the shoulder would have to make to move the exoskeleton. The glenohumeral articulation of the shoulder, has 3 degrees of freedom, and therefore the three movements that the shoulder is capable of carrying out born on this same union (see figure 35). Separating in the exoskeleton the starting point of shoulder rotation movement and flexion-extension shoulder movement, force the patient on the task of performing an unusual movement.

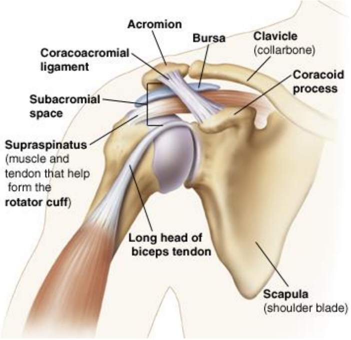


Figure 35: Glenohumeral articulation of shoulder joint [41][4]

Previous height of exoskeleton’s point of attachment (yellow part on left side of figure 32) was at the same level of user’s shoulder. This fact made that the patient adquired an uncomfortable position when using the mechanism because shoulders desalignment was created.

To give the exoskeleton height for creating distance between the user’s shoulder and the point of attachment between the exoskeleton and the support platform, position between pieces 1,2 and 3 will be changed and a step on part 3 will be created. To improve user's posture when having the exoskeleton on, and to make sure that patient’s shoulders are no longer misaligned, bar 2 (green bar on figure 32) will no longer connect with part 3 (purple pice on figure 32) by a reccess but part 2 will be connected to the upper part of the purple piece to give thus greater margin to the mechanism. The total height gained with respect to the original mechanism is 12.5 cm, enough for the subject’s shoulder attached to the exoskeleton to not be lower or higher than the released shoulder, thus reducing the possibility of compensation on the part of the patients.

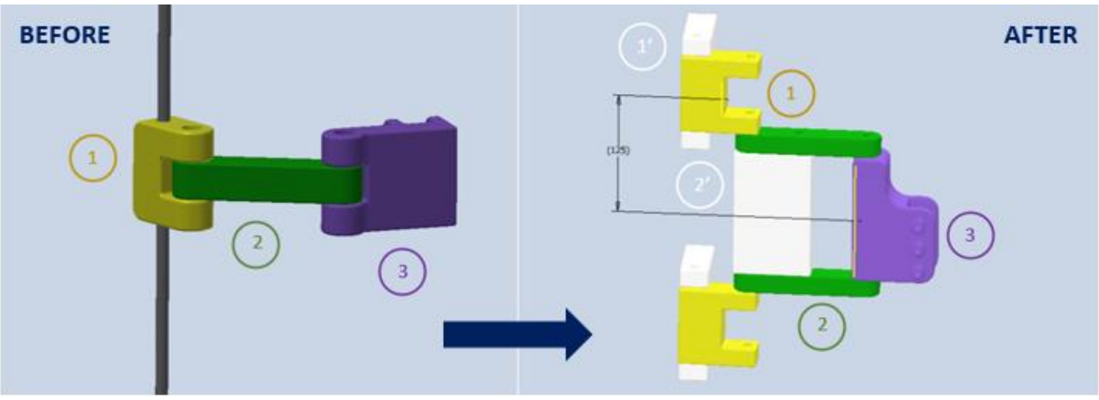


Figure 36: Interaction between shoulder pieces. On left side previous exoskeleton designed, on right side last mechanism designed taking into account the increased height of exoskelton attachment point with external platform (Autodesk Inventor Professional 2021)

3.4.2 Upper arm support design

In order to adjust the exoskeleton to the user, a simple velcro is not enough. The pacient need to take a comfortable position when taking the exoskeleton on. For this to happend, the upper part of the arm should be resting on a small platform, that helps the user resting the arm weight when being tired or that helps elastics rubbers when taking the arm to highest positions pushing the upper arm upward. This support will have velcros or elastic straps for taking an easy adjustment of the exoskeleton to the user.

The position and the union of this new piece with the exoskeleton will be through low piece 4 as it is seen in the folowing figure. This part called 4 will have different holes in order to being able of moving upper arm support and adjust it to the user along ith humeral length (see Figure 37).

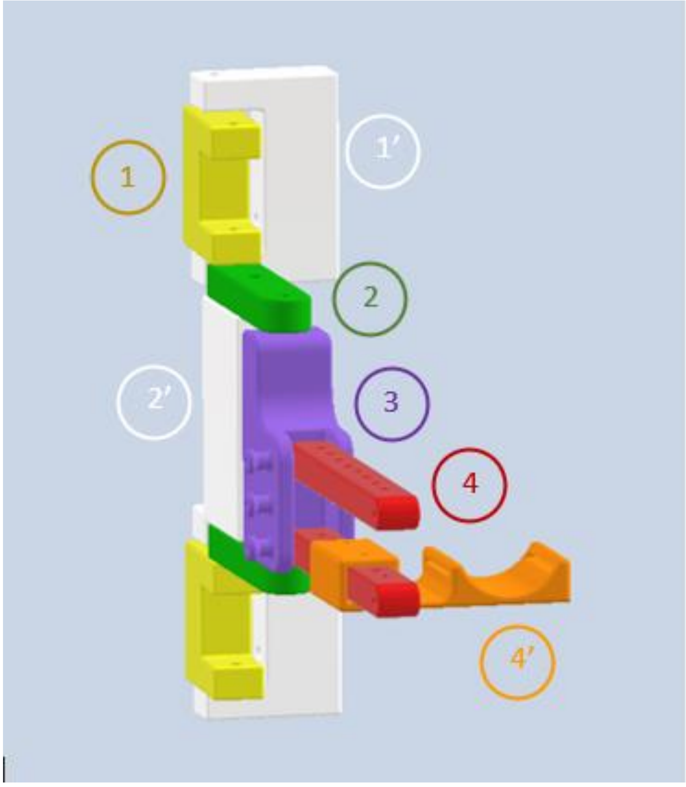


Figure 37: Upper arm support assembly with upper arm longitudinal bars (Autodesk Inventor Professional 2021)

In order to avoiding feeling rough surfaces or puncturing elements coming from 3D printing, the upper arm support will be lined with Eva rubber material.

Modifications on shoulder pieces

When testing previous version of the exoskeleton for detecting errors and view possible changes that could lead to better mechanism, low noises came from interaction of pieces 5 and 6 (light and dark blue on figure 31). These noises where produced because when resting arm weight on the exoskeleton, the narrow profile below the joining flanges of parts 5 and 6, suffers bending stresses that take the parts to the limit of breakage.

To solve this issue, reinforcement on this profile has been performed in a way that taking higher width does not interfere flexion and extension elbow’s movements (see Figure 38).

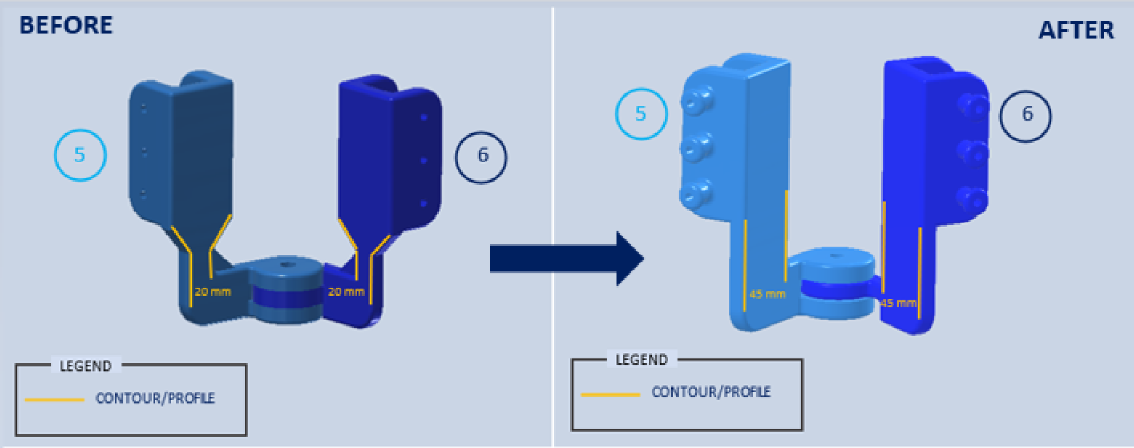


Figure 38: Elbow mechanism before and after modifications (Autodesk Inventor Professional 2021)

The profile width increases from 20 mm till 45 mm, the higher the surface is, the lower posibilities of reaching breakage states.

Width profile is not the only aspect that has changed on pieces 5 and 6. In the previous version of the exoskeleton, the buttons for assisting the mechanism; where the elastic bands are attached, were extra units that were added to the mechanism by means of screws and nuts. It has been decided to implement the buttons to the own design of parts 3, 5, and 6 since although the printing process becomes a more arduous and complex process, it prevents the buttons from rotating around a screw, giving more rigidity to the system.

3.4.3 Changes on pronation and supination mechanism

Pronation and supination movements were not optimum on the original exoskeleton. The previous mechanism for pronosupination performance consisted on a circular rail that served as a guide to a rocker where the wrist rested. The problem with this system was that once the user rested all the forearm weigth on the rocker, the rocker stuck in the guide, generating friction between both pieces. This friction force was difficult to combat and prevented an easy circular movement of one piece over another.

Another issue found on the previous exoskeleton when talking about pronosupination mechanism, was that in order for the wrist to easily enter the mechanism, the outer circle was very wide. Having this such huge circe guide made that when the forearm rested on the rocker, it was not possible to perform a concentric movement on the guide, but the user, in addition to pronosupination, needed to perform an elbow flexoextension to rotate the rocker.

A new design came out to get a better pronosupination movement performance without elbow flexoextension intervention. This new design promises a concentric turn of the support mechanism and the outer guide.

The first change is that the pronosupination system will be positioned right at the wrist of the patient. The following explains why the placement of the pronosupiation mechanism on the distal part of the elbow is better than the placement of this system on the proximal part of the elbow or middle of the forearm:

- At the proximal level of the elbow: the articular surface of the radius rotates on the humeral condyle at the same time that this rotation occurs, the radial notch of the ulna slides over the articular capsule of the elbow [42][4] (see Figure 39).
- At the distal elbow level: the ulnar notch of the radius slides anteriorly over the convex shape of the head of the ulna (see Figure 39).

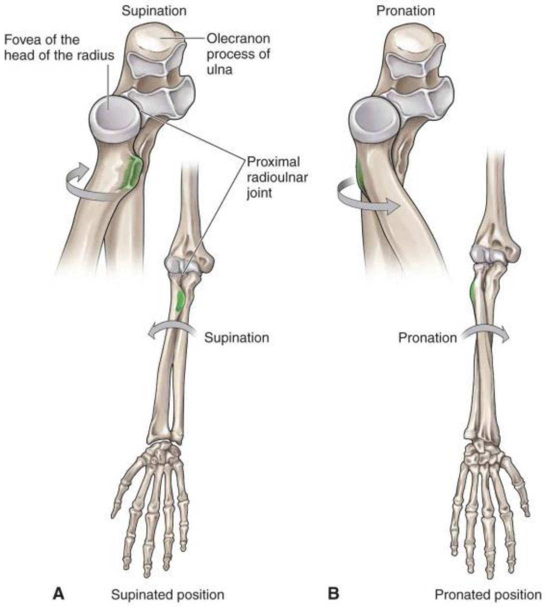


Figure 39: Ulna and radius bones on pronation and supination movements [43][4]

Since the main pronosupination movement originates from the elbow, the further we are from this joint, the easier it will be to perform this movement. So, the higher distance, the lower force the user will need to take, to perform the necessary torque for rotation movement.

Also, as long as going further from the elbow, the forearm decreases it size, so the nearer from the wrist we install the pronosupination mechanism, the smaller the pieces could be, leading to lower weight of the exoskeleton and less nuisance to patient’s movements around surronding environment. So the first conclusion about this new pronosupination mechanism, is that it should be located around wrist joint.

Taking into account that a concentric rotation of two elements is needed, three pieces will be designed that fulfill this mission. Two of them (8 and 8’ on right side of figure 40) will form the outer circle (part 9 on right side of figure 40) that will serve as a guide to the inner circle (support of the upper extremity of the user).

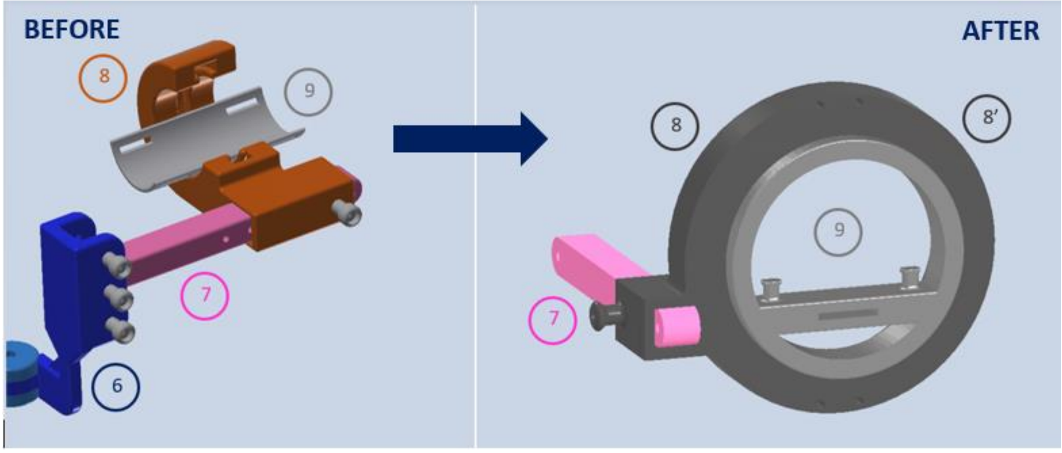


Figure 40: Previous and last mechanisms of pronation and supination (Autodesk Inventor Professional 2021)

Part number seven named in the above figure, where pronosupination system is attached, performs exactly as the same way as it did in the previous version of the exoskeleton.

Although in figure 40, the outer circle of right side seems to be a unique piece, is composed of two parts joined by small lugs. One of the two parts has the lugs and the other the holes for the perfect adjustment of both parts. In addition, a small rectangle will be designed to reinforce the union of both pieces by means of a pair of screws:

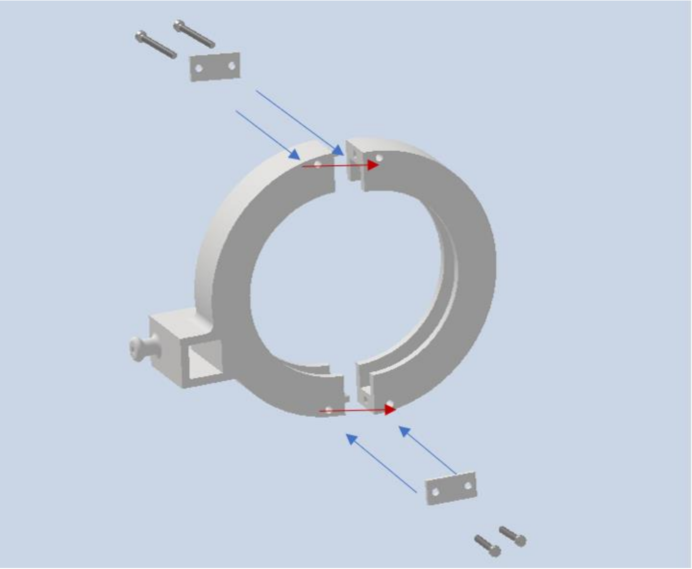


Figure 41: Assembly method of pronation and supination mechanism (Autodesk Inventor Professional 2021)

The real change resides in the inner circumference, where a horizontal apposition will be spread 2 cm below the center of the circle (see Figure 42), so that the rotation the mass center of the wrist will be concentric to the guide circle. The 2 cm remain on the fact that approximately a wrist measures 2 to 4 cm in height, so aproximately, every children wrist's size, will take a concentric rotation on outer circle.

From next figure, we can apreciate a blue colored circunference, the one that will be rotating on guide canal. Although guide width is higher than blue circumference width, pieces will not have allowance in frontal plane thanks to foreground circle that acts as a stopper:

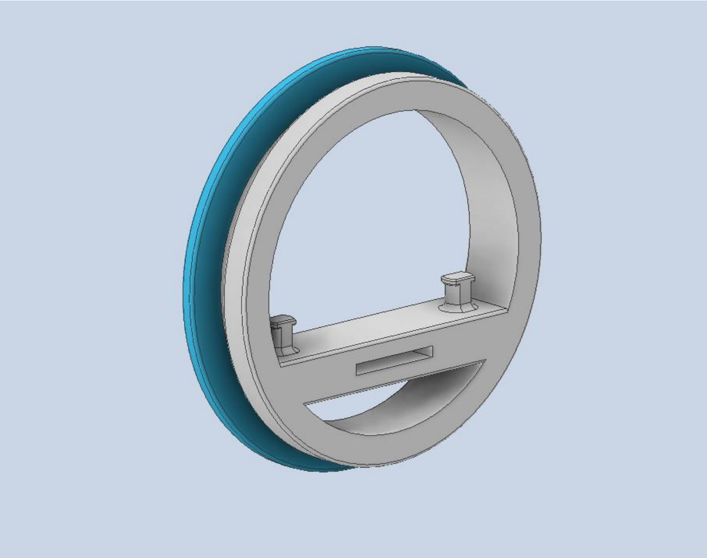


Figure 42: Internal circled piece for pronato-supination movement. Blue section refers to connectin with external rotation guide (Autodesk Inventor Professional 2021)

Therefore, the new design, despite having a larger size, is much easier to print it since it does not have hidden conducts, something that made printing very slow. Greater robustness and greater resistance are also improved characteristics of this new design as pieces are completely solid inside.

The horizontal support on the inner circle (see Figure 42), will include two structural elements for attaching an elastic band adjustable to the wrist to tie the exoskeleton to the upper limb. Also, this support, as the upper arm support, is going to be lined with Eva rubber material to avoid feeling rough surfaces or puncturing elements coming from 3D printing.

3.4.4 Hand support design

Due to CP, many kids have by default wrist flexion, what makes hand looking down because of luck of force to support it. For solving this issue and reach an standard hand and wrist position and extra piece will be designed. This extra piece (called 10 on figure 43) will connect with the inner circle of pronosupination system, and it will be a flat surface at the same height as the top of the horizontal bar where the wrist of the inner circle rests.

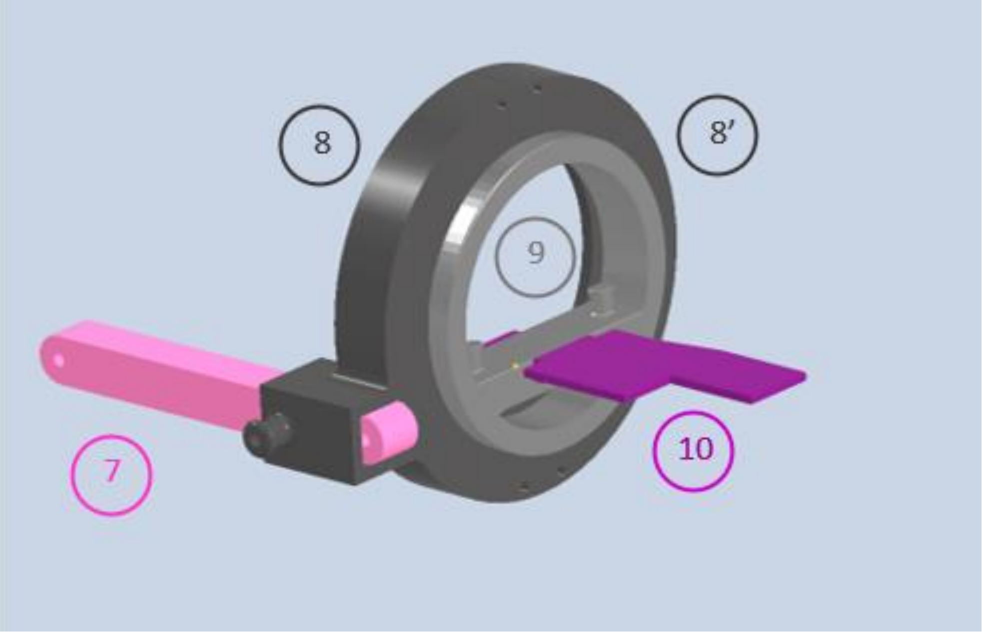


Figure 43: Pronato supination mechanism with hand support (Autodesk Inventor Professional 2021)

As happends with upper arm support, and wrist support, this piece will be covered by Eva rubber material to avoid damage and scratches to users.

3.4.5 External platform structure

To give consistency to the exoskeleton, it is not only important that the mechanism works properly, but also that the structure on which the weight of the exoskeleton will fall and therefore the weight of the user's arm is a consistent rigid platform, easy to move for its adjustment to the patient but at the same time easy to brake to avoid tipping over when user's pull.

