Generative Forearm
for Transradial Upper Limb Prosthesis

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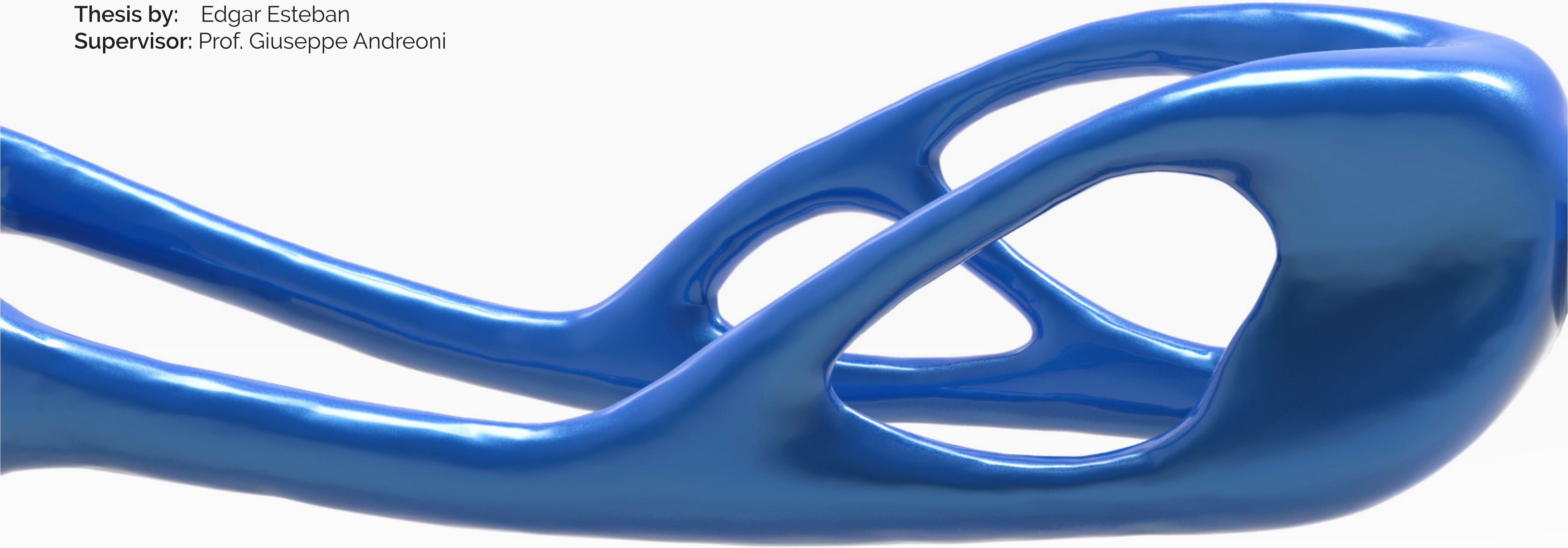

POLITECNICO DI MILANO
SCHOOL OF DESIGN
MASTER OF SCIENCE IN DESIGN AND ENGINEERING

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Thesis Topic:

Generative Forearm for Transradial Upper Limb Prosthesis

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“It always seems impossible until it’s done”
N.M

ABSTRACT

Over the time, technological advances have allowed the development of multiple prosthetic devices with a high functional value, mainly focused on minimizing the gap between an artificial limb and the lost limb.

A special effort has been focused on the development of prosthetic hands that mimic in a high percentage the range of movements of a normal hand, most of them because of the advances in robotics technologies.

However, despite the development of multiple stump-prosthesis interfaces, current products still do not consider factors such as control of sweating, adequate weight distribution and the biomimesis of the prosthetic device, which allows a better psychological and emotional adaptation of the amputee patient.

For each of the problems shown above, this thesis proposes: firstly, the design of a new socket as a patient-prosthesis interface, which allows greater perspiration capacity, better comfort conditions and functional characteristics of adjustment to the segment of amputated arm. Secondly, the design of the missing member section using generative CAD modeling, proposing a biomimetic design of the ulna and the radius as structural components. Finally, the design of an external surface that mimics the geometry of the arm and can also be customized to suit the user.