The previous support platform was an umbrella tripod that held a threaded rod where the exoskeleton was fitted. This support system caused many problems, the most significante one was that the threaded rod began to bend after using it many times and after suffering many jerks from different users. This option was no longer viable when the already bent threaded bar prevented a good and equitable fit of the exoskeleton on users.

The low weight of the tripod together with the bar, was not enough resistance when the patient made abrupt movements resulting in the support tipping over. To avoid this problem, 10 kg of weights were introduced into the base of the tripod (see Figure 44), what generated another issue: the exoskeleton was more difficult to move because of weights and because of the lack of wheels. The cost of moving the exoskeleton and the difficulties in adjusting the mechanism to the patient, meant that it was not worth using such a simple tripod, which is why a new solution was implemented.

Figure 44: First support platform made with umbrella tripod, weights and threaded rod

New solution (see Figure 45), became more expensive but very profitable for using at physiotherapy clinics:

Figure 45: Current support platform (TV Rolling Stand)

The new platform is a height-adjustable, rolling cart for televisions. The wheels have brakes that prevent unwanted movements of the structure when the user is using the exoskeleton. The material of this new external support is metal, which gives it a great weight and eliminates the need to use extra weights as before. The adjustable legs allow the exoskeleton to be easily and quickly placed at the user's height without influencing the anthropometric measurements of the patients.

Also this new platform support allows having two different exoskeletons mounted on the same support, one for the left arm and the other for the right arm, we remove the situation of having two exoskeletons with their respective supports, being able to mount everything in one platform.

3.4.6 Assistance-resistance system

In order to help children with CP to lift their arm's weight, the exoskeleton makes use of elastic rubber bands attached to certain points of the mechanism, thus generating a system of assistance and resistance.

This system not only has the possibility of helping the child to lift the weight of their arm, but it can also be used as a resistive element, so that children have to make an extra effort to lift their arm. The objective of the resistive mechanism is to maintain the muscular strength gained by children, to avoid falling back into weak muscles. In this way, a progressive exoskeleton is created, which could help children at the beginning of therapy by assisting their movements, and continue with them once they have gained muscle strength, preventing them from easily performing certain movements to continue maintaining muscle tone.

This assistance-resistance method is implemented in the exoskeleton through lugs and elastic rubers. First difference between previous and actual exoskeleton is that lugs where at first impressed as different pieces, needing therefore nuts and bolts to assembly to the mechanism. This complicated assembly and having lugs impressed apart from pieces 3, 5, 6 and 8 (see Figure 31), made rotation movements because of screws leading to difficulties when installing elastic rubbers. In the last version of exoskeleton, lugs have been impressed as a whole with pieces 3, 5, 6 and 8 (see Figure 46). This change gives lugs more resistance, now the force provided by the elastic rubbers is not transmitted to the exoskeleton through the screws, but acts directly on the piece to be lifted.

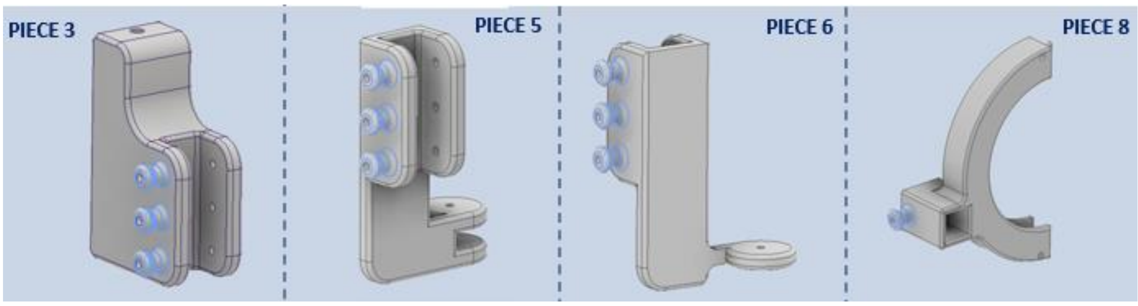


Figure 46: Lugs for elastic rubber on pieces 3, 5, 6 and 8 (Autodesk Inventor Professional 2021)

Always, elastic rubbers will have two points of attachemnt: first point is the reference point, from the one that elastic rubbers pry for lifting second point position (assisted point).

The exoskeleton can carry elastic rubbers:

- Between pieces 3 and 5 (see Figure 47), for lifitng or making descending forces on the upper side of the arm, what translates into shoulder flexion and extension. Lugs from part 3 are the reference points and lugs for part 5 are the asisted points.

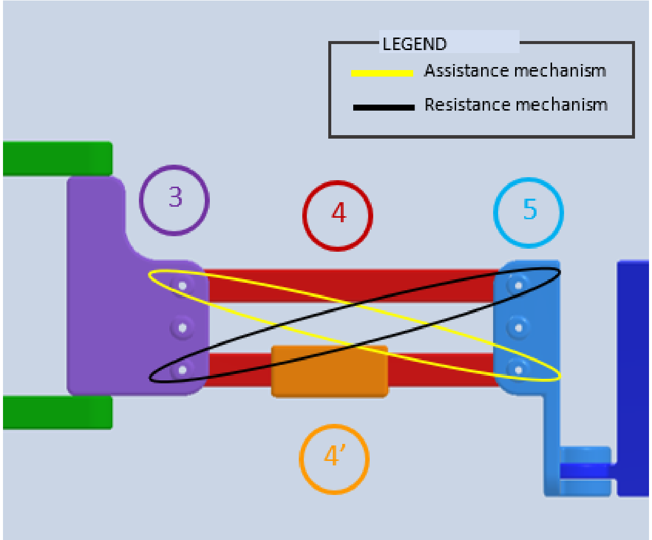


Figure 47: Elastic rubbers positions for shoulder flexion or shoulder extension assistance (Autodesk Inventor Professional 2021)

- Between pieces 5 and 6 (see Figure 48), new implementation for last exoskeleton version, for assisting children forcing them elbow extension. This combination allow abolish the elbow internal flexion that many children with CP have by default. In this case, part 5 acts as reference point and 6 as assisted point. Elastic rubbers always between middle lugs for avoiding interferences with shoulder or elbow flexoextension.

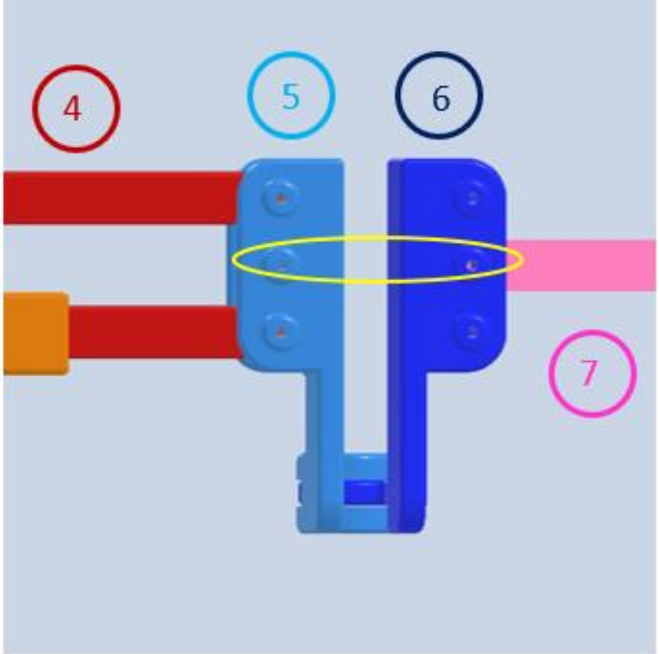


Figure 48: Elastic rubbers position for blocking an external rotation elbow position (Autodesk Inventor Professional 2021)

- Between pieces 6 and 8 (see Figure 49), for lifitng or making descending forces on the forearm, what translates into elbow flexion and extension. Part 6 acts as reference point and part 8 as assited point. This time, assisted point is the same for lifting and for for descending forearm.

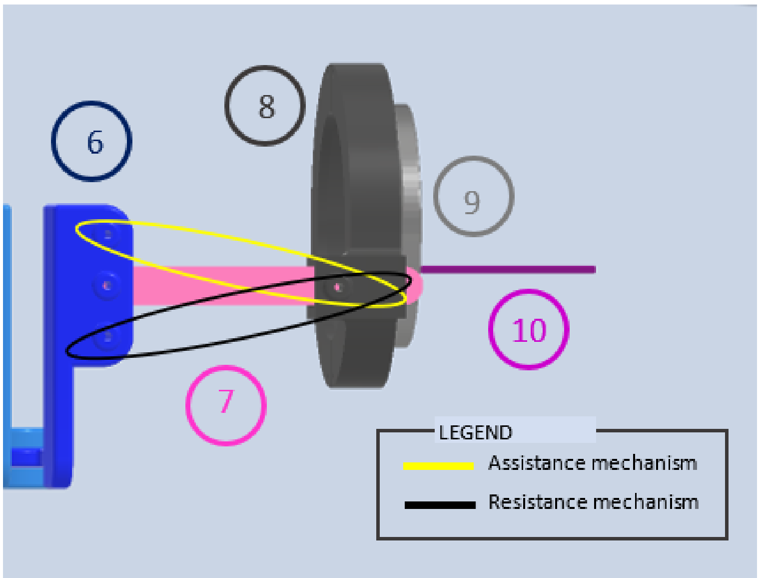


Figure 49: Elastic rubbers position for elbow flexion or elbow extension assistance (Autodesk Inventor Professional 2021)

Different elastic rubbers position, makes the exoskeleton evolve at the same time as the user does it. At the beginning for helping the patient, any quantity of elastic rubbers can be used for assistance action until the user feel helped. After many working sessions, once the user gained some muscles strength needing lower assistance to lift the arm, less number of elastic rubbers can be used. Once the child is completely able of lifting the arm without assistance, elastic rubbers in resistance position could be positioned in order to avoid user from loosing strength gained after working therapies with exoskeleton.

3.4.7 Final Prototype design

Final exoskeleton have 4 degrees of freedom which each one corresponds to next movements:

- Shoulder pieces allows:
    - ✓ Shoulder extension and flexion
    - ✓ Internal and external shoulder rotation
- Elbow parts perform:
    - ✓ Elbow flexion and extension
- Wrist pieces deal with:
    - ✓ Pronation and supination movements

Not assisted movements are:

- ✗ Shoulder aduction and abduction: Due to how shoulder pieces 1,2 and 3 (see Figure 50) interact between them, abduction and adduction can take place althought not in complete and comfortable position.
- ✗ Wrist movements: there are no pieces in the mechanism that represent wrist adduction, abduction, flexion and extension movements. However

the user is able of moving the wrist below elastic textile bands attached to the forearm, without fully development of movements.

A diagram of the pieces and the movements that can be performed is presented in figures 50 and 51:

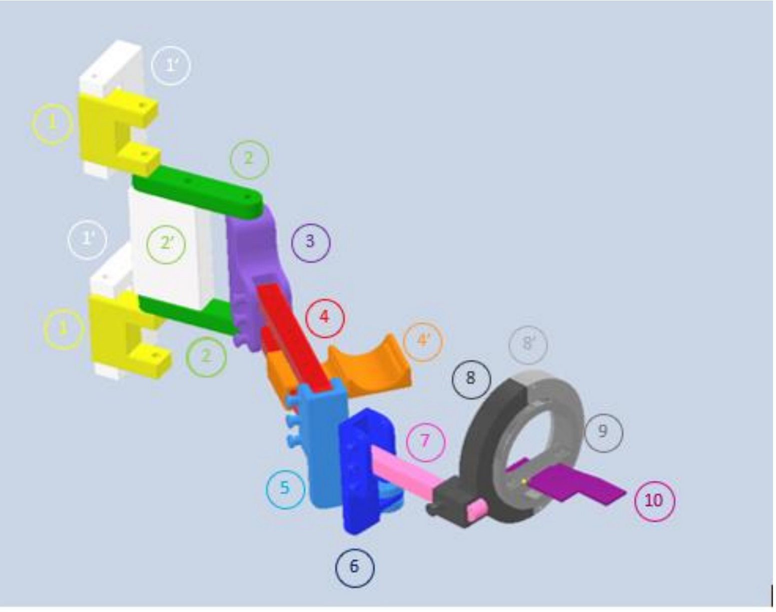


Figure 50: Current exoskeleton with numbered pieces (Autodesk Inventor Professional 2021)

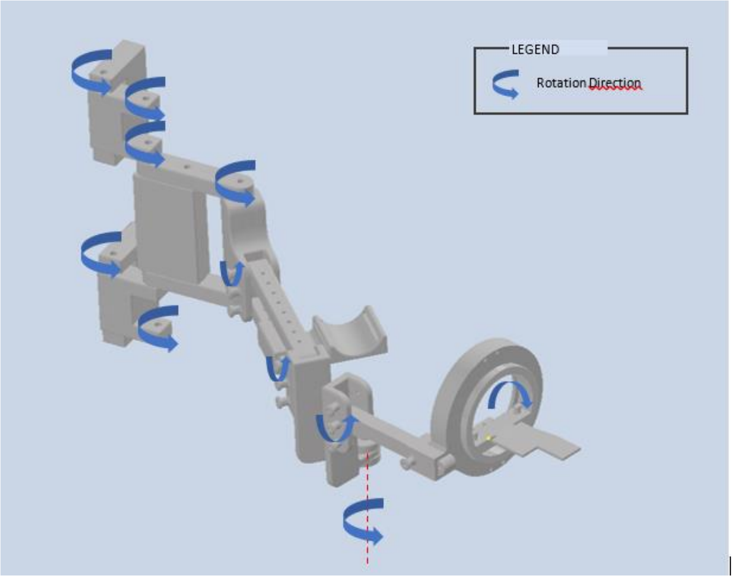


Figure 51: Rotation directions of current exoskeleton (Autodesk Inventor Professional 2021)

Table 4, include functions, anatomic representation and assistance posibilities of each piece:

Piece number	Function	Anatomic representation	Possibly Assistance
1’	Attachment to platform	No anatomic representation	✗
1	Internal and external shoulder rotation	Shoulder joint	✗
2	Internal and external shoulder rotation	Shoulder joint	✗
2’	Reinforcement for avoiding breaking pieces of type 2	No anatomic representation	✗
3	Internal and external shoulder rotation Shoulder flexion and extension	Shoulder joint	✓
4	Longitudinal upper arm length Shoulder flexion and extension	Upper arm	✗
4’	Upper arm support	Upper arm transverse diameter	✗
5	Colaboration on shoulder rotation when elbow is bent Elbow flexion and extension	Elbow	✓
6	Colaboration on shoulder rotation when elbow is bent Elbow flexion and extension	Elbow	✓
7	Longitudinal forearm length Elbow flexion and extension	Forearm	✗
8	External Circle pronosupination movement	No anatomic representation	✓
8’	External Circle pronosupination movement	No anatomic representation	✗
9	Internal Circle pronosupination movement	No anatomic representation	✗
10	Wrist support	Hand	✗

Table 3: Current exoskeleton's pieces identifiers

Not all pieces can be used for both arms rehabilitation. Elbow pieces 5 and 6 are different for right and left arm since the base of rotation must go on the outside of the arm. In addition, the coupling parts of the pronosupination mechanism (part 8) must be symmetrical for the left and right arm since the coupling point must always face outwards.

For taking to every rehabilitation institute the posibility of rehabilitate both arms from same mechanism, it has been decid to attach two exoskeletons to the same platform. Both mechanism are equal but simmetrical respect sagittal plane.

Also, for good acommodation of the exoskeleton platform with chairs where patients rest, mechanism from left arm has been attached to right platform side and right exoskeleton is hooked at left platform side. In this way, we avoid or reduce posittioning inconvenience between chair and support platform.

Figure 52: Right and left exoskeletons assembled in current support platform

4 CLINICAL VALIDATION OF THE EXOSKELETON

4.1 Clinical Study objectives

In order to discover all neccesary modifications on original exoskeleton, many testing sessions with children with different pathologies were taken. Sessions were performed at *IRF La Salle*, one of the most complete and comprehensive rehabilitation center in Madrid that offers many multidisciplinary services to adults and children. During these therapy sessions, children with reduced mobility on some upper limb, were asked to perform 1D and 2D exercises on a determined workspace.

Therapy sessions could be divided into two stages which differs on: long lasting, workspace to work on, exoskeleton designs, game's interfaces and participant list.

On one hand, first stage sessions were performed every week during aproximatly 2 months. During this phase, patients interacted through direct contact with a touchable screen while having the exoskeleton attached, needing as setup: exoskeleton, touchable screen with FittsStudy interface installed, chair and desk adjustable in height given by the institute for children coupling. Each session lasted 20 minutes, of which the first 10 minutes were used to adjust the exoskeleton to the patient, and the last 10 minutes were used intersct with FittsStudy application, whose measures and characteristics will be explained in the next section. This first stage allowed to identify design flaws and work methodology errors.

Attending to those issues detected during stage one, a break on clinical sessions was taken for analysing first stage's results and determined next steps. Once errors were solved; exoskeleton's design improved and work area reorganised, second stage took place.

Second clinical step took place during third week of May, were 3 patients participate on 50 minutes sessions. The setup needed for this phase, as well as previous stage, also include the exoskeleton and the touchable screen but this time with Wereium Solutions interface installed, as well as chair and desk adjustable in height provided by te institute, and a new item for indirect interacion: inertial sensors. This time, Werium Solution's interface; whose characteristics will be explained in section 4.3.1; was used achieving indirect interaction thanks to Werium sensors which made it possible to adjust the spatial range of work to each patient. This second stage made it possible to study the impact of the exoskeleton on the patients when performing the exercises.

All clinical analysis presented in this project occurs during March, April and May months. During first stage sessions, pyshiotherapist were not present, therefore, only data obtained by technical or engineering part is counted for this first stage. On next stage, during the intense week of therapy, pyshiotherapists were present. The clinicians not only evaluated the posture and performance of the children at the time of activities execution, but also the sessions were recorded for later evaluations and validations with the AMS scale previously explained, so second stage analysis count with clinical and technical evaluation points of view.

The main objective of this short clinical study is to present a functional exoskeleton, ready for a next and longer clinical study in which more patient could be involved. Children moving freely with exoskeleton on and feeling supported by the mechanism is a great achieved goal.

The characteristics of the different clinical stages are summarized in table 5:

Stage	**Duration**	**Pyshiotherapists presence**	**Number of participants**	**Workspace**	**Exoskeleton**
1	20 min	No	6	Direct interaction	Littly functional
2	50 min	Yes	3	Indirect interaction	Tightly functional

Table 4: Differences between clinical phases

4.2 Functional evaluation through FittsStudy software

4.2.1 First stage: FittsStudy test performance

Fitts’ law characterizes pointing speed-accuracy performance as throughput measured in bits/s for investigating human performance in target acquisition tasks. Throughput equation is shown below:

$$TP = (ID_e)/MT$$

Equation 1: FittsStudy’s throughput

Where MT is the mean movement time recorded over a sequence of trials measured in seconds and ID_e is the index of difficulty measured in bits computed from movement amplitude (A) and target width (W) as following:

$$ID_e = log_2\left(\frac{A_e}{W_e} + 1\right)$$

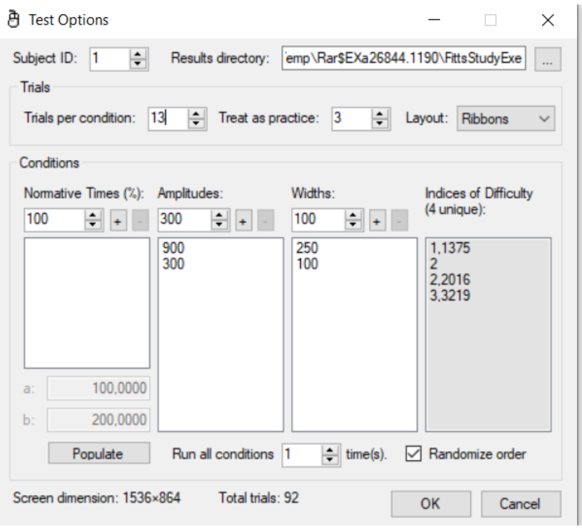
Equation 2: FittsStudy's index of dificulty

The higher the index of difficulty, the more complex it will be for the user to achieve targets. Having large distances between targets which is the same as high amplitudes, forces the user to perform more extreme movements, focusing on arm movements, large amplitudes achievement targets will be required complete elbow flexion for near targets, complete elbow extension for far away targets and huge internal and external shoulder rotation. On the other hand, the shorter the targets width, greater precision and higher fine motor skills work will be performed by the patient, which translates into higher hand precision when talking about arm therapy sessions. In fact, when using large amplitudes and short widths, ID becomes higher, which makes lot of sense because reaching faraway and small targets is more complicated than reaching near and big targets.