The resulting project makes use of polymer 3d printing technologies to manufacture the structural components, in addition to the use of electroconductive and 3d fabrics to develop the device’s electronics and aesthetical appeal respectively.

ABSTRACT

Nel corso del tempo, i progressi tecnologici hanno consentito lo sviluppo di più dispositivi protesici dall`alto valore funzionale, principalmente focalizzati a ridurre al minimo il divario tra un arto artificiale e l'arto perso.

Uno sforzo particolare è stato incentrato sullo sviluppo di mani protesiche che riproducono in alta percentuale la gamma di movimenti di una mano normale, la maggior parte dei quali grazie ai progressi delle tecnologie di robotica.

Tuttavia, nonostante lo sviluppo di più interfacce moncone-protesi, i prodotti attuali non considerano ancora fattori come il controllo della sudorazione, un'adeguata distribuzione del peso e la biomimetica del dispositivo protesico, in modo da consentire un miglior adattamento psicologico ed emotivo del paziente amputato.

Per ciascuno dei problemi sopra esposti, questa tesi propone: in primo luogo, la progettazione di una nuova calza come interfaccia paziente-protesi, che consente una maggiore capacità di traspirazione, migliori condizioni di comfort e caratteristiche funzionali di regolazione del segmento del braccio amputato. In secondo luogo, la progettazione degli arti mancanti utilizzando la modellazione generativa CAD, proponendo un progetto biomimetico dell'ulna e del raggio come componenti strutturali. Infine, il design di una superficie esterna che imiti la geometria del braccio e possa anche essere personalizzata per soddisfare l'utente.

Il progetto che ne deriva utilizza le tecnologie di stampa 3D polimeriche per fabbricare i componenti strutturali, oltre all'uso di tessuti elettroconduttori e 3d per sviluppare rispettivamente l'elettronica del dispositivo e l'estetica.

CONTENT

INTRODUCTION

Design and technology have served as engines of the development of societies thanks to the endless curiosity of the human being and the use of its talents in terms of solving the problems that affect its life.
In this sense it is valid to affirm that the technological and creative resources are part of a functional triad in which the human being is the generator element of innovation.

But is nowadays the innovation fully available to the integral resolution of human needs?

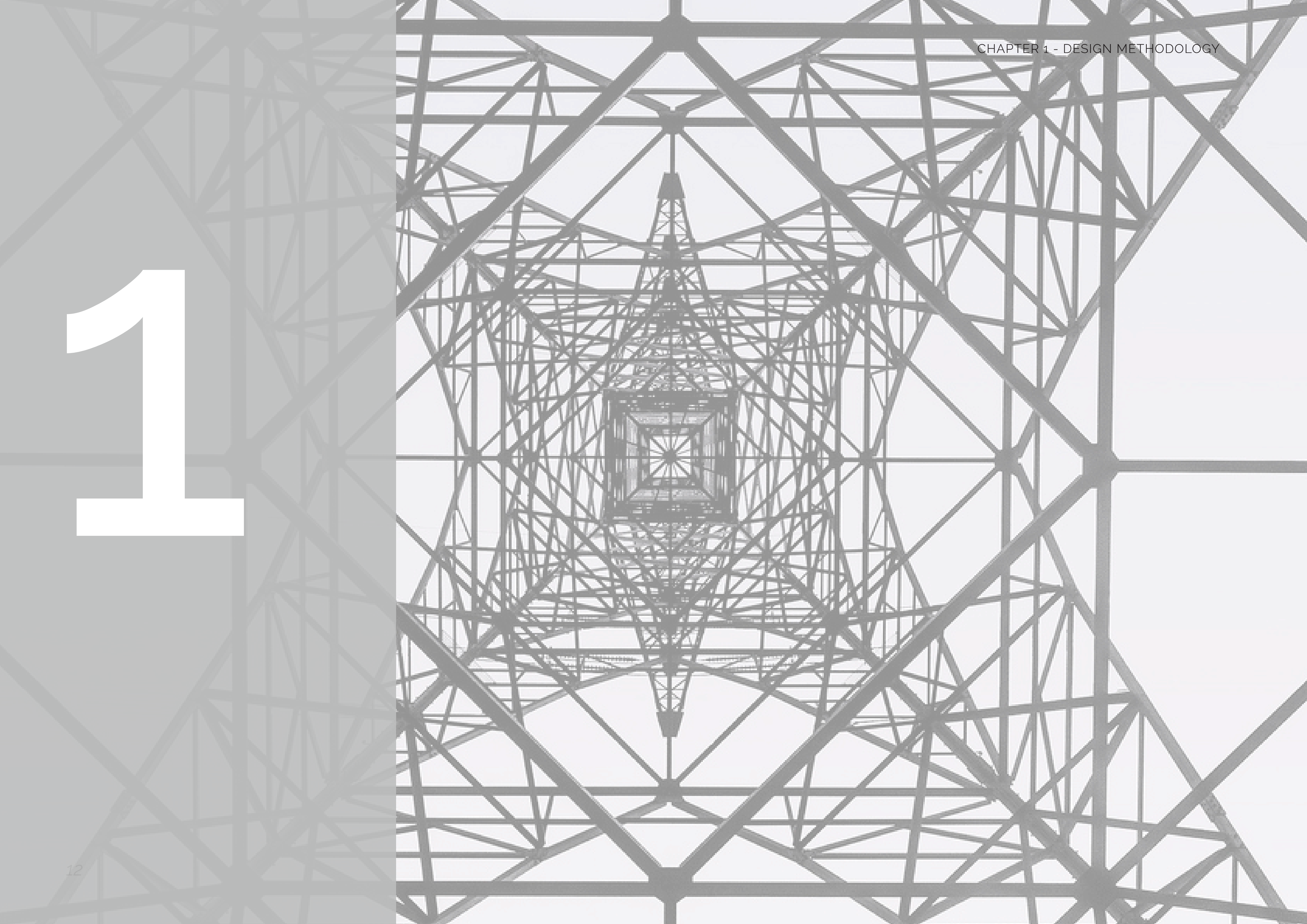
According to what Maslow expressed in his pyramidal interpretation of human needs, are not only the physiological necessities (such as eating, breathing, sleeping, etc.) and safety (health, employment, economic resources) those that provide a total state of satisfaction and fullness to people. There are still gaps in areas within the complexity of human nature, in which despite years of social and technological innovation, a fully proper development of individuals is not complete.

In the precise case of people with some level of amputation, throughout history, doctors, scientist and engineers have managed to find solutions that based on the use of technology, have improved the functional aspects of amputee's life routines. The use of prostheses, orthosis, implants, among other developments, have aimed to provide the patient with a similar state like that before its limitation. Despite the efforts these replacement elements can imitate the performance of a natural limb, this scenario has not yet been totally achieved, and is part of actual scientific research goals.

Considering a wider human scenario, it's found that most of the actual prosthetically elements in the market, are purely focused in the resolution of physiological requirements. Even this approach is relevant in technological terms, most of the times prosthetically gadgets are not properly integrated with the extensive human set of conditions, routines, aspirations and personal self-conception, leaving aside the accomplish of steem and belonging levels of patient needs.

It is then this context, which provides an opportunity in the development of a upper limb prosthetic interface, which in addition to meeting the functional requirements, can serve as a mean to express a sense of personal identity, and a breakdown of the social perception paradigm in which the use of a prosthesis is no longer a symbol of limitation and lackness to become a wearable and why not, fashion accessory. All the above focused to be achieved with the application of most innovative technologies that are currently available to design and engineering.

Carried out with the collaboration of the research group TeDH (Technology and Design for Healthcare), advised by INAIL Centro Protesi, this thesis project is conceived as a way to accomplish a better integration among technology, design and user experience, in order to put them all together at the service of a better quality of life for patients with a trans-radial amputation level. The details of the development methodology and the specific aspects on which this thesis project will be focus, are shown in the following chapter.



1

DESIGN METHODOLOGY

This chapter presents the design methodological framework in which the thesis project is developed, giving a guideline for the reader to follow and understand the document.