Throughputs comparison between separate test conditions, can be used to assess performance differences. The higher the throughput, the lower time the user used while reaching objects, which indicates that patient could move faster between targets because movement is basically controlled. In addition, high throughputs indicate complex exercises which is the same as large ID.

FittsStudy offer two task's methods: 1-D method, based on vertical ribbons for horizontal pointing; and 2-D method, a ring-of circles. In this project, just 1-D methods have been used. The exoskeleton lifted user's arm, so that user only had to performed left-right movements on the same plane.

Set target's parameters (amplitude, width, trials and layout) and FittsStudy interface is shown in figure 53:



Subject ID: 1
Results directory: emp\Rar$EXa26844.1190\FittsStudyExe
Trials per condition: 13
Treat as practice: 3
Layout: Ribbons
Normative Times (%): 100
Amplitudes: 300
900
300
Widths: 100
250
100
Indices of Difficulty (4 unique):
1,1375
2
2,2016
3,3219
a: 100,0000
b: 200,0000
Run all conditions 1 time(s).
☑ Randomize order
Screen dimension: 1536×864
Total trials: 92

Figure 53: FittsStudy parameters (FittsStudy)

Once amplitudes and widths are set, ID for each combination is shown: the largest value (3.3219) corresponds to the largest amplitude (900) and the smallest width (100), and the least ID value (1.1375) agrees with the smallest amplitude (300) and the highest width (250). As it is shown, 13 trials per condition (a pair of amplitude and width) were set because higher number of trials carried out to tired patients. For showing an example of how the game looks like, the following figure shows what the user see when a value of 900 is set for amplitude and 250 is stablished for width (see Figure 54):

Subject: 1 Layout: 1-D Block: 0 Condition: 0 Trial: 0 A: 900 px W: 100 px ID: 3,32 bits MT%: -1,00 MTPred: -1 ms MT: -1 ms a: 100 ms b: 200 ms/bit v4.2.8

Figure 54: FittsStudy interface’s appearance (FittsStudy)

Besides FittsStudy application, information about patients involved on this first stage of clinical study are attached. During March and April months, 5 children with CP colaborated on the project, participating in 20 minutes sessions where the main objectives were tp check and adjust the size of the exoskeleton and confirm that the children could move freely through the imposed work area. Data from participants is collected on table 6:

Children ID	Age	Pathology	Number of sessions	Upper limb side
A	6	Left hemiparesis	3	Left arm
B	20	CP, tetraparesis	3	Left arm
C	8	Left hemiparesis	1	Left arm
D	5	CP, autism	1	Left arm
E	9	CP, right hemiparesia	1	Right arm

Table 5: First Clinical Analysis patients

Upper limb side column of the previous table, refers to the arm of the patient to which exoskeleton was attached. In all cases, patients used the arm with lower mobility capabilities for activities performance.

Besides all these patients, also a patient of 4 years old was at first included in the clinical study but so many pieces need to be resized for its use so finally we decided to remove this subject from clinical analysis.

4.2.2 FittsStudy conclusions

Altough first objective with these two months sessions was to obtain data from FittsStudy application to determine patient evolution along sessions and to analyse patients interaction with the environment when having the exoskeleton on, issues found during sessions made us change the goal of this project first clinical stage to a process of exoskeleton improvement in order to reach to a functional mechanism at the end of this period.

Antropometric sizes became a huge problem during these sessions due to just one exoskeleton size was printed and brought to *La Salle Institute* at the beginning. On one side, children of slimmer constitution could not work with the exoskeleton because if velcros on the top were adjusted, the forearm did not reach the lower end of the exoskeleton making the adjustment impossible and vice versa. On the other hand, children with wider consitution could not performance good movements because shoulder pieces were positioned at middle longitudinal upper arm distanceand pronosupination mechanism were positioned at the middle of longitudinal forearm distance, leaving wrist and hand without any support. For fast problem solving, different measures were printed from pieces number 4 and 7 (see Figure 50) to adapt them to each user because are the ones that follow and represent the longitudinal length of the arm. Being aware that the future of the exoskeleton is to stay in a physiotherapy clinic, and that the constant change of all these pieces would subtract time from therapy in each session, telescopic bars will be design for faster adaptation of the mechanism to the children arms length.

At the beginning, the exoskeleton that was tooken to La Salle facilities didn’t include pieces 1 and 2 (see figure 31) and the mechanism was fitted on the threaded bar of the tripod through a joint that allowed cylindrical movement with part 3 (see Figure 55):

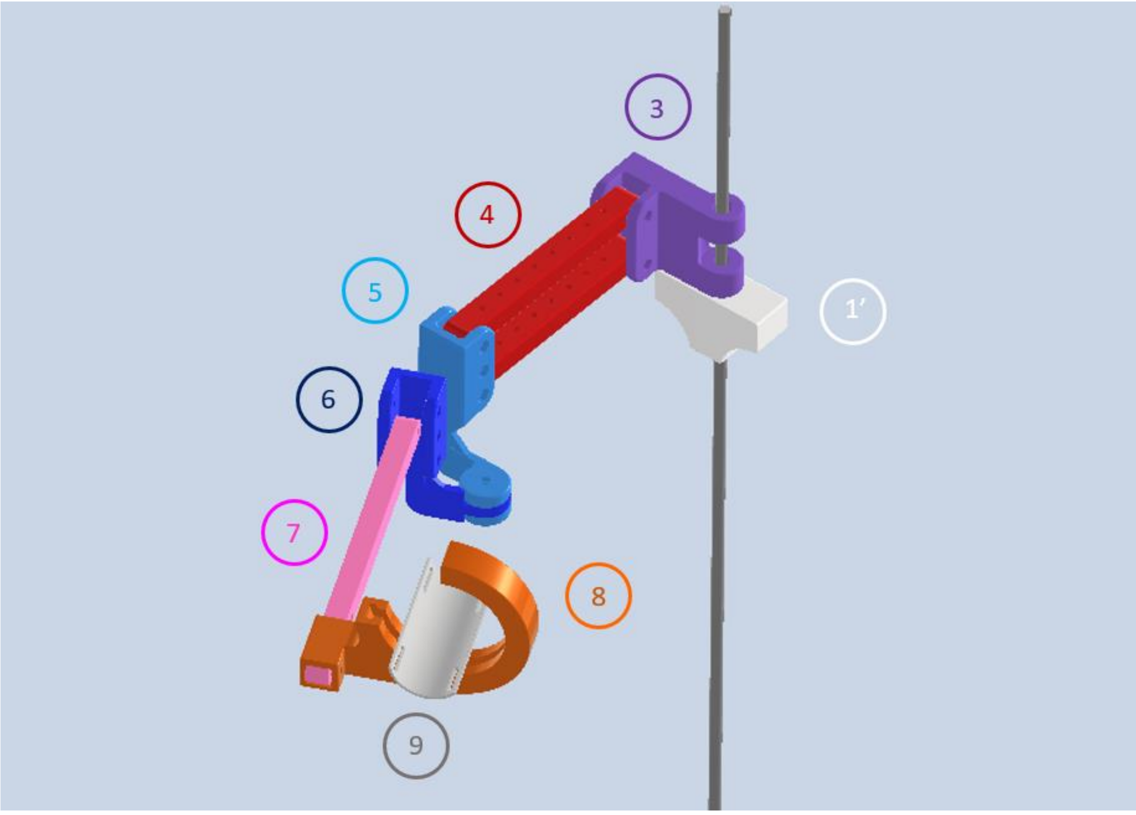


Figure 55: First prototype brought to La Salle facilities (Autodesk Inventor Professional 2021)

Pieces 1 and 2 (see Figure 31) were at first instance eliminated from the mechanism because they did not participate on any assistance-resistance movement and also thery did not support any body structure. Erasing these two pieces from exoskeleton brought consequences; patients did not seem so comfortable when reaching objectives at flexion and extension extreme positions when interacting with the touchable screen by direct contact. This uncomfortable position prevents subjects from compensate with body trunk, but did not allow the shoulder joint to perform extension on transversal plane.

However, bringing back shoulder pieces did not solve uncomfortable movements when moving from reaching far away targets to close targets. The union position of the 3 pieces, as well as the attachment to the tripod at the same height as the patient's shoulder, still prevented from an easy movement of the patient's arm. Interactions between pieces 1,2 and 3, when lefting weight on exoskeleton, produced huge flexor torques that lead to not easy allowance of performing freely movements when using elastic rubbers. Also, the fact that exoskeleton was attached to the platform at the same level height of shoulder joint generates a shoulder decompensation leading to an unnatural posture. Finally, in order to align both shoulders, the shoulder mechanism was radically changed as described previously in the section 3.4.1.

Third issue detected was that the original exoskeleton did not count with a hand support for avoiding wrist flexion by default. This issue also difficulted interaction between patients and touchable screen, because FittsStudy just accept one surface contact at each time, and patients touched the screen with external hand surface avoiding FittsStudy for detecting a real contact. This issue was solved thanks to hand support and wristbands, that let the user to take just one contact with screen.

Despite hand position stablished with new hand support and wristband, the exoskeleton is not a mechanism for hand rehabilitation and does not help on hand movements. This still causing difficulties when interacting with touchable screen because most of the patients did not perform active motor movements with index finger to make contact with the screen. Children, instead of lifting their finger to touch the touchable screen, compensated with the trunk to move their arm forward so that the longest finger contacted the screen.

As body trunk compensation removal was an objetive of the exoskeleton, continuing involving children in a work area where they have to perform compensatory movements in order to perform the rehabilitation exercises is pointless. In addition, for children, the frustration created as a result of not being able to fulfill the objectives that were imposed, caused on them a feeling of rejection towards the exoskeleton and therefore they refused to work in a therapy that could help them in improvement upper limb mobility. In fact, patients C and E refused to participate again in any test after first session was taken because they felt uncomfortable during first session.

Frustration and difficulties of interaction led this project path to change strategy and methodology during exercises. For this reason, for the 50-minute sessions week, the workspace was changed and indirect contact through sensors introduced so that children had to move in a closer and more comfortable environment for them, thus eliminating the possibility of generating a feeling of rejection at rehabilitation therapies to improve arm mobility.

Despite this two months stage have led to a functional exoskeleton and to a better work methodology, no statistical analysis can be done on FittsStudy data. In most of the sessions the interaction with the screen did not give good results due to the lack of contact detection by the touchable screen because multipoint contact. So that the sessions could take place and the user could interact with the interface, was necessary the intervention of a third person who touch the ribbons for stablish real contact, what led to tainted MT measures because time counted unitl contact (did not performed by the patient) was done. Also, the continuous movement’s obstacles of the shoulder joint led the patient to perform forced movements with large trunk compensations which in the few data recorded, have generate great noise.

4.3 Second stage: Functionaal validation through inertial sensors

4.3.1 Werium solutions interface

This second clinical stage consisted of sessions of 50 minutes where patients interacted indirectly through inertial sensors with Werium Solutions games having the exoskeleton on.

ENLAZA sensor is an inertial wearable device developed by Werium for capturing movements. It integrates a 3D accelerometer, a 3D gyroscope and a 3D magnetometer to provide a very high accuracy and precision. Through these wearable sensors, patients are able of interacting with the Werium videogame by moving mouse’s pointer. The goal of the videogame is airplane’s control for making it pass through circles that appear at different points on the screen, thus forcing the patient to perform elbow and shoulder rotational, flexion and extension movements.

Sensor devices are connected to the tablet; where the videogame is executed; through Bluetooth standard that make possible the shipment of sensor’s data orientation through and Yaw, Pitch and Roll angles for airplane’s control. In this way, when the user raises, lowers, moves the arm to the left or to the right, the plane also do it in the same direction and proportional range.

When for instance, the user moves the arm upward, the sensor send signals via Bluetooth for moving the pointer of the computer mouse upward the same angle range as the patient did it. Elevating the point means that the plane moves upward. Interface looks as in figure 56:

Figure 56: Werium Solutions game appearance (Werium Solutions)

Best contribution of Werium Solutions to this project is the possibility of regulating the work area to adapt it to patient's capability, varying the angular ranges of flexoextension and left-right displacements. Therefore, we can eliminate the previous way of training (direct contact) which imposed the same workspace on all patients while using the exoskeleton, thus leading to a much more flexible and customizable method.

Werium Solution videogames creates an csv extension file for each session. In such file, alfa and beta angles are saved for every single instance. The meaning of those alfa and beta angle are related with flexion or extension movement since the resting position (alfa) (see Figure 58) and with right and left displacement since the resting position (beta) (see Figure 57).

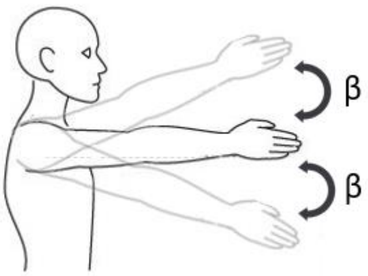
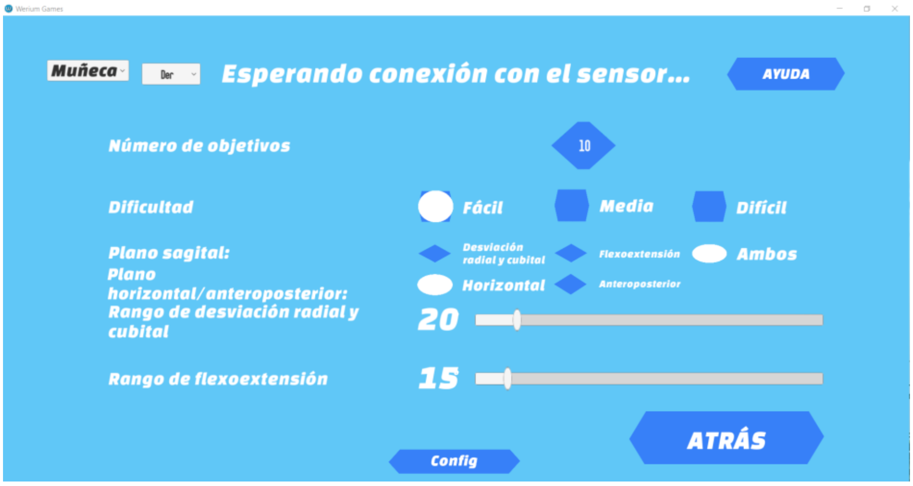


Figure 57: Beta angle measured by Werium sensors

Figure 58: Alfa angle measured by Werium sensors

Parameters' window selection is shown in figure 59:



Muñeca | Der
Esperando conexión con el sensor...
Número de objetivos: 10
Dificultad: ● Fácil ○ Media ○ Difícil
Plano sagital: ○ Desviación radial y cubital ○ Flexoextensión ● Ambos
Plano horizontal/anteroposterior: ● Horizontal ○ Anteroposterior
Rango de desviación radial y cubital: 20
Rango de flexoextensión: 15

Figure 59: Werium Solutions parameters' window (Werium Solutions)

Number of objectives, speed of appearance of successive targets and alfa and beta angles can be personalised.

The possibility of varying the angular range of each movement, let us adapt the videogame to patient's needs. In this way, Werium Solutions game can evolve at the same time as the child does; that is, once the child adapts to the video game throughout the session, the difficulty of the game can be increased by expanding the ranges of movement. In the same way, just as the exoskeleton will be able to accompany the child during their evolution, going from assistance to resistance, to prevent children from losing the muscular strength acquired during therapies thanks to the use of the exoskeleton, the video game will also be able to take out new targets with a shorter time interval between one and the other and the ranges could be set on higher values to accompany the patients in their evolution.

4.3.2 Participants of second clinical stage

This time, from patients mentioned in section 4.2.1, just A and B continued participating. Also, another child (patient F) was included in the study so the final list of participants would be as in Table 7:

Children ID	Age	Pathology	Number of sessions	Upper limb side
A	6	Left hemiparesis	1	Left arm
B	20	CP, tetraparesis	2	Left arm
F	9	Myelitis, tetraparesia	2	Left and right arm

Table 6: Second Clinical Analysis patients

During second clinical stage week, sessions took 50 minutes. All sessions started with aproximatly 10 minutes dedicated to the placement of the exoskeleton onto the patient. This was the most importante part in order to perform a good exercise and for patient to feel comfortable when working with the exoskeleton.

4.3.3 Preparation protocol

Always, sessions requires from patient to be sitting with straighted back, knees bent 90 degrees and feet flat on the floor or on a solid and smooth surface and are simmetric for both arms, so references were set to assure comfortability on the posture (see Figure 60).

Figure 60: Initial position on correct sitting way

For tesing, if the exoskeleton was correctly attached, patient on resting position should be comfortable and with no shoulders desalignment. Also, comfortability must be present on not resting position when using elastics rubbers to raise arm to the new assisted resting position (see Figure 61).

Figure 61: User seated on resting and assisted position

Some references were drawn in the exoskeleton for reaching a comfortable and no desaligned shoulder resting position. Marks were taken on shoulder pieces and angles between right shoulder parts (see Figure 62).

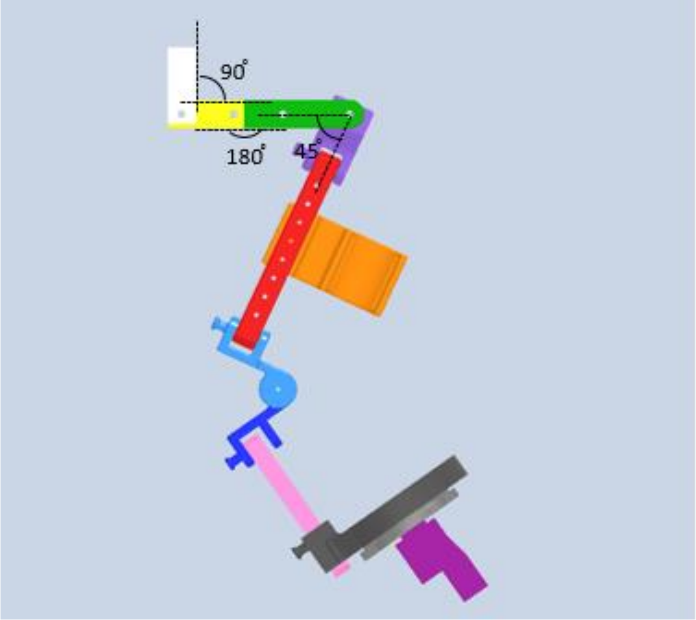


Figure 62: Position between exoskeleton's pieces while resting position: 90 degrees between piece 1 and piece 1', 180 degrees between piece 2 and piece 2, 45 degrees between pieces 2 and 3 (Autodesk Inventor Professional 2021)

Besides these drawn references, upper piece 2 should be aproximatly 4 centimeters above shoulder’s height(see Figure 63).

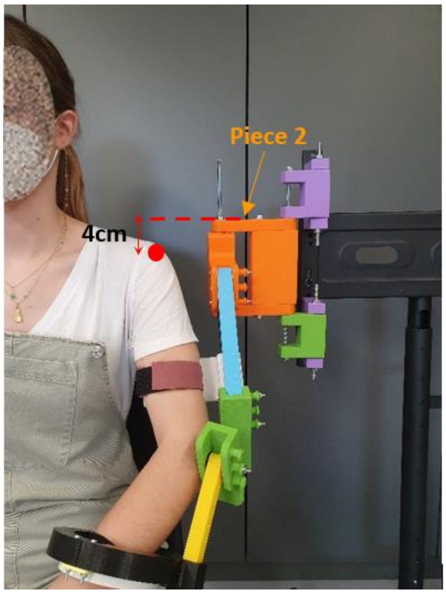


Figure 63: Height difference between shoulder and piece 2 (approximately 4 cm)

Also, for a good coupling of the exoskeleton with the patient, part 3 frontal face plane, should be aligned with back frontal plane (see Figure 64).

Figure 64: Correct alignment between frontal back plane and piece 3

Moreover, upper arm support colocation was important for avoide contact between ribs and part 4' (upper arm support referenced on figure 50) and for avoid shoulders desalignment. If velcro attaches are extremely closer to the elbow, lifting movements would result hampered; and if velcro attached are extremely closer to the shoulder, descending movements would result hampered (see Figure 65).