1.1 Generalities

The project, will follow a methodological framework, based on a double diamond design process. A reference development framework will allow the reader to understand better each of the chapters and the reason because they are organized in a specific order. The explanation of the method applied to the project is described below.

1.2 Double Diamond design process

Double diamond diagram was developed through in-house research at the Design Council in 2005 as a simple graphical way of describing a design process.[1]

Its divided in four different phases: *Discover, Define, Develop and Deliver,* mapping divergent and convergent stages of the design process. Each of the stages is briefly described below and explained in detail in each chapter.

- ***Discover***

During the first quarter of the double diamond, are defined the initial guidelines of the project. The seed or initial idea is based in the question:

"How could be possible to apply additive manufacturing techniques, the use of smart and conductive textiles and generative CAD modelling to create an alternative way to conceive a prosthetic forearm interface for transradial upper limb amputees, prioritizing simultaneously the role of the human being as the center of an integral design process?"

Starting from that point is necessary to identify the specific characteristics of the problem to solve. A complete revision of the state of art related with upper limb amputation levels, search of causes and patients' problematics and a complete benchmark of similar projects around the world, will give a first insight, allowing to identify development opportunities that counteract unmet needs (Chapter 2)

- ***Define***

In the second quarter of the double diamond, all the insights and needs collected are translated into objectives that the project could achieved. A translation in terms of which technological resources are available (technological benchmarking) and which of them could be used to carry out the project, its proposed under a detailed selection criteria. That filter/selection process define and gives free rein to the initial conception of a solid product's design brief.

At this stage of the project are presented the possibilities in terms of CAD modelling, 3d printing technologies, textiles and fabrics, electronics and batteries (Chapters 3, 4, 5, 6, 7).

- ***Develop***

Having clear which opportunities are opened to be taken and the tools that possibly will solve the base question, the next step will involve a specific case study, where the end user has the central role as generator of functional

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design requirements.

During this stage is described the patient case study and is formulated a detail design brief to accomplish the project goal. From that description will come the generation of several concepts and first attempts of prototyping (Chapters 8 and 9).

- ***Deliver***

A resulting product is presented, making use of the different technologies and methods explained above, and fitting with specific setting problem at the discovery stage. The scope of the project will arrive until the presentation of the 3d modeled prototype (Chapter 10), and leave for future analysis the patient evaluation and testing[2].

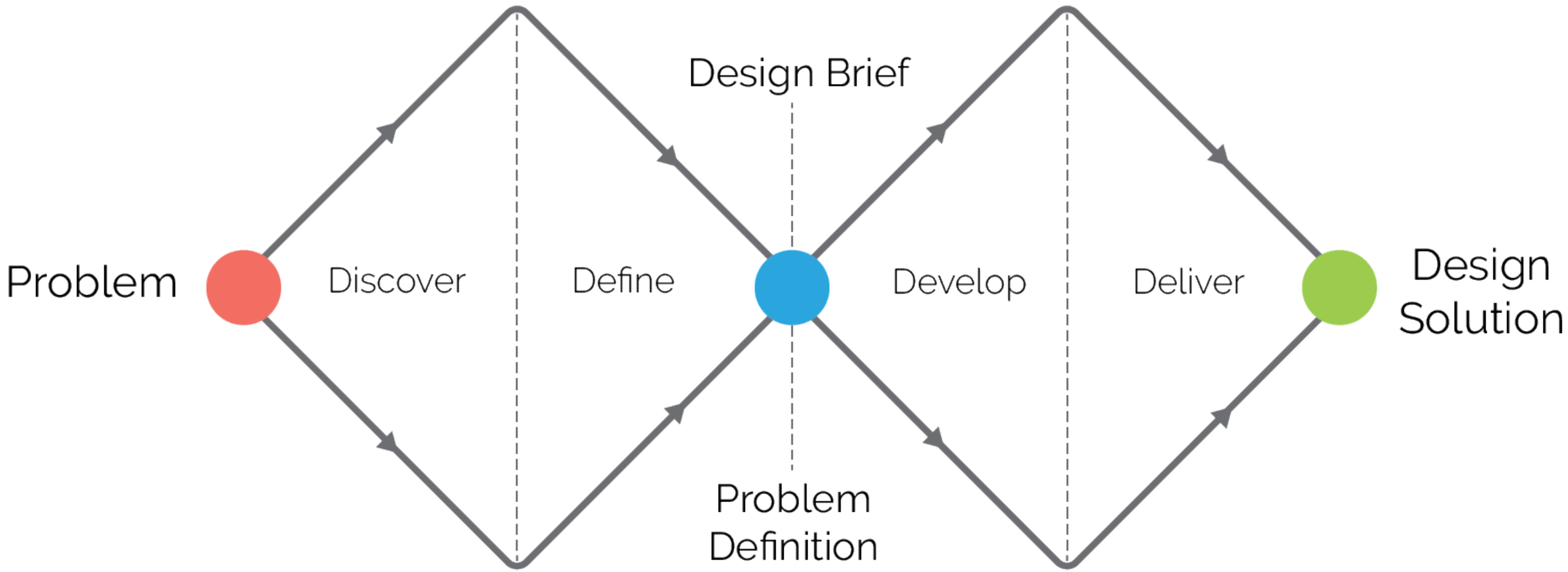


Figure 1 Double Diamond design method


2

STATE OF ART

This chapter explains the historical background of upper limb protheses and put in context to the reader the anatomy of the arm (bones, muscles and tendons) that is part of the research. Furthermore, are explained the several types of upper limb amputation, the treatment for patients with this handicap and the different solutions developed in terms of prosthetic devices.

2.1 HISTORICAL OVERVIEW

Historically, the oldest known artificial limb in existence was a copper and wood leg found at Capri, Italy in 1858, which was supposedly made about 300 B.C.

However, the first documented attempts of artificial hands were made of iron and used by knights in the 15th century. The Alt-Ruppin hand, shown along with other hands from 15th century in the Stibbert Museum, Firenze, Italy is a good example of the work of that age [3].

But a real beginning of currently known prosthetic technologies, it has the war as generative reason. Important improvements of amputation surgical techniques and technologies related with prostheses manufacturing were developed after the Second World War. Just after the war, amputees in military hospitals in the United States, began voicing their disappointment about the performance afforded by their artificial limbs.

To ensure the best treatment for these patients and a proper develop of prosthetics technologies, were created several organizations with a holistic conception of orthopedics and amputation treatment. Its basic goal was to provide engineers, enough physiological and medical information to search methods that combine technological advances at that time (materials, manufacturing process, etc.) and could solve properly many of the problems of amputee population. One of the most outstanding organizations was the Committee on Artificial Limbs (CAL), created by the National Academy of Sciences (NAS) in United States.