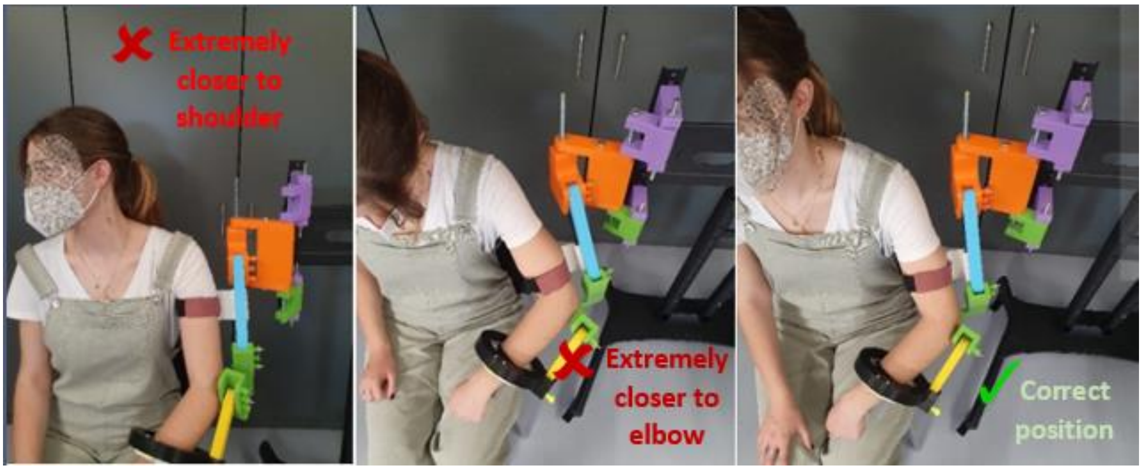


Figure 65: Wrong and correct position of Velcros for attaching upper arm support

Once exoskeleton was completly attached and patient in a comfortable position, practique exercises could took place.

For interacting with the screen, sensor was placed at the botton of hand support, and once it was connected, the video game could begin (see Figure 66).

Figure 66: Sensor position on exoskeleton

4.3.4 Validation protocol

The workflow follow with each patient was the following:

- Without exoskeleton:
    - Before starting the session and before attaching the exoskeleton to the arm, the children were asked to perform 3 tasks: touching their head, extending the arm forward as if they wanted to touch the screen, and going up and down in the frontal plane as if they were stroking a domestic animal.
- With exoskeleton:
    - Once they had the exoskeleton on, before interacting with the video game, they were asked to perform the same 3 tasks again.
    - Three 1D exercises: during these exercises patients needed to perform shoulder and elbow flexoextension movements on sagital plane to reach objectives.
    - Three 2D exercises: during these exercises patients needed to performed shoulder and elbow flexioextension on sagital plane and shoulder and elbow rotation on transversal plane.
    - A break was taken.
    - Another 2D exercise was performed.
    - A last 2D exercised took place but this time without the mechanism attached.
- Without exokeleton:
    - And finally when the session came to an end, once they had removed the mechanism, they repeated the 3 tasks again.

Once paremeters are set for each exercise, sensor need to be calibrated. For this reason until the video game place the plane in the center of the screen ready to start the exercise, the patient must maintain the arm at an initial position: upper part of the arm close to the body and the elbow bent 90 degrees (see Figure 67).

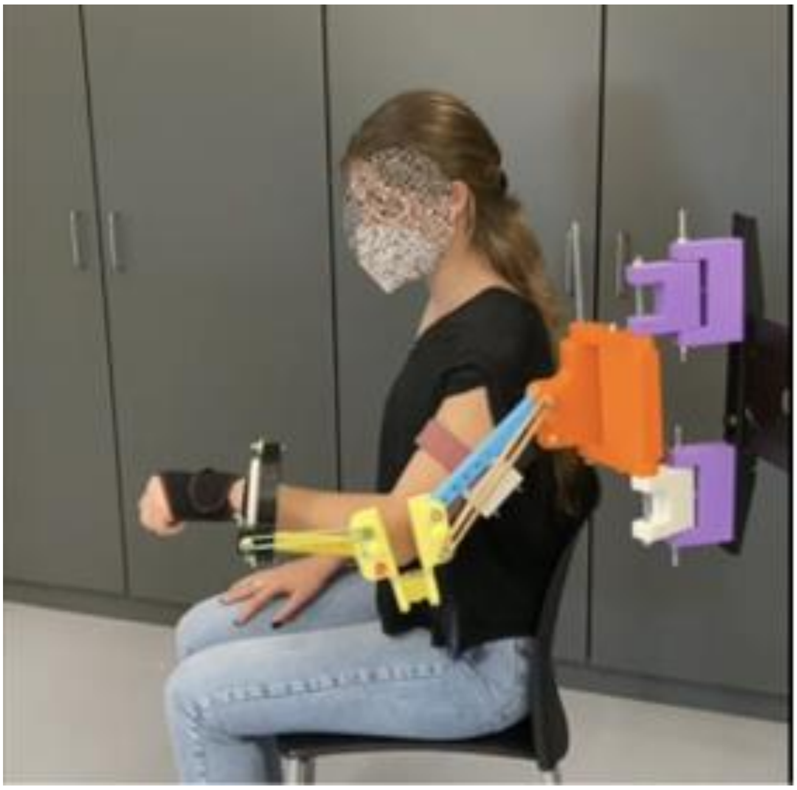


Figure 67: User's solution for beginning playing with Werium Solutions videogames

Before reaching conclusions section, it is important to note that the 3 subjects were assisted in shoulder flexion, elbow flexion and external elbow rotation by elastic rubbers.

4.3.5 Visual conclusions

First visual conclusion thrown after second clinical stage is that the exoskeleton is functional and it allows patients to move the arm freely without feeling discomfort or any movement restriction. This has been possible thanks to changes performed on pronosupination system and on shoulder pieces, that have made possible a great interaction of the patient through the environment when being assisted by elastic rubbers. Also, eliminating direct interaction between the patient and the screen, has led the project to perform sessions where children are not frustrated.

During sessions, an aspect noted by physiotherapits was that patients could reach extreme arm postures when having the exoskeleton on. In order to explain why children can better perform tasks in extreme positions with exoskeleton on than without it, first, it will be explained how human beings achieve any objective.

When the human being wants to touch, for example, an object that is up and to the right, the subject has to perform two independent tasks: support the weight of the arm as a consequence of raising the upper limb, and move the arm through the work area to establish contact with the object. Hence, the individual has to perform two forces:

- First force overcomes the action of gravity to lift the weight of the arm. This force is performed by shoulder and elbow flexion.

- Second force let move the arm along a transversal plane parallel to the ground and at the same height than the objective to be achieved. This force is taken when performing internal and external shoulder rotation.

The mechanism helps children with CP by assisting them in one of the two tasks necessary to perform outreach work. The exoskeleton helps children supporting arm weight, leaving them greater freedom and ability to perform the last task: using precision to achieve goals. The help provided by the elastic rubbers is essential, because in general children with CP do not have enough muscular strength to support the weight of their arm, so the first task is already difficult for them and they never get to perform the second task well as a consequence of their effort focused on lifting weights.

Without the help of the exoskeleton, the range of motion on a plane parallel to the frontal plane of the body is much lower than with the help of the exoskeleton (see Figure 68).

Figure 68: Workspace frontal area with and without exoskeleton

This frontal plane of training, can be personalised to child movement's characteristics through Werium Solution games possibility of selecting angle ranges for each movement. In second clinical stage, angular ranges used for 1D and 2D exercises for each patient are listed in Table 8:

Patients/Exercises	Angle type	Patient A Left Arm	Patient B Left Arm	Patient C Left Arm	Patient C Right Arm
1D	**Alfa**	-	-	19°-23°	-
	Beta	60°	60°	-	50°
2D	**Alfa**	25°-27°	25°-27°	-	25°-27°
	Beta	60°	60°	-	50°

Table 7: Angle ranges per child and per exercise

To clarify, the following observations were viewed from a clinical (physiotherapists) and technical (engineers) point of view, and none of the assessments expressed below are based on any kind of validation or scale.

Analyzing patient A performance, big differences were observed when the subject was asked to lift the arm in vertical position and near the head. Before working with exoskeleton, the user could not fully extend the arm, bending the elbow quite a bit. After practising during 40 minutes aproximatly with the exoskeleton, when lifting again the arm, patient A could extend the arm perfectly up, without elbow bending, being able of reaching a higher position than before.

Reviewing patient B performance, big differences were noted by the usual therapist with which work habitually, during working perfomance with the exoskeleton on. The therapist noted a better posture of the patient as a whole, highlighted lower neck compensation and streching when performing arm extensions than with other robots used in rehabilitation therapies. Also therapist indicated that patient reached points further away from subject’s usual work space.

About patient C performance, the before and after of the work session were very evident. Usually, in order to lift the arm, the patient first touched the back of his neck, climbed up along the back of the head until reaching the top and finally from that position the subject pushed to raise the forearm and put the arm vertically. Patient C did that because of the low muscular capacity of the biceps; he needed to lean on the head because otherwise subject got tired and never got to raise the arm. After the exoskeleton work session, the patient was able to raise the arm directly without first leaning on the head although with huge effort. This could be due to the fact that after 40 minutes of the session, the muscle could have acquired a certain memory of strength, which it still had immediately after the therapy.

Great conclusions cannot be concluded from the visual evaluation but we can assure that at the moment the exoskeleton is functional, it allows patients to move their arms in a comfortable work space and even the mechanism could assist them in some movements.

4.3.6 AMPS scale

AMPS validation scale used by pyshiotherapists for visual evaluation of users performance when having the exoskeleton attached, assesses the quality of a person on ADL by rating the effort, efficiency, safety and independence of 16 ADL motor and 20 ADL process skill items [43][4].

Motor skill items are divided into 4 domains while process skill items into 5 as it is shown in table 9:

	MOTOR SKILLS ITEMS	**PROCESS SKILLS ITEMS**
1.	Body Position	Sustaining Performance
2.	Obtaining and holding objects	Applying Knowledge
3.	Moving Self and Objects	Temporal Organization
4.	Sustaining Performance	Organizing Space and Objects
5.	-	Adapting Performance

Table 8: AMPS ítems [43][4]

Items are scored on range from 1 to 6, where 1 means no problem for executing the activity and 6 means inordinate, no test possible.

Just Motor Skills Items data are included in this validation. These assesments were realized over 3 different exercises that clinical staff ask patients for doing it first without the exoskeleton and then with the mechanism attached. Activities performed for AMPS validations were:

1. Touching head
2. Reaching out to try to touch the screen
3. Simulate petting a domestic animal from top to bottom

From these activities, validations made by more than 1 clinical professional for each patient are:

Patient A	**Actvity 1 No exo.**	**Activity 1 Exo.**	**Activity 2 No exo.**	**Activity 2 Exo.**	**Activity 3 No exo.**	**Activity 3 Exo.**
BODY POSITION						
Stabilizes	4	4	4	4	4	4
Aligns	4	4	4	4	4	4
Positions	3	3	4	4	3	3
OBTAINING AND HOLDING OBJECTS						
Reaches	4	4	4	4	3	4
Bends	-	-	-	-	-	-
Grips	-	-	-	-	-	-
Manipulates	-	-	-	-	-	-
Coordinates	4	4	4	4	4	4
MOVING SELF AND OBJECTS						
Moves	-	-	-	-	-	-
Lifts	-	-	-	-	-	-
Walks	-	-	-	-	-	-
Transports	-	-	-	-	-	-
Calibrates	-	-	-	-	-	-
Flows	3	4	4	4	3	3
SUSTAINING PERFORMANCE						
Endures	4	4	4	4	4	4
Paces	4	4	4	4	4	4

Table 9: Patient A evaluations

Pyshiotherapists concluded that the patient A got better hand position with exoskeleton for excercise 1. Although with and without exoskeleton the patient lowered the head, with the device attached, the user could performed the activity with less effort and more fluency. During exercise 2, with the exoskeleton on, the patient was able of extend the arm further than without device, but little trunk compensation was done.

Finally, exercise 3 was performed with no arm extension when no mechanism was attached and little extension was observed when working with the exoskeleton, a positive point that means that the mechanism supported the patient.

Patient B	**Actvity 1 No exo.**	**Activity 1 Exo.**	**Activity 2 No exo.**	**Activity 2 Exo.**	**Activity 3 No exo.**	**Activity 3 Exo.**
BODY POSITION						
Stabilizes	4	4	3	4	2	3
Aligns	4	4	3	4	3	4
Positions	4	4	3	4	3	3
OBTAINING AND HOLDING OBJECTS						
Reaches	-	-	-	-	-	-
Bends	-	-	-	-	-	-
Grips	-	-	-	-	-	-
Manipulates	-	-	-	-	-	-
Coordinates	4	4	3	4	4	4
MOVING SELF AND OBJECTS						
Moves	-	-	-	-	-	-
Lifts	-	-	-	-	-	-
Walks	-	-	-	-	-	-
Transports	-	-	-	-	-	-
Calibrates	-	-	-	-	-	-
Flows	4	4	3	4	3	4
SUSTAINING PERFORMANCE						
Endures	4	4	4	4	4	3
Paces	4	4	4	4	4	4

Table 10: Patient B evaluations

Pyshiotherapists conclude for Patient B that the exoskeleton help the user on elbow extension, which is perfectly noticed when practising activity number 2. This better elbow extension also let the patient go more directly to the target, thereby increasing speed performance and reducing time spent. On the other hand, higher body compensation was denoted when performing diagonal movements with the exoskeleton than without it, clinical staff believe that this is due to the position of the patient, leaning with the opposite arm on a table.

Patient F	**Actvity 1 No exo.**	**Activity 1 Exo.**	**Activity 2 No exo.**	**Activity 2 Exo.**	**Activity 3 No exo.**	**Activity 3 Exo.**
BODY POSITION						
Stabilizes	4	4	3	4	3	4
Aligns	4	4	3	4	4	4
Positions	3	3	3	4	3	3
OBTAINING AND HOLDING OBJECTS						
Reaches	4	4	3	4	2	3
Bends	-	-	-	-	-	-
Grips	-	-	-	-	-	-
Manipulates	-	-	-	-	-	-
Coordinates	4	4	4	4	4	4
MOVING SELF AND OBJECTS						
Moves	-	-	-	-	-	-
Lifts	-	-	-	-	-	-
Walks	-	-	-	-	-	-
Transports	-	-	-	-	-	-
Calibrates	-	-	-	-	-	-
Flows	3	4	3	4	3	4
SUSTAINING PERFORMANCE						
Endures	4	4	4	4	4	4
Paces	4	4	4	4	3	4

Table 11: Patient F evaluations on left arm

Patient F when performing first task without exoskeleton, bent the head down, brought the arm to the neck and from there and reached up on the back of the neck to touch his head. However, when using the mechanism, the patient did not need to stop at the neck for reaching the top of the head; despite still ducking the head, the user was already able to perform the exercise directly, which indicates greater effectiveness of movement. When talking about activity 2, the patient performed trunk compensation when no exoskeleton was helping, and no body movement was perceived when using the mechanism. Finally, task 3 was not really completed with or without exoskeleton.

By collecting the data of the 3 previous patients, adding their scores, and observing the differences between the use or non-use of the exoskeleton, Table 13 is obtained:

	Actvity 1 No exo	**Activity 1 Exo.**	**Activity 1 Differences**	**Activity 2 No exo**	**Activity 2 Exo**	**Activity 2 Differences**	**Activity 3 No exo**	**Activity 3 Exo**	**Activity 3 Differences**
BODY POSITION									
Stabilizes	12	12	0	10	12	2	9	11	2
Aligns	12	12	0	10	12	2	11	12	1
Positions	10	10	0	10	12	2	9	9	0
OBTAINING AND HOLDING OBJECTS									
Reaches	8	8	0	7	8	1	5	7	2
Bends	-	-		-	-		-	-	
Grips	-	-		-	-		-	-	
Manipulates	-	-		-	-		-	-	
Coordinates	12	12	0	11	12	1	12	12	0
MOVING SELF AND OBJECTS									
Moves	-	-		-	-		-	-	
Lifts	-	-		-	-		-	-	
Walks	-	-		-	-		-	-	
Transports	-	-		-	-		-	-	
Calibrates	-	-		-	-		-	-	
Flows	10	12	2	10	12	2	9	11	2
SUSTAINING PERFORMANCE									
Endures	12	12	0	12	12	0	12	11	-1
Paces	12	12	0	12	12	0	11	12	1

Table 12: AMPS final scores

Colored cells show which differences between not using the exoskeleton and using the mechanism are not 0. Non null values on difference's cells indicates that the exoskeleton has contributed on perfomance of activities 1, 2 and 3, being therefore the exoskeleton a functional device.

After both clinical stages, pyshiotherapist noted a huge evolution between first exoskeleton brought to La Salle facilities and last mechanism used on last clinical stage. They highlited how changes on pronosupination system and on shoulder pieces made possible easy and comfortable arm movements. Moreover, changes on manipulative task, leaving direct interaction with the touchable screen by indirect interaction, was also a success that has improved and facilitate the use of the exoskeleton.

About the platform where the exoskeleton is attached, a huge enhacement has took place with the new support. Thanks to the inclusion of wheels that the television trolley has, the exoskeleton is much easier to move. Also, wheel brakes and the rigid structure makes the whole mechanism more stable, avoiding the use of weights to prevent the exoskeleton from moving when the user pulls on it. Another point to be highlighted refereing to the platform, is that two exoskeletons can be attached to the same television trolley; one for the left limb and one for the right ar; making it unnecessary to have two different platforms, one for each side. Finally, the structure is composed of two telescopic bars that allow to adjust the height of the exoskeleton through clips. However, this system has brought a small drawback during the last clinical stage since TV trolley has fixed heights, so that with younger children it was difficult to adapt the height of the exoskeleton to the height of the patient's shoulder. For fast solving, during therapy session the environment was adapted for make it possible the usage of the exoskeleton but clinicians has asked us to modify TV trolley height in order to use the mechanism with greater diversity patients.

Focusing on Werium Solutions games, the clinicians have requested for a couple of changes for the next phases of testing. On the one hand, the possibility of setting non symmetrical tarjets in one direction, since currently if 20 degrees of angular range is set on the transverse plane, the targets will appear 10 degrees to the left and 10 degrees to the right. An asymmetry in terms of the targets is required since each child has difficulties for reaching a spatial environment which may be different for another child. Asymmetric targets would allow the creation of even more personalized therapies. On the other hand, a greater variety of games would be useful to motivate the children throughout the therapies.

Finally, although the current hand support avoids a wrist default flexion, physiotherapists believe that it would be desirable to have several types of hand supports, so that each user can choose the most comfortable.

4.3.7 Technical conclusions

This section will discuss the conclusions obtained from the data stored in the Werium Solutions interface after each exercise.

First noticiable conclusion, is that the possibility of varying the angle ranges for 1D and 2D exercies, allows the user to reach each of the targets printed on the screen. Werium Solutions game provides graphs of the objectives achieved in each activity by the user with the performance (see Figure 69).

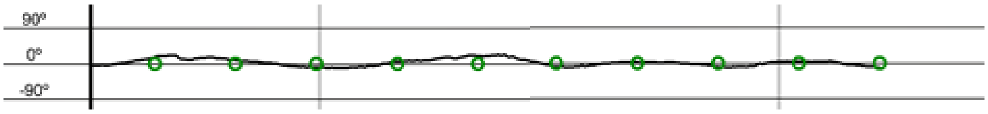


Figure 69: Werium graphics obtain for each session (Werium Solutions)

In figure 69, the ‘*x*’ axis represent time variable and the ‘*y*’ axis refers to angle range. Werium Solutions record this graph for alfa and beta angles. These graphs, show a set of circles that turn green when target is reached and red when is not. Getting green circles on every single target means that the user is working on the correct angle range.

The Table 12 shows the objectives achieved by each patient in each of the exercises developed with the exoskeleton on:

	Session Day	Arm	Exercise 1D	Exercise 2D
Patient A	1	Left arm	10/10	10/10
			10/10	10/10
			30/30	9/10
		Left arm + elastic bands on elbow joint	10/10	30/30

Patient B	1	Left arm	10/10	10/10
			10/10	30/30
			30/30	29/30
	2	Left arm	30/30	27/30
			30/30	29/30
			14/15	12/15
Patient F	1	Left arm	10/10	10/10
			20/20	10/10
			15/15	10/10
	2	Right arm	8/10	-
			10/10	-
			10/10	-
		Left arm	8/10	-
			10/10	-
			15/15	-
			15/15	-
			15/15	-
			15/15	-

Table 13: Targets reached per user by session with the exoskeleton on

	Session Day	**Arm**	**1D**	**2D**
Patient A	1	Left arm	-	14/15
Patient B	1	Left arm	-	15/15
	2	Left arm	-	9/10
Patient F	1	Left arm	-	9/10
			-	10/10
	2	Right arm	-	-
		Left arm	-	-

Table 14: Targets reached per user by session without the exoskeleton

Calculating success rates, it could be said that 97% of the objectives are achieved. This value denote that children worked on correct angle ranges because they were able of reaching moslty all targets. Furthermore, being able of reaching most of the targets proposed, indicate that the exoskeleton is a functional device that let the user move freely in a comfortable environment.

Also, Werium Solutions creates a file with csv extension from which have been obtained 2 data values: first column is refered to alfa angle; that is the angle present when moving from left to right; and second column, that is refered to beta angle that is the angle present when moving up to down.

Initial activity asked to patients, was performing a shoulder and elbow flexion and extension (1D exercise). Taking into account that flexo-extension is performed on sagittal plane, just beta angle should get values different from 0. However, human being, when lifting or descencing the arm also performed some movements on transversal plane measured by alfa angle.