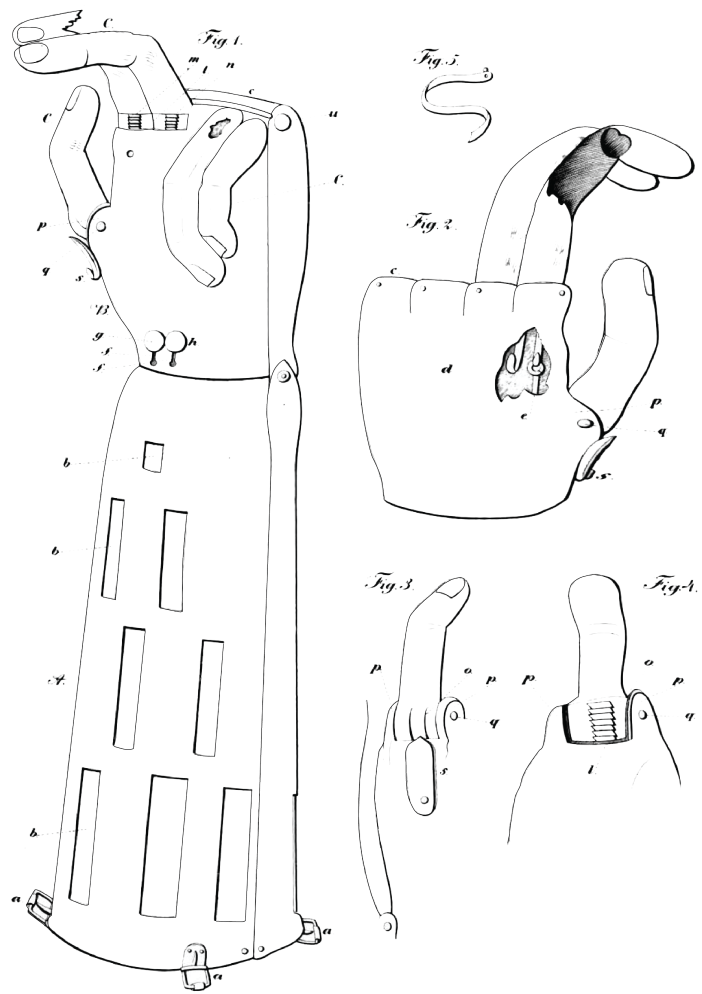


Figure 2 Altruppin Hand, iron artificial hand

2.2 Justification

2.2.1 Statistics: Population and Amputation Causes

The World Health Organization (WHO) estimated that in 2005, 0.5% of the world's population needed orthotic and prosthetic (O&P) assistive devices and related rehabilitation services. [4].

Specifying by zones, the number of persons in the US with a major upper extremity amputation - amputation level between the wrist and glenohumeral joint of the shoulder- is conservatively estimated to be approximately 41000 persons, near to the 3% of the U.S amputee population, in the year 2011.[5]. In Italy and UK are reported approximately 3500 [6] and 5200 upper limb amputation cases per year, respectively.

Based upon conservative US and UK statistical analyses, could exists a possible 2 million major upper limb amputees around worldwide, especially in developing world countries. Given a 10:1 ratio between the prevalence of lower limb and upper limb amputation cases [7] technological advance in upper limb prosthesis is less recognized and prioritized.

In general, are younger age groups the population that tend to suffer some level of upper limb amputation. Near of 75% of all referral cases in UK, were people less than 55 years old [8].

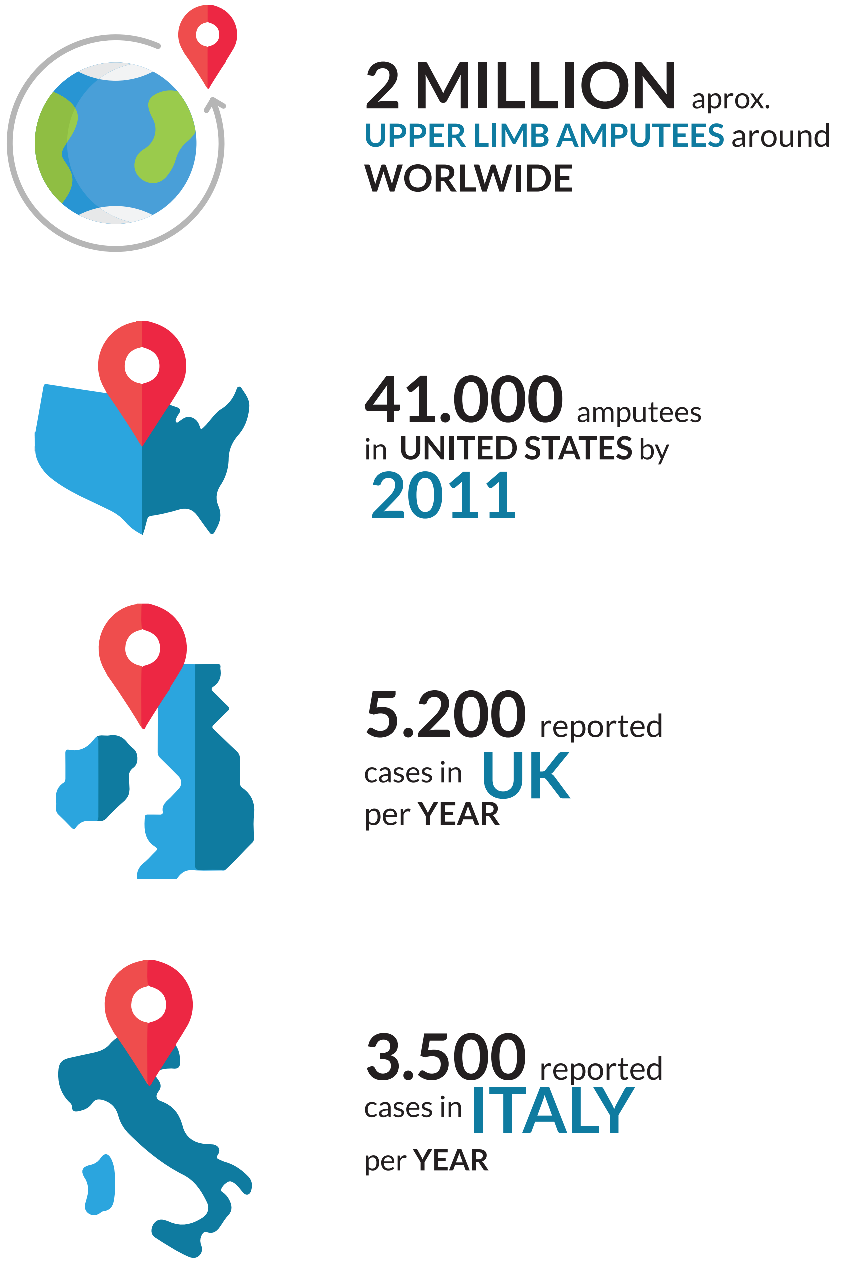


Figure 3 General statistics

Statistics in UK show that trans-humeral and trans-radial level are the most common level of upper-limb amputation seen by the prosthetist. Both together are a total of 43%. In the remaining percentage, the most representative levels of amputations are partial hand and upper digit amputation with a 41% [9].

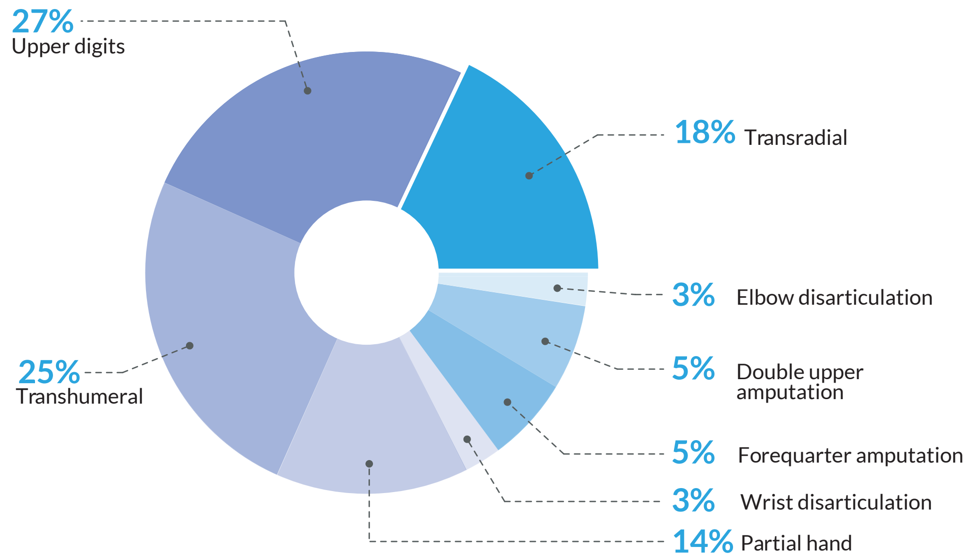


Figure 3: Statistics per amputation level

Regard the causes, trauma is the second common reason after congenital deficiency, followed by neoplasia* [10] and dysvascularity** [11].

Amputation's trauma incidents are related with work accidents (clothes trap in machinery, farming accidents) and road traffic accidents. On the other side, near to a quarter of congenital limb deficiency cases, have like condition the absence of the hand or forearm.