Next, graphically, it will be compared alfa angles obtained from healthy subject exercises and an example of alfa angles obtained from Patient A who participated in the clinical study.

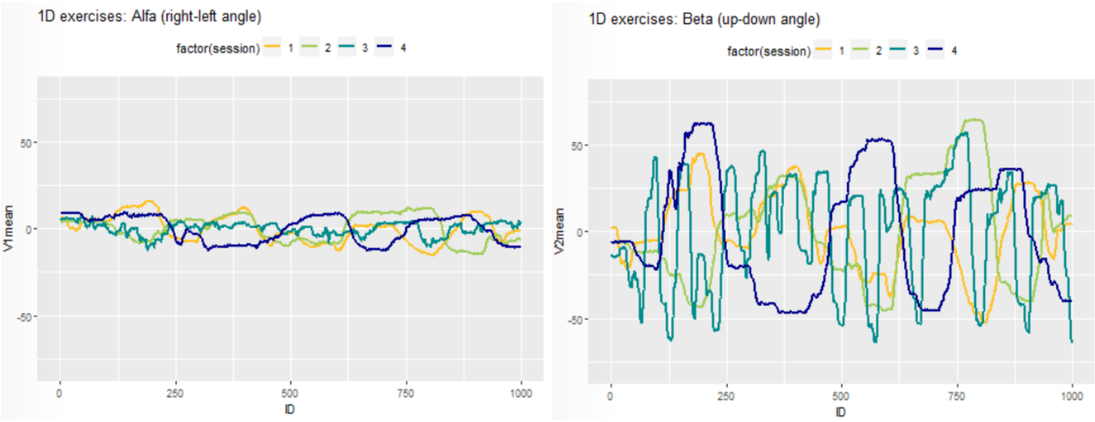


Figure 70: Alfa and Beta angles when a healthy patient performed 1D exercises (Rstudio)

Each of the colored curves that appeared on figure 69 represent angle ranges for a determinate exercise differentiated by number in the factor legend above each graph. The ‘x’ axis does not represent time, just instances, and ‘y’ axis represent alfa or beta possible values.

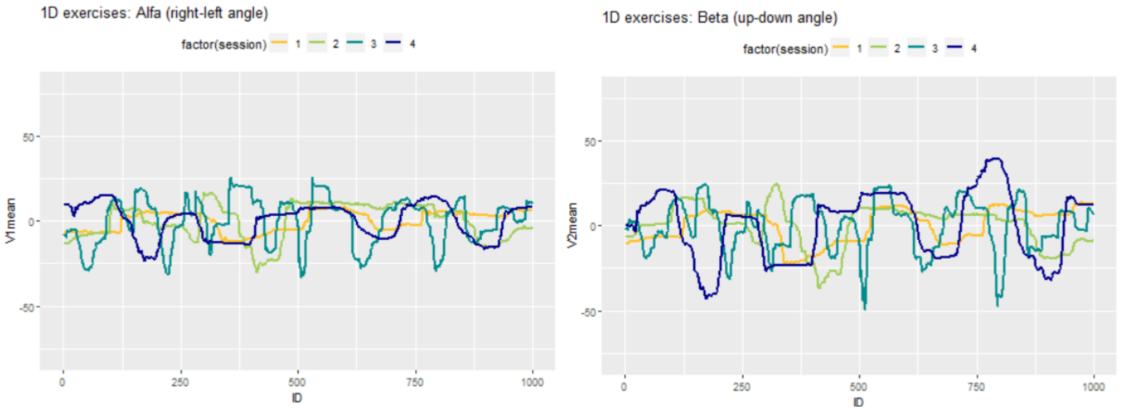


Figure 71: Alfa and Beta angles when patient A performed 1D exercises (Rstudio)

Comparing the graphs of the healthy patient and patient A under study, it can be observed that, both perform compensatory movements in the transverse plane when performing exercises along the sagittal plane. Although the appreciation is small, there is a certain difference between the two subjects in terms of the alpha angle in 1D exercises- The healthy patient seems to have a smaller angular amplitude than patient A. This greater angular range observable in patient A could be due to the characteristics of the child's pathology; the children participating in the study are children who make large compensations with the trunk of the body when they find certain exercises complex or difficult.

The alfa amplitude of the healthy patient is 25.26 degrees on average, while this same value is 42.14 degrees on average in patient A. For patients B and C, average value of the alfa range for patient B is 32.38 grades and for patient C 63.01 grades. The angles recorded are shown in figures 69 and 70.

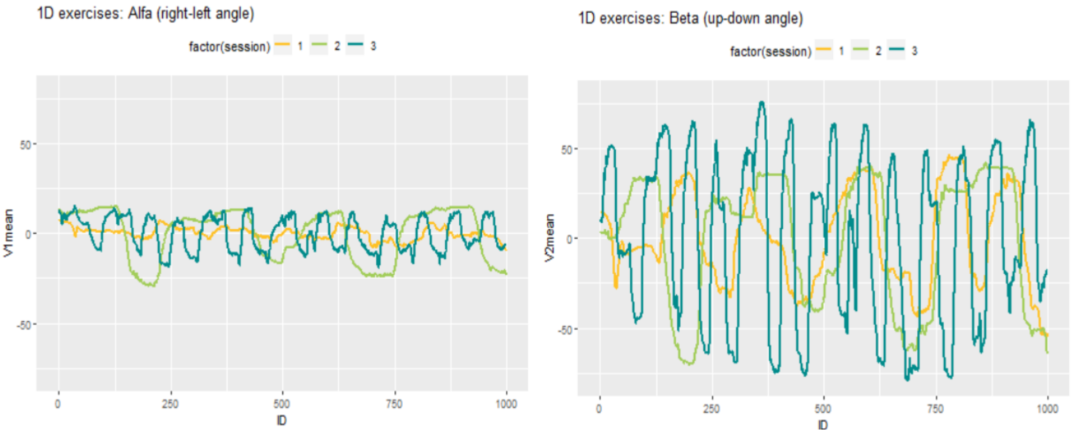


Figure 72: Alfa and Beta angles when patient B performed 1D exercises (Rstudio)

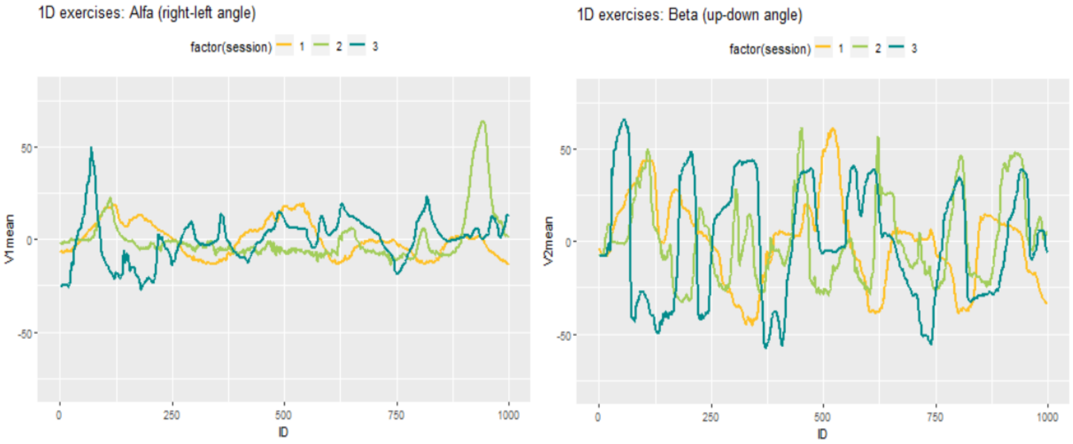


Figure 73: Alfa and Beta angles when patient C performed 1D exercises (Rstudio)

Average value of alfa range for patient B is 32.38 grades and for patient C 63.01 grades.

Due to the small amount of data obtained, any certain conclusion can be drawn about this greater amplitude present in patients A, B and C is due to their pathology. However, is a starting point for future clinical studies where with a greater number of sessions and activities, will be tried to discover if indeed, this greater angular amplitude is related to the compensation of patients by the characteristics of their pathologies.

The following are examples of graphs showing alpha and beta for the same exercise:

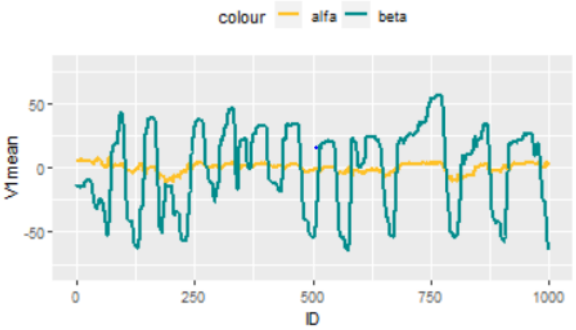


Figure 74: Alfa and beta angles for 1D exercise performed by healthy patient (Rstudio)

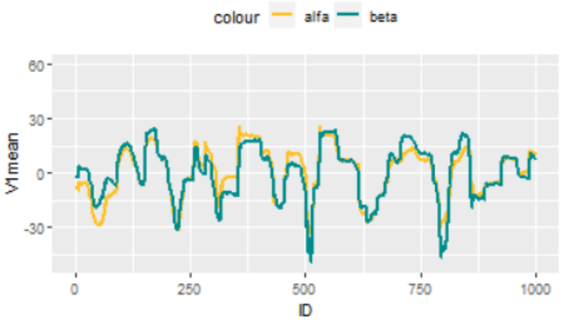


Figure 75: Alfa and beta angles for 1D exercise performed by patient A (Rstudio)

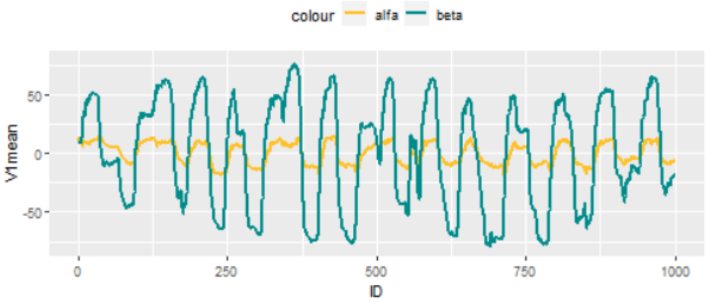


Figure 76: Alfa and beta angles for 1D exercise performed by patient B (Rstudio)

Figure 77: Alfa and beta angles for 1D exercise performed by patient C (Rstudio)

The most important objective of this project is that children can move comfortably and feel free to perform any type of movement during the use of the exoskeleton,. One way to observe that this is accomplished, is by comparing the angular ranges of 2D exercises with and without the exoskeleton on. These graphs are shown below for each patient, where left curves are alfa and beta angles extracted from exercises with the exoskeleton on, and right curves collected alfa and beta data from exercises without exoskeleton.

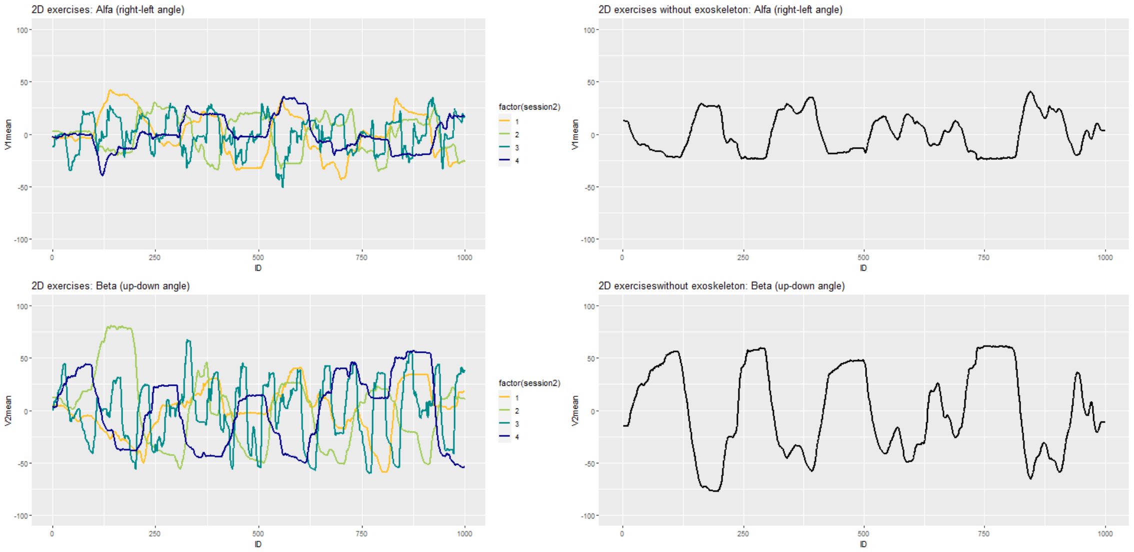


Figure 78: Angular amplitudes with and without exoskeleton for healthy patient (Rstudio)

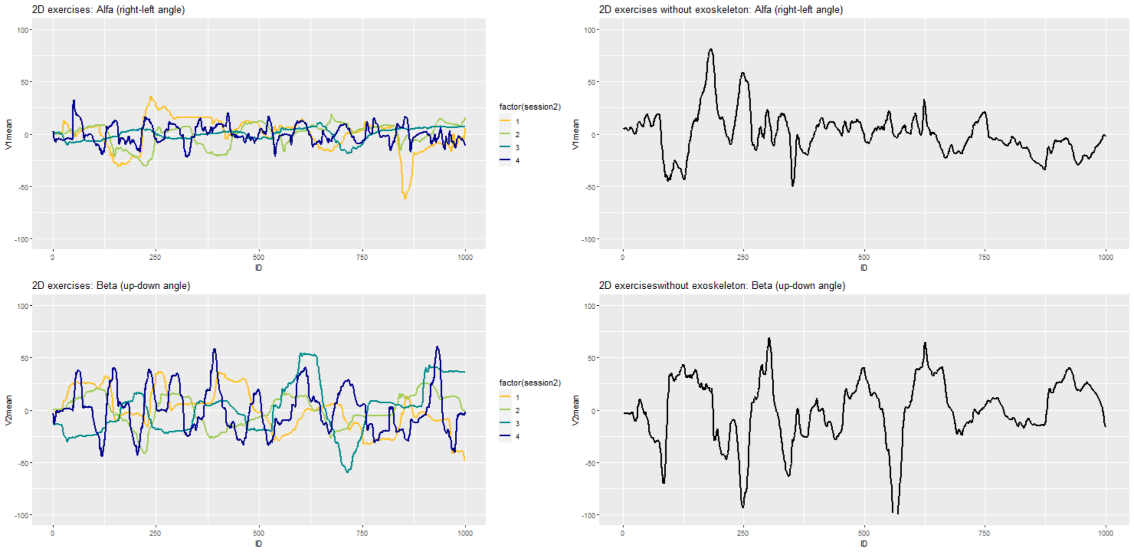


Figure 79: Angular amplitudes with and without exoskeleton for patient A (Rstudio)

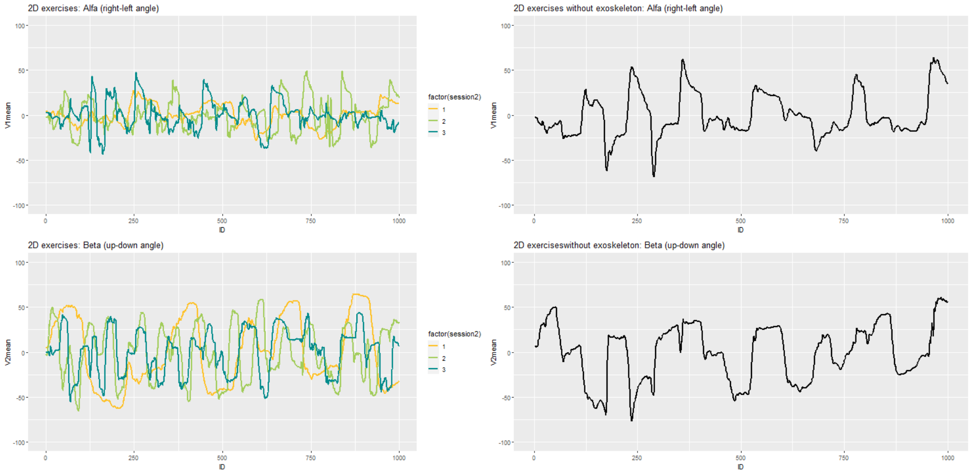


Figure 80: Angular amplitudes with and without exoskeleton for patient B (Rstudio)

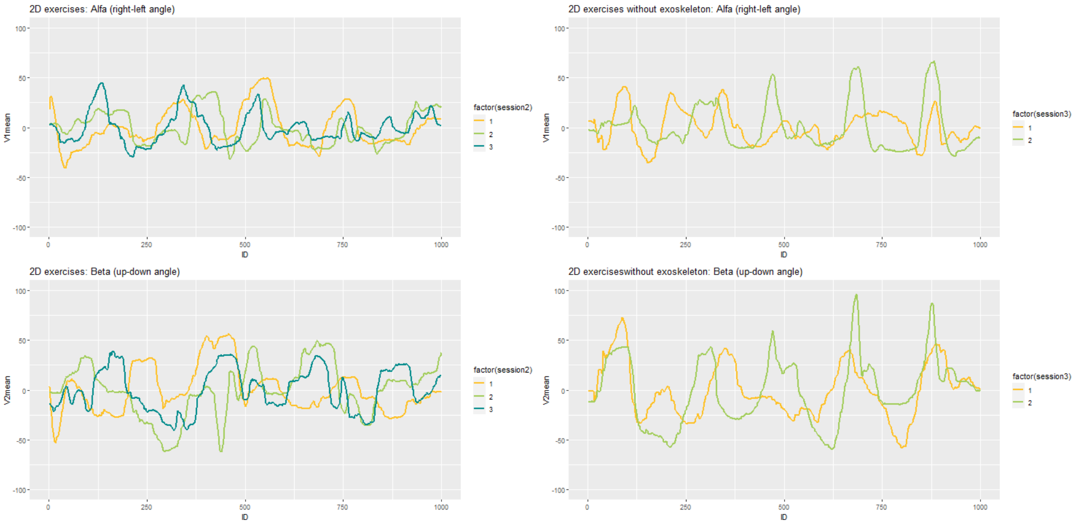


Figure 81: Angular amplitudes with and without exoskeleton for patient C (Rstudio)

Angular amplitudes being similar with and without the exoskeleton attached, is a good result from technical point of view, which indicates for the moment that the mechanism does not limit the patient when performing activities and movements (Despite the fact that there are limitations in extreme flexions and extensions due to collision of pieces).

For subsequent clinical trials, it is desired to carry out measurements before and after exercise, a measurement without exoskeleton to evaluate whether the use of the exoskeleton for 50 minutes in a row produces an increase in the angular range of motion.

CONCLUSIONS AND FUTURE WORKS

4.4 CONCLUSIONS

A functional passive exoskeleton with 4 degrees of freedom has been developed for children with CP as rehabilitation system. The fourth degrees of freedom allow the user performing shoulder flexion and extension, internal and external shoulder rotation, elbow flexion and extension and pronation and supination movements.

The evolution of the exoskeleton has followed an iterative design process that stems from a long collaboration with the rehabilitation institute of La Salle, where two clinical validation stages has been taken with a total amount of 6 children with different pathologies. First clinical analysis was performed in sessions of 20 minutes each time during approximately 2 months, where patient interact through direct contact with a touchable screen. Second clinical analysis consisted of sessions of 50 minutes where direct contact was erased because it took the participants out of a comfortable workspace, and was replaced by indirect interaction through sensors.

The final mechanism, can evolve as the same time as the user does, helping the patient with assistive position at first steps when muscles have no strength, and going against the patient with resistance position at last stages once muscles have gained strength. This easy adaptation of the system to the user's needs is achieved thanks to the resistance assistance system developed by the interaction of the elastic bands with the different parts of the exoskeleton. Regarding exoskeleton coupling with patients, the system is attached to user’s arm through Velcro. In terms of materials and manufacturing, the model has been 3D printed, a way to achieve a low-cost and easily reproducible device to be used in any rehabilitation institute.

Changing from direct contact to indirect interaction with the screen, has contributed to patient felling comfortably. The importance of working on a workspace personalised for each patient, removes frustration variable from sessions, and this customization has been possible thanks to Werium Solution games, which with interaction occurs through sensors instead of by direct contact as in FittsStudy.

New pronation and supination system, and hand support has led patient to feel more forearm supported. Moreover, shoulder parts changes, have been very important enhancements on the road to a functional exoskeleton. The current 7 pieces that currently conform the shoulder system, let the user feel free when performing flexion, extension, internal and external shoulder rotation without shoulder dealignment, objective achieved thanks to the new height of attachment to the platform and the alignment of the axes of part 3 previously explained in the design section.