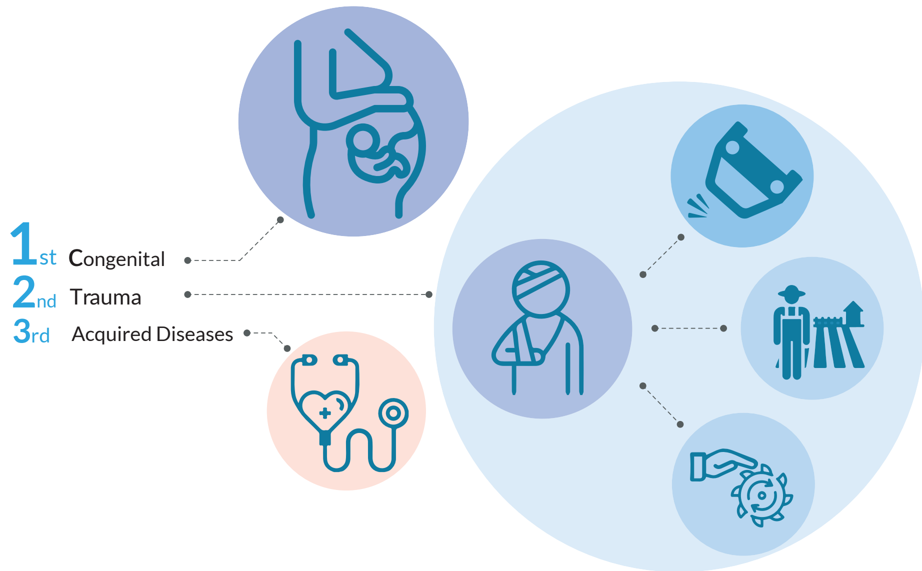


Figure 4 Amputation etiology

** Neoplasia: Uncontrolled growth of cells that is not under physiologic control. A "tumor" or "mass lesion" is simply a "growth" or "enlargement" which may not be neoplastic (such as a granuloma). The term "cancer" implies malignancy, but neoplasms can be subclassified as either benign or malignant.*

***Dysvascularity: Amputations that are caused or acquired from poor vascular status of a limb (i.e., ischemia). The prefix dys is Greek in origin and means abnormal, difficult, impaired or bad*

2.2.2 STATISTICS PROSTHETIC RANGE OF REJECTION

Rates of rejection of upper limb prostheses are related with certain factors inherent to the patient condition. Among the most common are:

- Proximal level of amputation
- Type of prosthetic device
- Poor training
- Late fitting
- Limited usefulness of devices
- Maintenance cost
- Poor fit-comfort
- Prostheses weight
- Repeated mechanical failure
- Un-natural look
- Lack of tactile sensation

In general, for major upper limb amputation levels, prostheses at trans-radial level reported the lowest rates of rejection (6%), followed by trans-humeral users (57%) and shoulder disarticulation with the highest statistics (60%)[12].

Statistics of rejection and acceptance in terms of type of prosthetic device reveal that the range of rejection is lower in the case of myoelectric devices in comparison with body powered and passive hands, according to the literature.

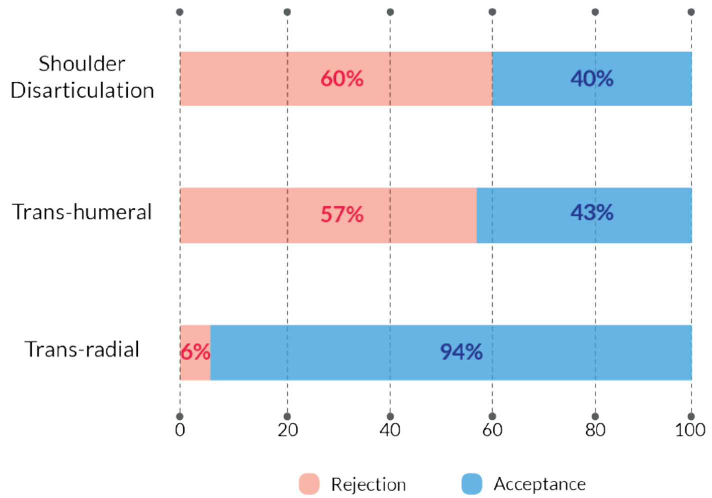


Fig 5 Prostheses acceptance-rejection rates by level of amputation