Workspace and redesigned changes were not the only important adjustments made during this project in order to achieve a functional exoskeleton. Using a more rigid and stable support such as the TV trolley, instead of a threaded bar that easily flexes, has been a key point in achieving a good posture of the patient when wearing the exoskeleton. The rigidity and the possibility of braking the wheels of the TV cart prevents children from making compensatory movements when performing activities with the arm being rehabilitated. In addition, a sturdier and easier to move support system, has reduced the preparation time of the sessions, thus reducing the waiting time for the child when starting the therapy.

Now, a wide range of children will be able to use the exoskeleton thanks to the easy and comfortable adaptation of the exoskeleton to the child's wingspan by means of the telescopic legs of the system where the exoskeleton is attached.

Large differences have been observed between the two clinical validation stages. The postural change of the patient from the first to the second phase has been a key point for the functional use of the device. The point and height of anchorage of the mechanism to the support platform of the first design brought to the La Salle facility resulted in shoulder misalignment. In addition, the mechanism did not allow participants to perform shoulder extension in the transverse plane. However, the change in height of the external platform attachment and the redesign of the shoulder pieces eliminated the shoulder misalignment, allowing patients to remain comfortable throughout the entire test.

Visually, physiotherapists and design engineers have been able to observe how the latest model of the exoskeleton was able to enhance children's abilities during sessions. Reaching extreme positions that had never been reached before, has been one of the observable aspects. In addition, the continuous use of the exoskeleton for 50 minutes also had consequences once the user removed the mechanism and performed the 4 required activities. The visual data suggest that the mechanism helps to gain some muscle strength during those 50 minutes and that the muscle retains movement memory, as patients were able to perform movements more fluidly and with less effort, reaching positions that were unreachable before the therapy.

The graphs extracted from the alpha and beta angles from the information provided by the Werium Solutions software accurately provide a conclusion that the mechanism does not influence or limit the individual, since the angular ranges achieved with and without the exoskeleton are similar.

To draw further conclusions, studies with larger numbers of participants are needed.

4.5 FUTURE OBJECTIVES

New clinical stages will take place on the future, in order to evaluate if the exoskeleton could be used as a rehabilitation mechanism. The objective is to collect a higher amount of data from larger stages studies, from which some technical conclusions about children evolution after exoskeleton’s therapies can be drawn. Also, the reason for the high correlation between the alpha and beta angles seen in section 4.3.5 will be studied, as well as whether the greater variation in alpha angle’s amplitude of the children with pathologies compared to the healthy subject during the 1D exercises, is due to the pathologies of each patient.

Before taking next clinical stages, some mechanical improvements are necessary. These are not changes that will modify the way of performing any movement, but they will improve the comfort of patients during therapy and the ease with which physiotherapists can work with the mechanism:

- The pieces that allow the development of an external and internal rotation movement of the shoulder placed at the elbow have some drawbacks: the axis of rotation is on the internal face of the exoskeleton which produces friction in users of greater complexion. It is intended to remove the axis of rotation to the outside to eliminate the possibility of contact between elbow and exoskeleton.

- Even though the design of different sizes of longitudinal bars that represent the upper parts of the arm and forearm, have allowed to adjust the exoskeleton during clinical trials to children of different anthropometric measurements, the costly and tedious moment of changing the nuts and screws has to be removed. Telescopic rod design will be designed to improve the adjustment process.

- Although the exoskeleton allows good turns and sliding movements of some parts over others, the use of bearings and grease would improve the movement allowance.

- All the Velcro’s fasteners used so far to tie the exoskeleton, will be replaced by elastic textile rubbers for better user comfort.

- Different hand support will be designed to give the patient the choice of which support he/she feels most comfortable with, to perform the exercises.

- More Werium Solutions games will be developed for motivating children during sessions, as well as the option asymmetric targets positioning will be displayed.

- The TV trolley should be able to reach smaller heights to adapt to smaller children, thus avoiding the need to adapt the environment to use the exoskeleton with smaller children.

- Finally, elastic bands are not standardized elements so that we cannot quantify in any way the assistance or non-assistance that we are providing to the user. As a future solution, the use of compression springs is proposed. Its purpose would be the same as elastic bands, but being standardized mechanical elements, we would be able of evaluating the evolution of the patient after several sessions of use with the exoskeleton.

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PLANES

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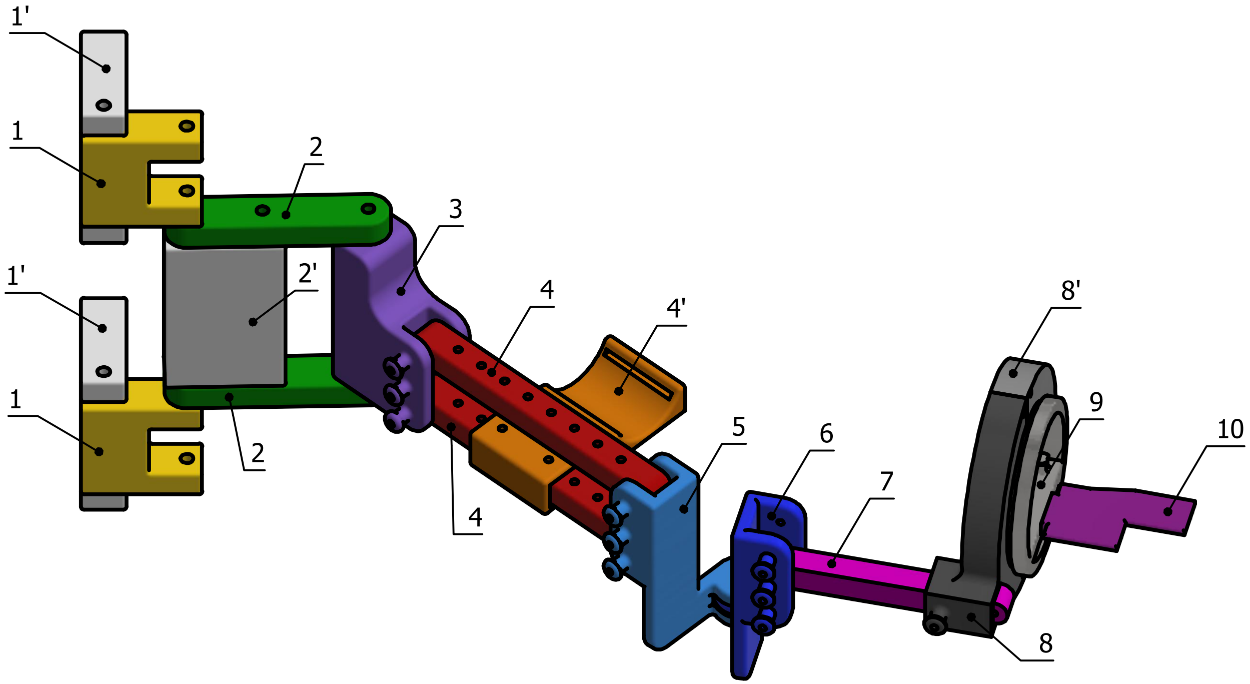


MARCA	CTDAD	DENOMINACIÓN	DESCRIPCIÓN	Nº PLANO	MATERIAL
10	1	Pieza10	Apoyo mano	14	PLA
9	1	Pieza9	Rotación pronosup.	13	PLA
8'	1	Pieza8'	Pronosup. hembra	12	PLA
8	1	Pieza8	Pronosup. macho	11	PLA
7	1	Pieza7	Longitud antebrazo	10	PLA
6	1	Pieza6	Rotación codo 2	9	PLA
5	1	Pieza5	Rotación codo 1	8	PLA
4'	1	Pieza4'	Apoyo brazo	7	PLA
4	2	Pieza4	Longitud húmero	6	PLA
3	1	Pieza3	Flex-ext. hombro	5	PLA
2'	2	Pieza2'	Refuerzo hombro	4	PLA
2	2	Pieza2	Conexión hombro	3	PLA
1	2	Pieza1'	Rotación hombro	2	PLA
1'	2	Pieza1	Amarre plataforma	1	PLA

U. DIM.: mm	FECHA	NOMBRE
Dibujado	01/07/2021	ELENA FERNÁNDEZ
Comprobado		Material
Normas		PLA
Escala 1:5		

UNIVERSIDAD SAN PABLO CEU
ESCUELA POLITÉCNICA SUPERIOR

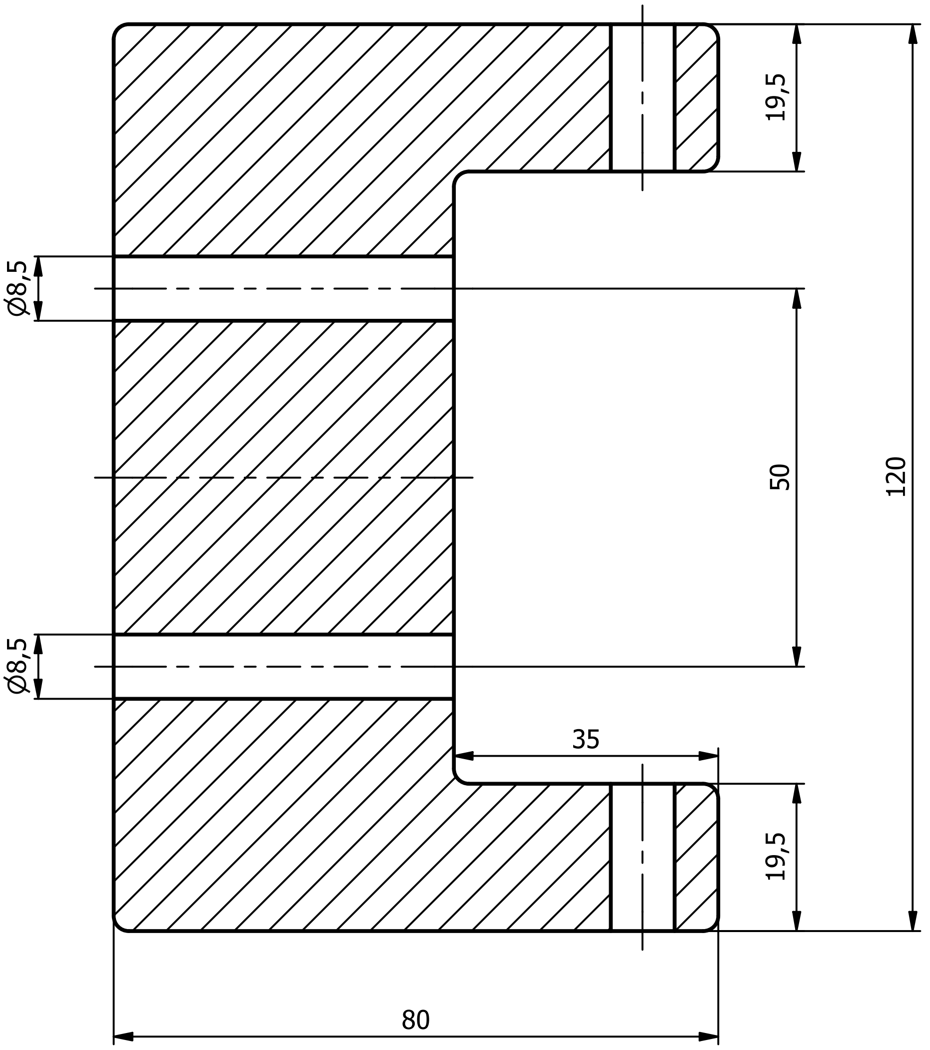
CONJUNTO

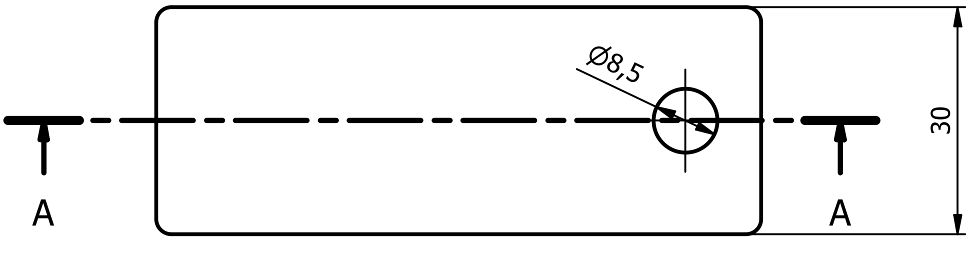
PLANO Nº.0

Sustituye a:

Sustituido por:

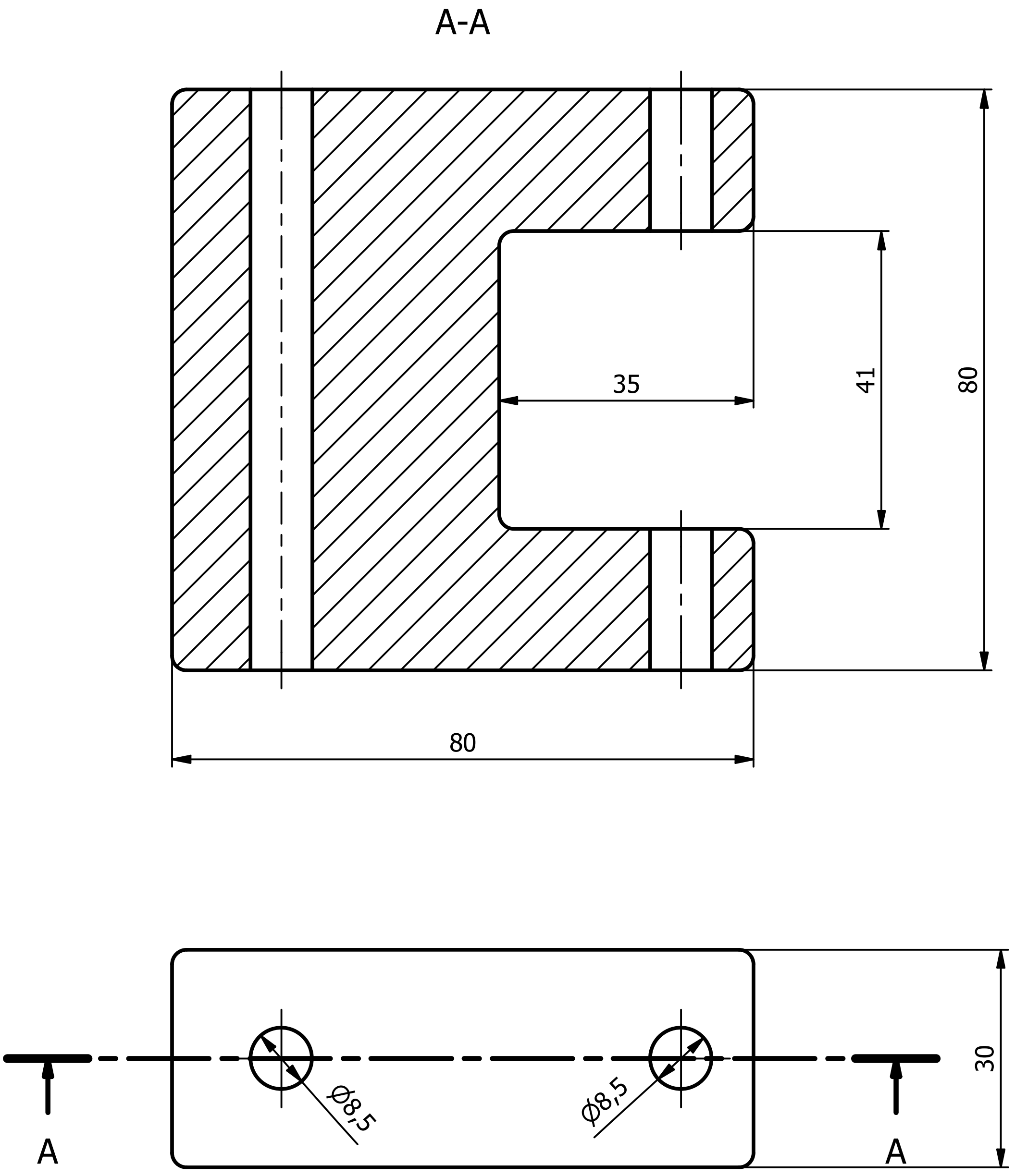
A-A



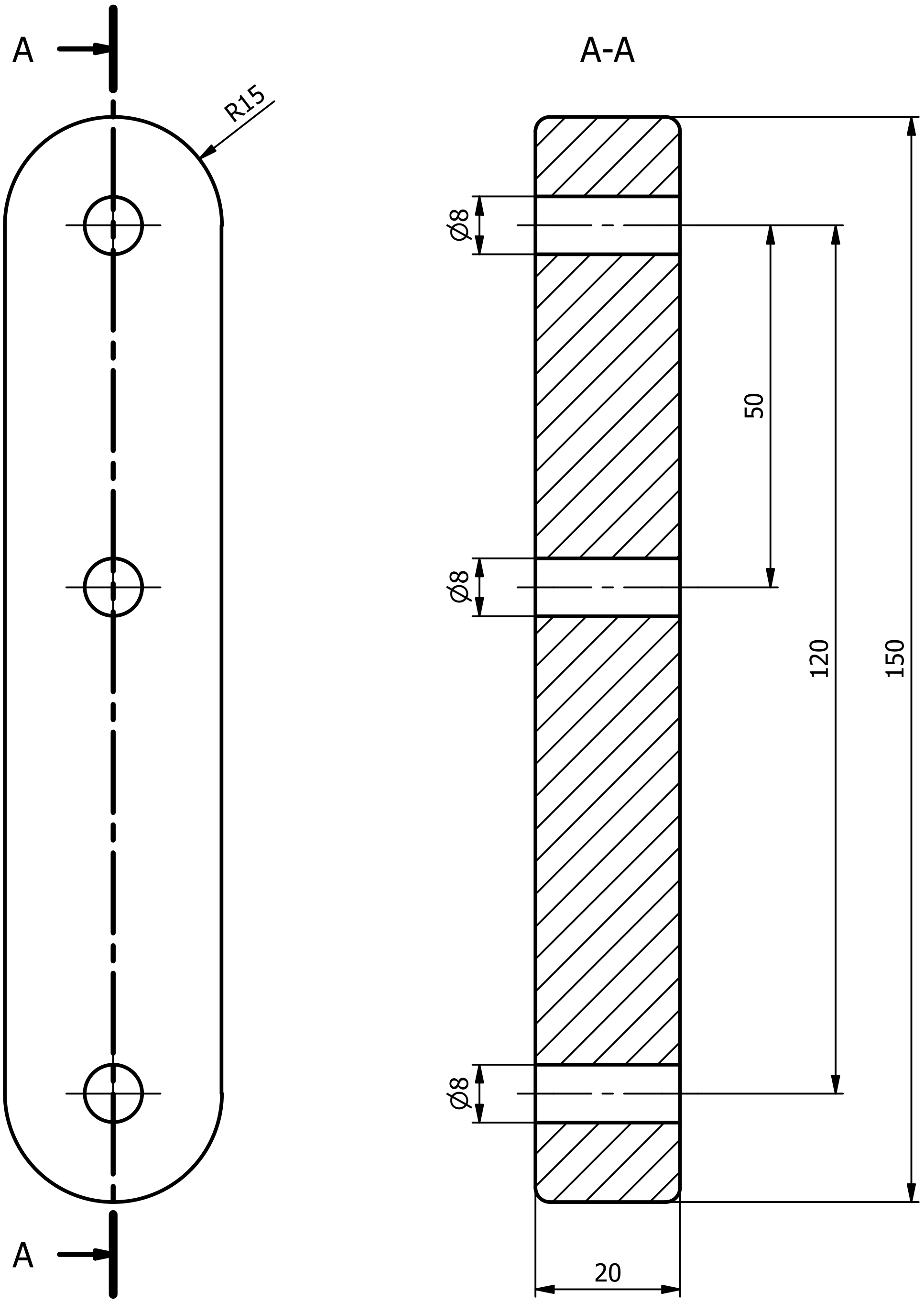


NOTA: Todas las aristas de la pieza incluyen un acabado de R2

U. DIM.:	FECHA	NOMBRE	UNIVERSIDAD SAN PABLO CEU ESCUELA POLITÉCNICA SUPERIOR
Dibujado	01/07/2021	ELENA FERNÁNDEZ	
Comprobado		Material	
Normas		PLA	
Escala 1:1	Pieza 1'		PLANO Nº.1 Sustituye a: Sustituido por:

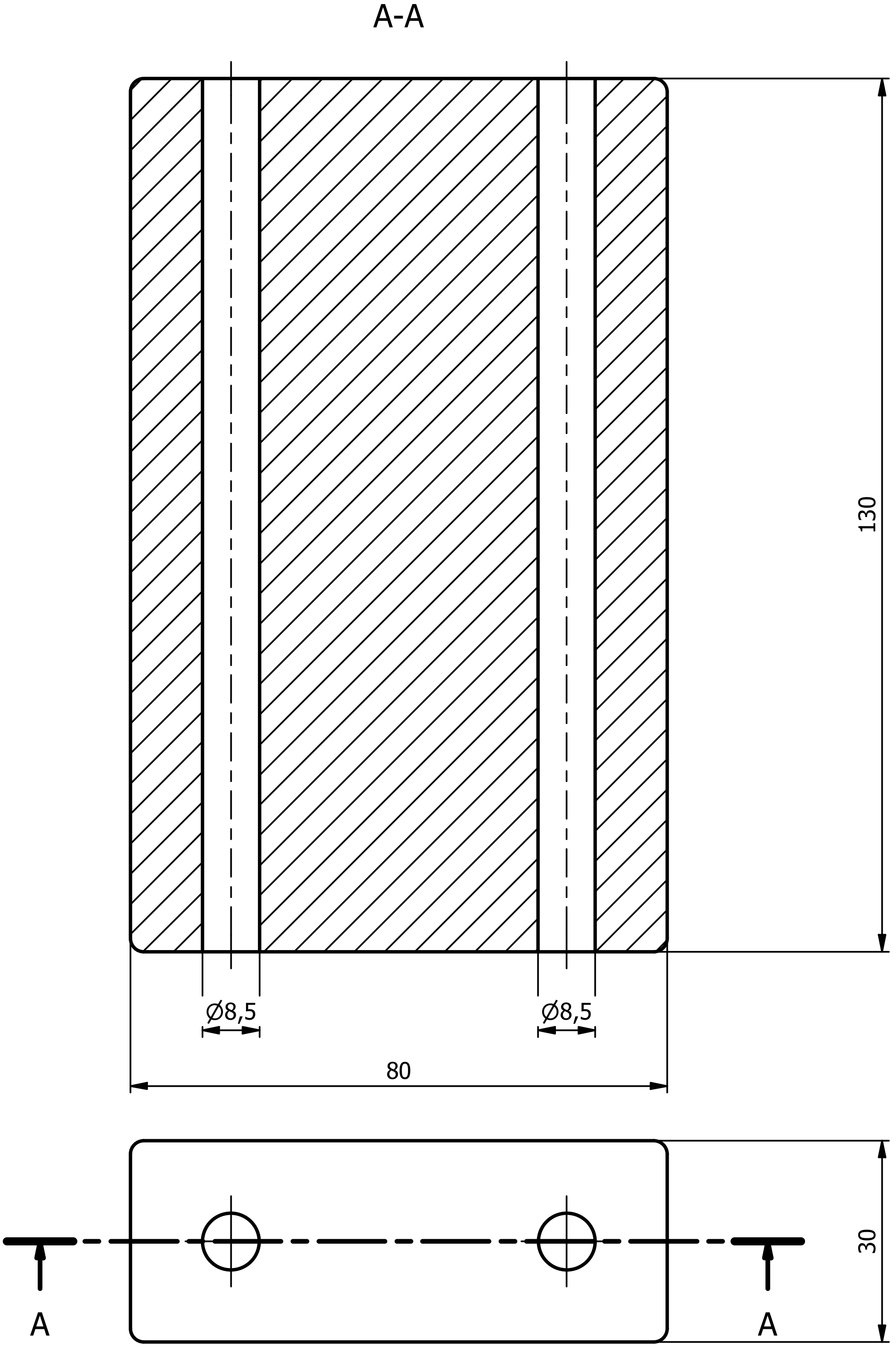


U. DIM.:	FECHA	NOMBRE	UNIVERSIDAD SAN PABLO CEU ESCUELA POLITÉCNICA SUPERIOR
Dibujado	01/07/2021	ELENA FERNÁNDEZ	
Comprobado		Material	
Normas		PLA	
Escala 1:1	Pieza 1'		PLANO Nº.2 Sustituye a: Sustituido por:



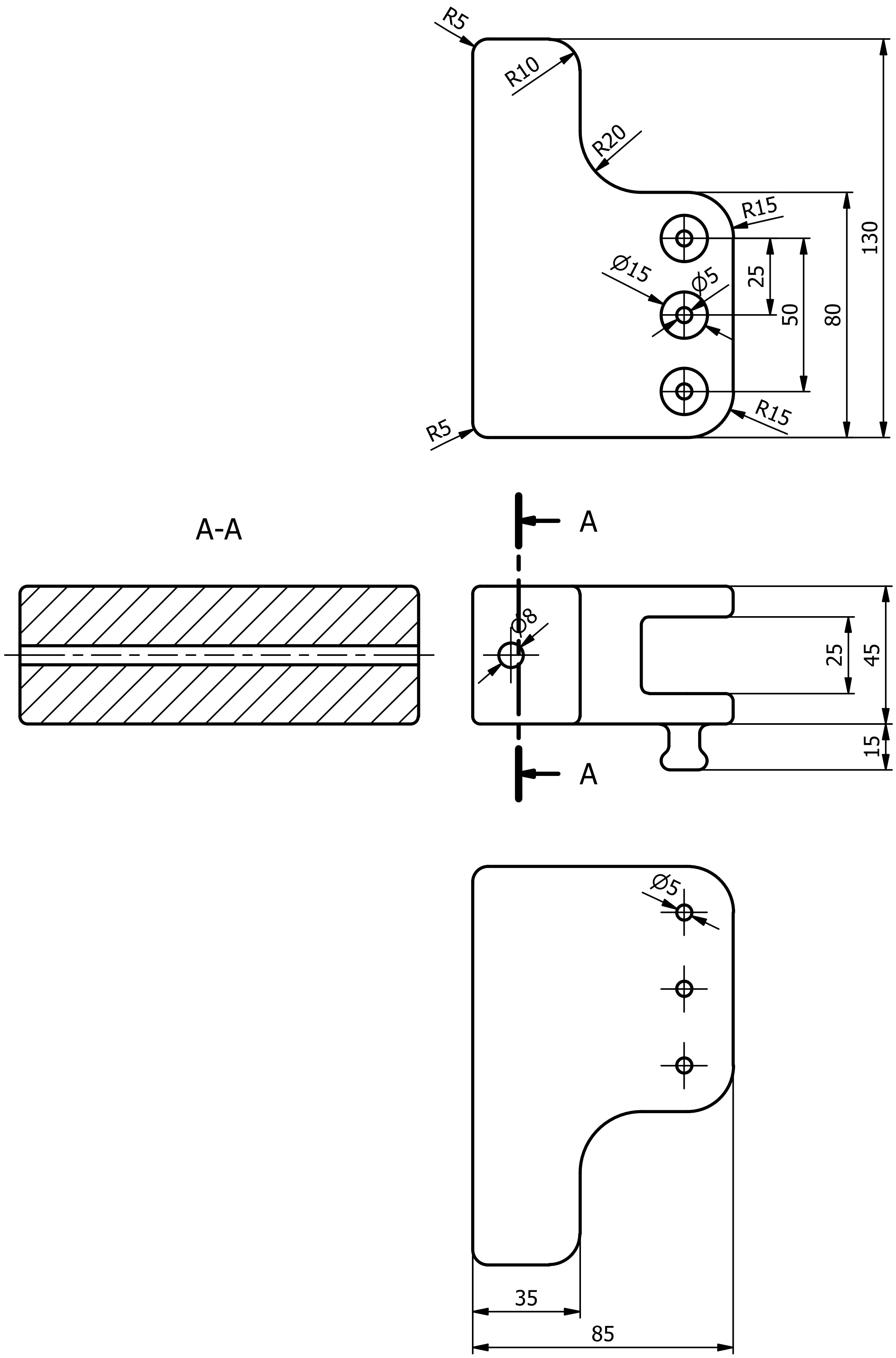
NOTA: Todas las aristas de la pieza incluyen un acabado de R2

U. DIM.:	FECHA	NOMBRE	UNIVERSIDAD SAN PABLO CEU ESCUELA POLITÉCNICA SUPERIOR
Dibujado	01/07/2021	ELENA FERNÁNDEZ	
Comprobado		Material	
Normas		PLA	
Escala 1:1	Pieza 2		PLANO Nº.3
			Sustituye a:
			Sustituido por:



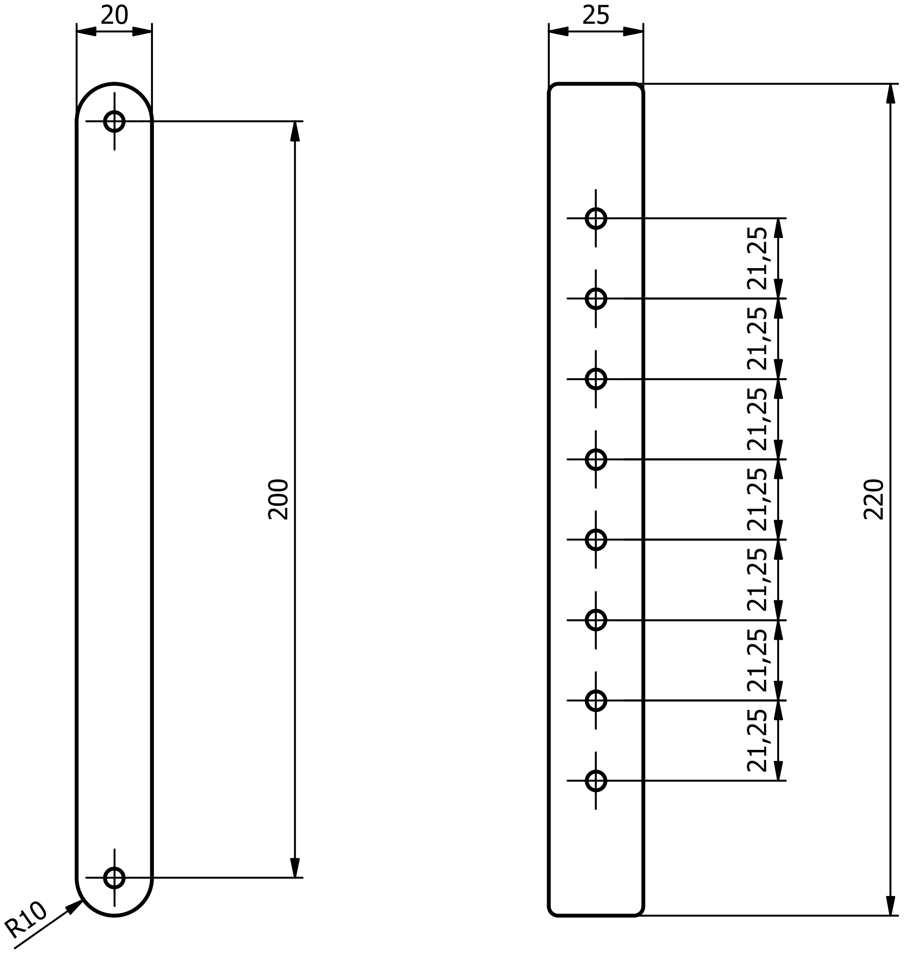
NOTA: Todas las aristas de la pieza incluyen un acabado de R2

U. DIM.:	FECHA	NOMBRE	UNIVERSIDAD SAN PABLO CEU ESCUELA POLITÉCNICA SUPERIOR
Dibujado	01/07/2021	ELENA FERNÁNDEZ	
Comprobado		Material	
Normas		PLA	
Escala 1:1	Pieza 2'		PLANO Nº.4
			Sustituye a:
			Sustituido por:



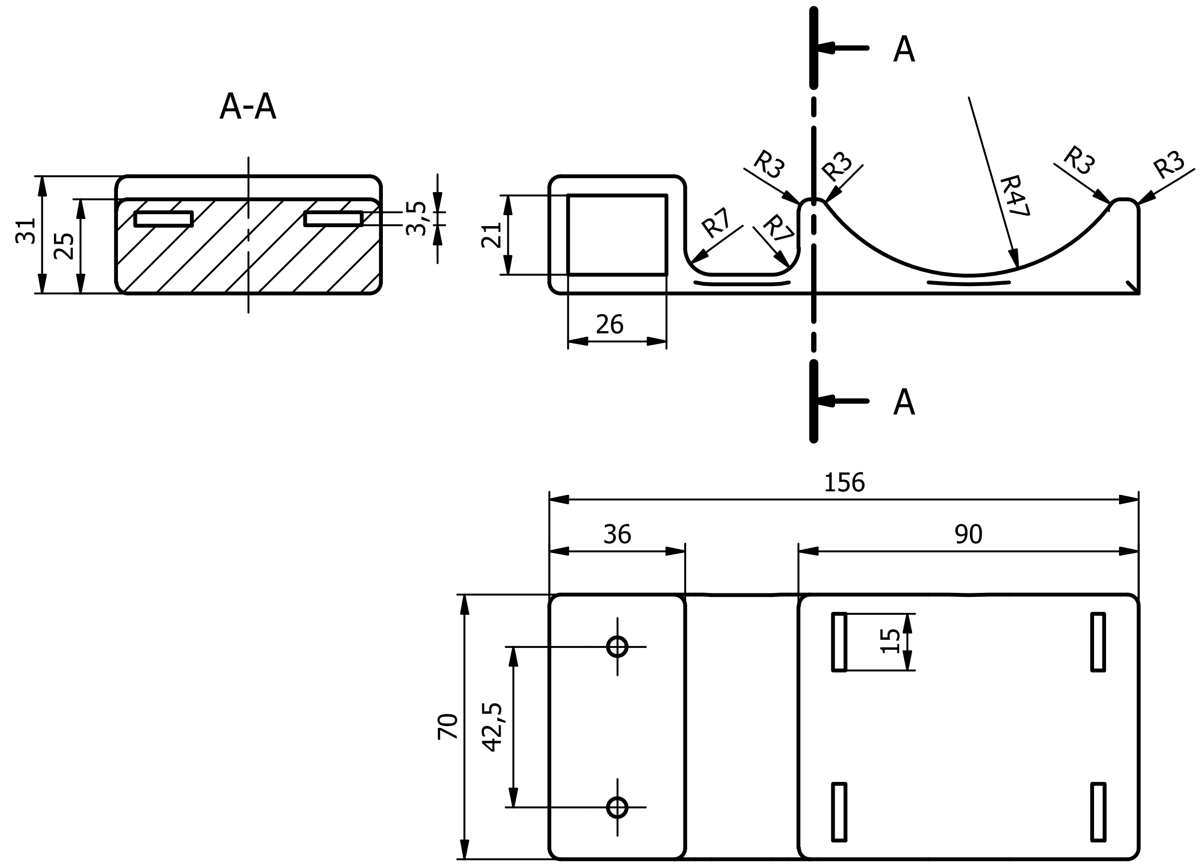
NOTA: Todas las aristas de la pieza incluyen un acabado de R2.5

U. DIM.:	FECHA	NOMBRE	UNIVERSIDAD SAN PABLO CEU ESCUELA POLITÉCNICA SUPERIOR
Dibujado	01/07/2021	ELENA FERNÁNDEZ	
Comprobado		Material	
Normas		PLA	
Escala 1:2	Pieza 3		PLANO Nº.5 Sustituye a: Sustituido por:



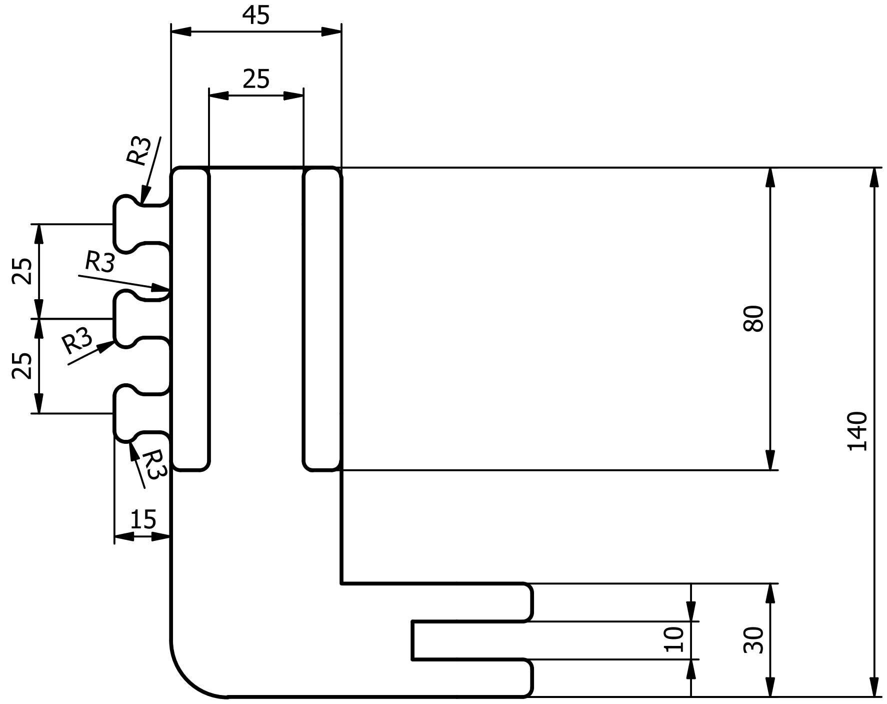
NOTA: Todas las aristas de la pieza incluyen un acabado de R2.5

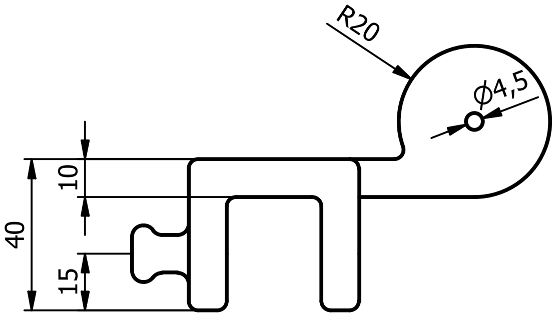
U. DIM.:	FECHA	NOMBRE	UNIVERSIDAD SAN PABLO CEU ESCUELA POLITÉCNICA SUPERIOR
Dibujado	01/07/2021	ELENA FERNÁNDEZ	
Comprobado		Material	
Normas		PLA	
Escala 1:2	Pieza 4		PLANO Nº.6 Sustituye a: Sustituido por:

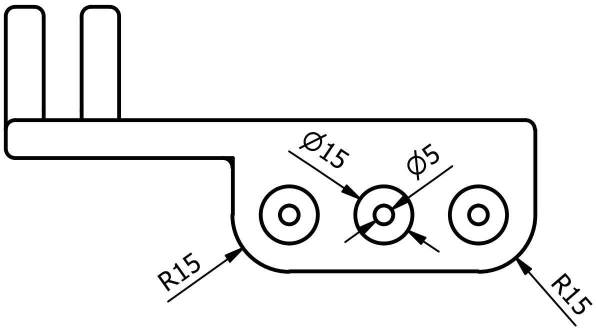


NOTA: Todas las aristas de la pieza incluyen un acabado de R3

U. DIM.:	FECHA	NOMBRE	UNIVERSIDAD SAN PABLO CEU ESCUELA POLITÉCNICA SUPERIOR
Dibujado	01/07/2021	ELENA FERNÁNDEZ	
Comprobado		Material	
Normas		PLA	
Escala 1:2	Pieza 4'		PLANO Nº.7 Sustituye a: Sustituido por:

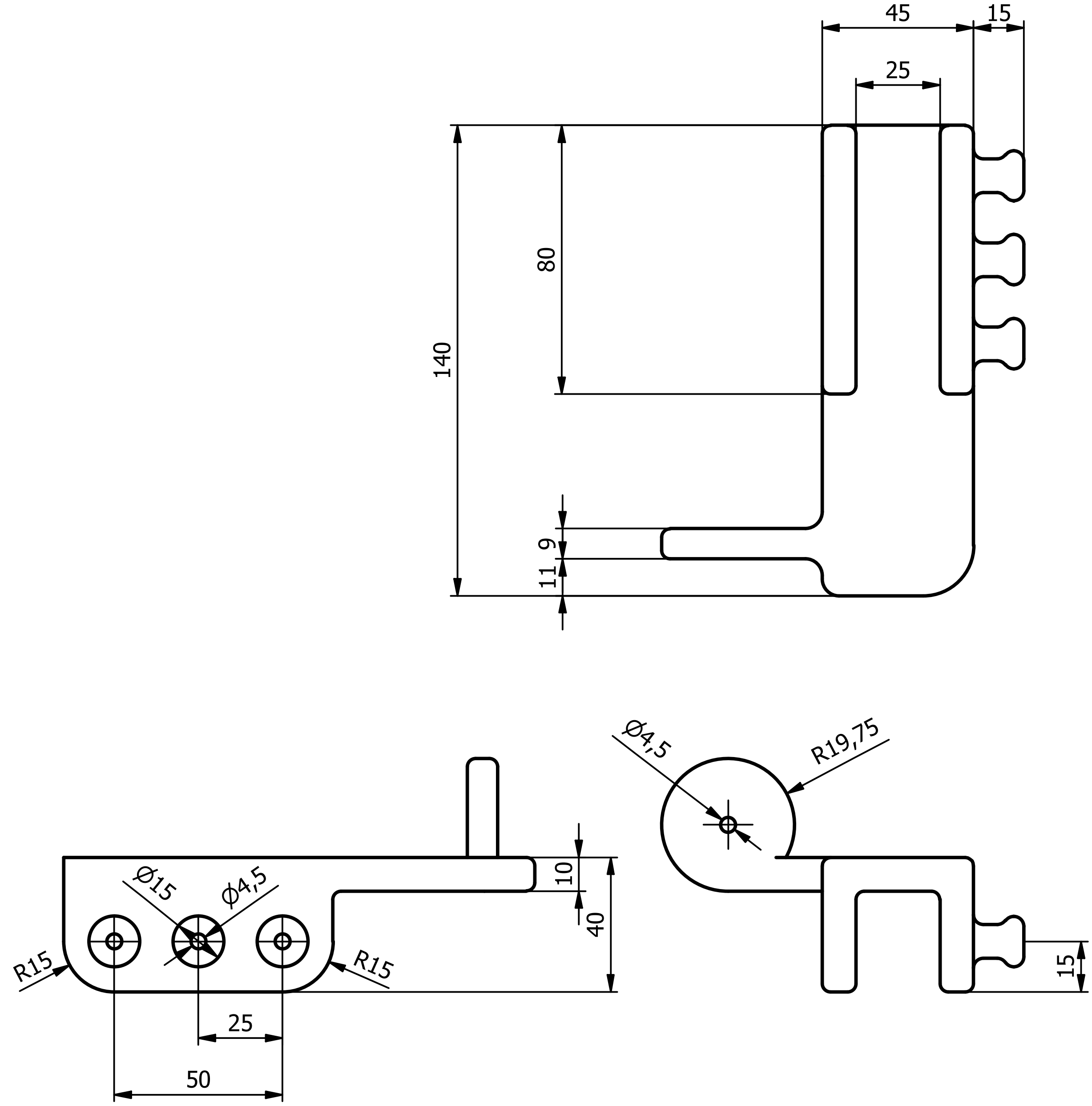






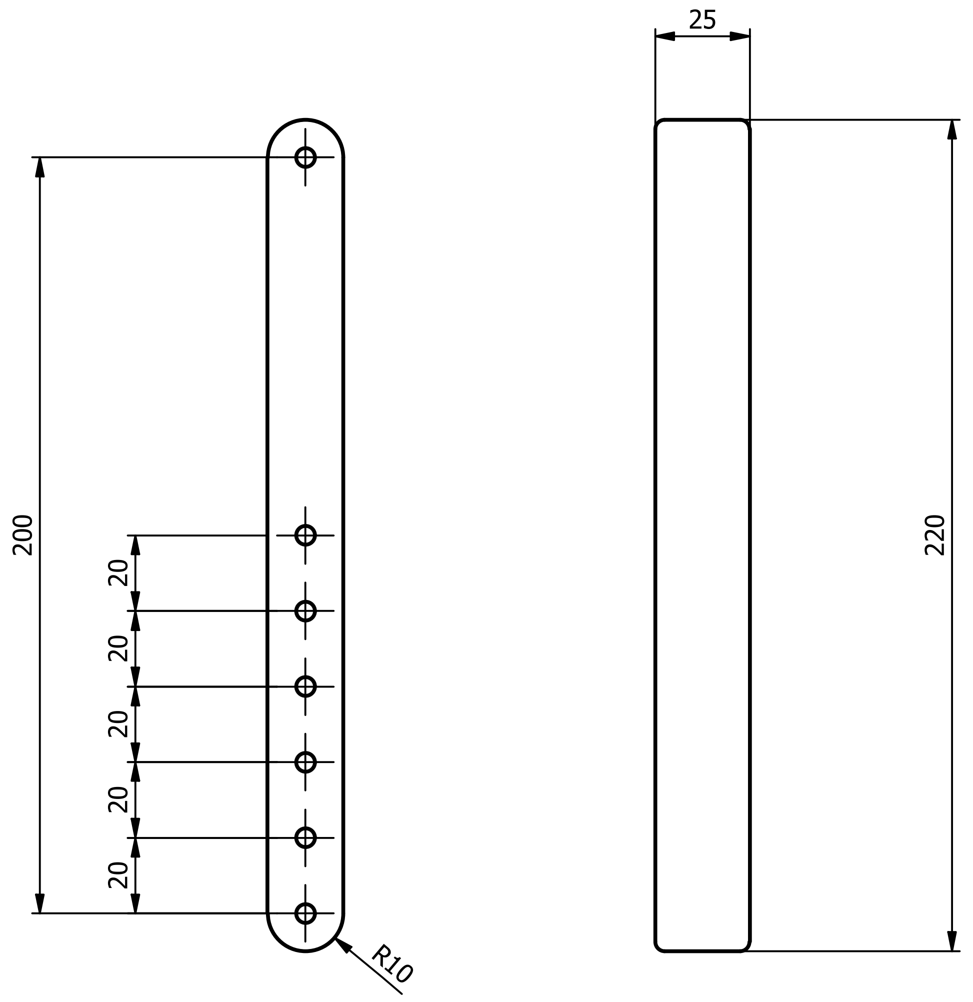
NOTA: Todas las aristas de la pieza incluyen un acabado de R3

U. DIM.:	FECHA	NOMBRE	UNIVERSIDAD SAN PABLO CEU ESCUELA POLITÉCNICA SUPERIOR
Dibujado	01/07/2021	ELENA FERNÁNDEZ	
Comprobado		Material	
Normas		PLA	
Escala 1:2	Pieza 5		PLANO Nº.8 Sustituye a: Sustituido por:



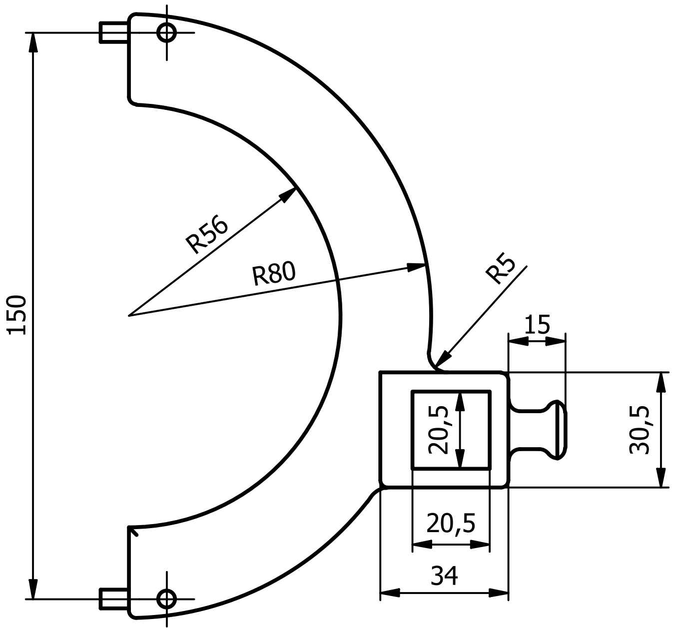
NOTA: Todas las aristas de la pieza incluyen un acabado de R3

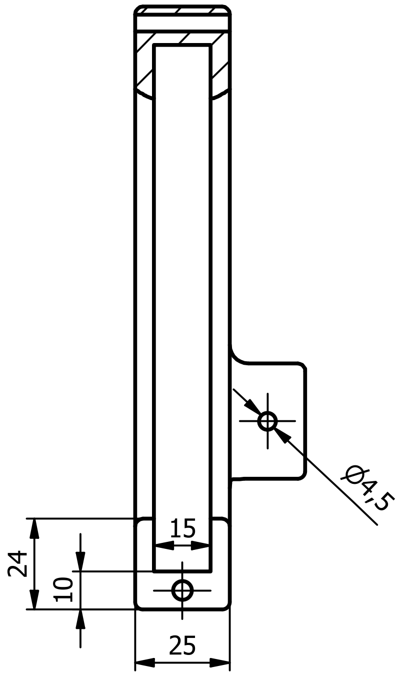
U. DIM.:	FECHA	NOMBRE	UNIVERSIDAD SAN PABLO CEU ESCUELA POLITÉCNICA SUPERIOR
Dibujado	01/07/2021	ELENA FERNÁNDEZ	
Comprobado		Material	
Normas		PLA	
Escala 1:2	Pieza 6		PLANO Nº.9
			Sustituye a:
			Sustituido por:

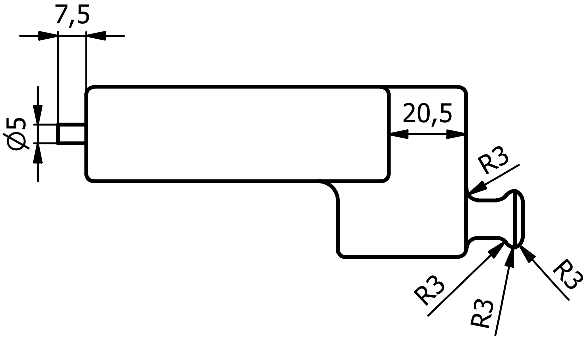


NOTA: Todas las aristas de la pieza incluyen un acabado de R2.5

U. DIM.:	FECHA	NOMBRE	UNIVERSIDAD SAN PABLO CEU ESCUELA POLITÉCNICA SUPERIOR
Dibujado	01/07/2021	ELENA FERNÁNDEZ	
Comprobado		Material	
Normas		PLA	
Escala 1:2	Pieza 7		PLANO Nº.10
			Sustituye a:
			Sustituido por:

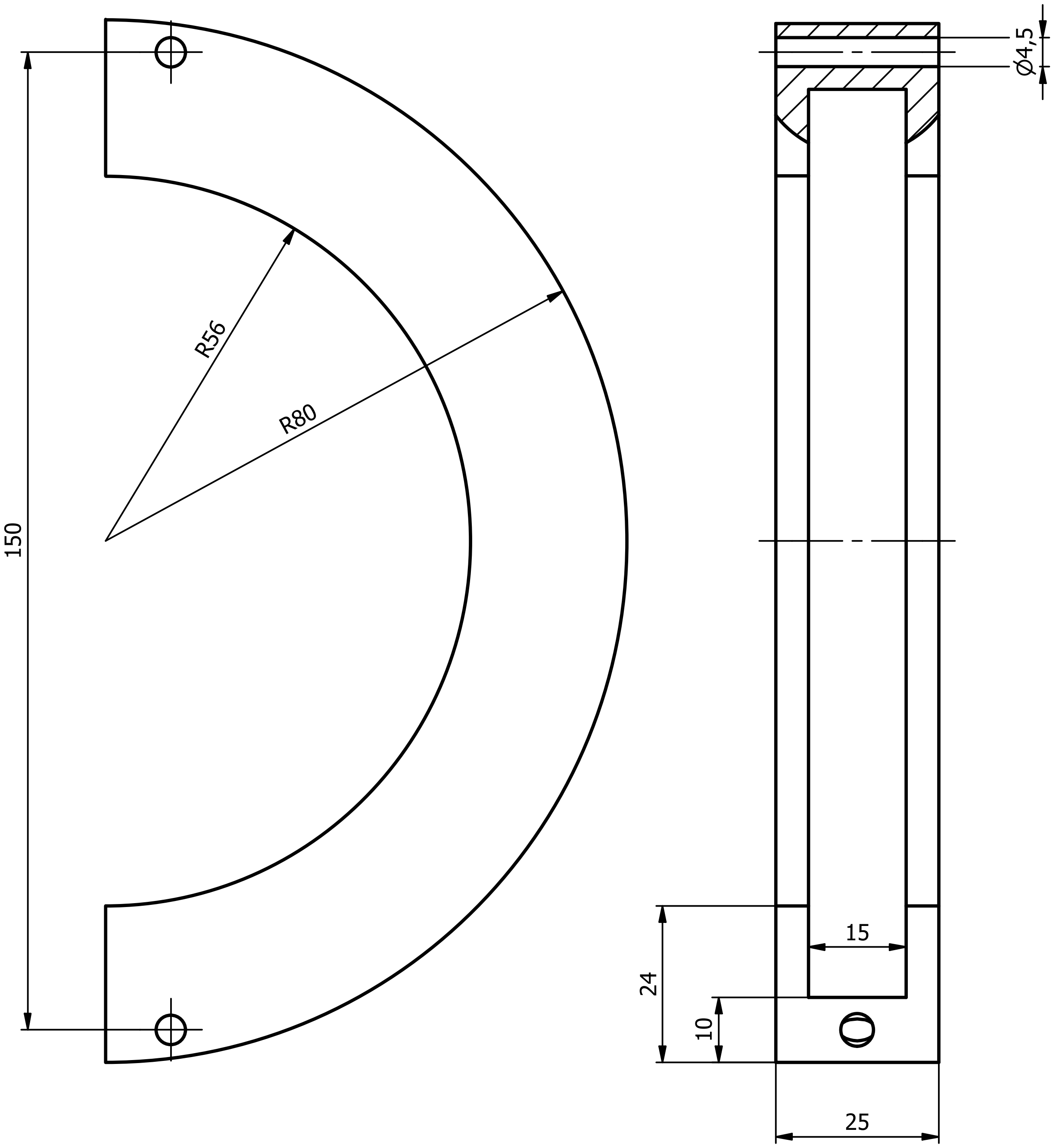






NOTA: Todas las aristas de la pieza incluyen un acabado de R1

U. DIM.:	FECHA	NOMBRE	UNIVERSIDAD SAN PABLO CEU ESCUELA POLITÉCNICA SUPERIOR
Dibujado	01/07/2021	ELENA FERNÁNDEZ	
Comprobado		Material	
Normas		PLA	
Escala 1:1	Pieza 8		PLANO Nº.11 Sustituye a: Sustituido por:



NOTA: Todas las aristas de la pieza incluyen un acabado de R2

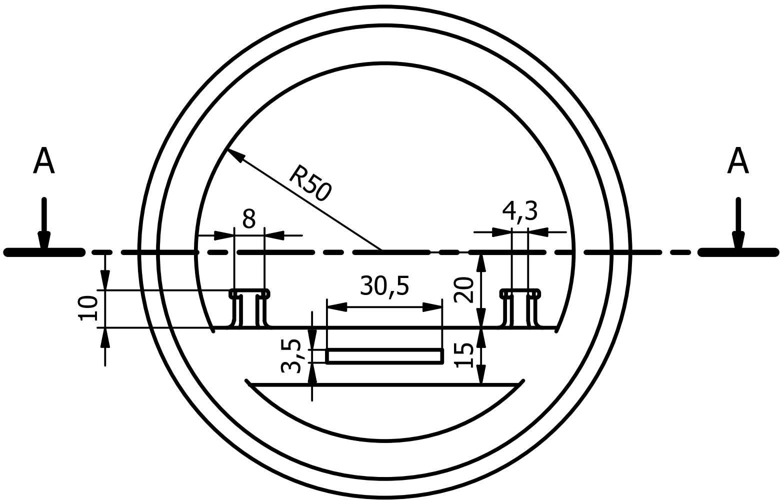
U. DIM.:	FECHA	NOMBRE
Dibujado	01/07/2021	ELENA FERNÁNDEZ
Comprobado		Material
Normas		PLA

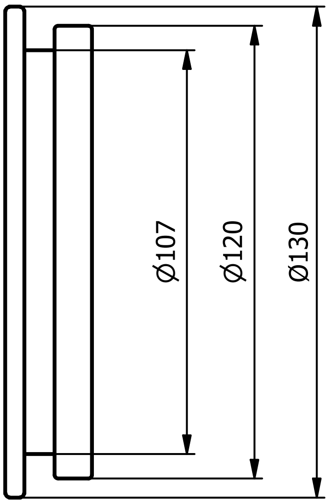
UNIVERSIDAD SAN PABLO CEU
ESCUELA POLITÉCNICA SUPERIOR

Escala
1:1

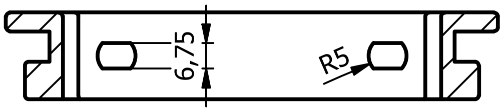
Pieza 8'

PLANO Nº.12
Sustituye a:
Sustituido por:



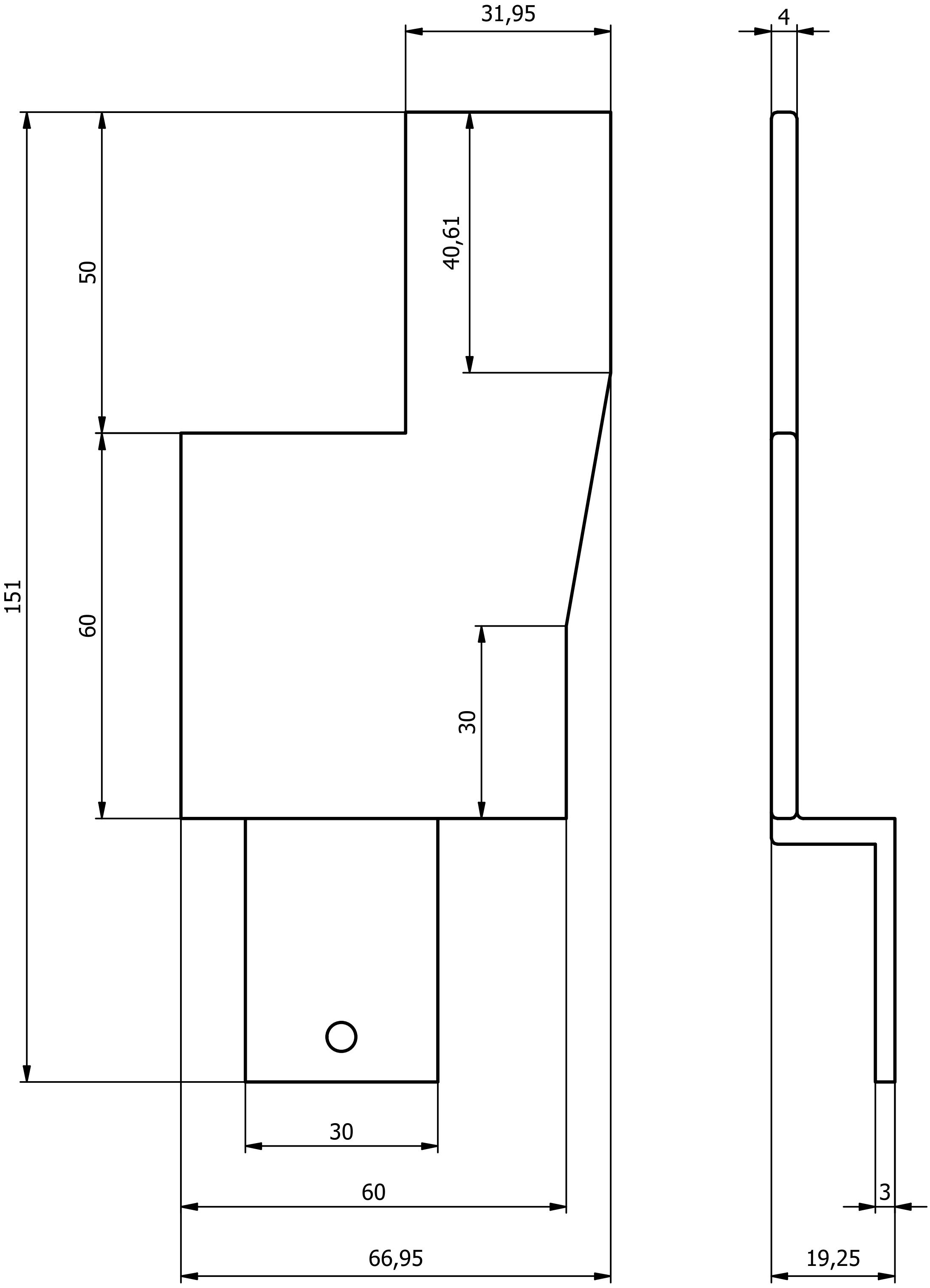


A-A



NOTA: Todas las aristas de la pieza incluyen un acabado de R1

U. DIM.:	FECHA	NOMBRE	UNIVERSIDAD SAN PABLO CEU ESCUELA POLITÉCNICA SUPERIOR
Dibujado	01/07/2021	ELENA FERNÁNDEZ	
Comprobado		Material	
Normas		PLA	
Escala 1:2	Pieza 9		PLANO Nº.13 Sustituye a: Sustituido por:



NOTA: Todas las aristas de la pieza incluyen un acabado de R1

U. DIM.:	FECHA	NOMBRE	UNIVERSIDAD SAN PABLO CEU ESCUELA POLITÉCNICA SUPERIOR
Dibujado	01/07/2021	ELENA FERNÁNDEZ	
Comprobado		Material	
Normas		PLA	
Escala 1:1	Pieza 10		PLANO Nº.14 Sustituye a: Sustituido por: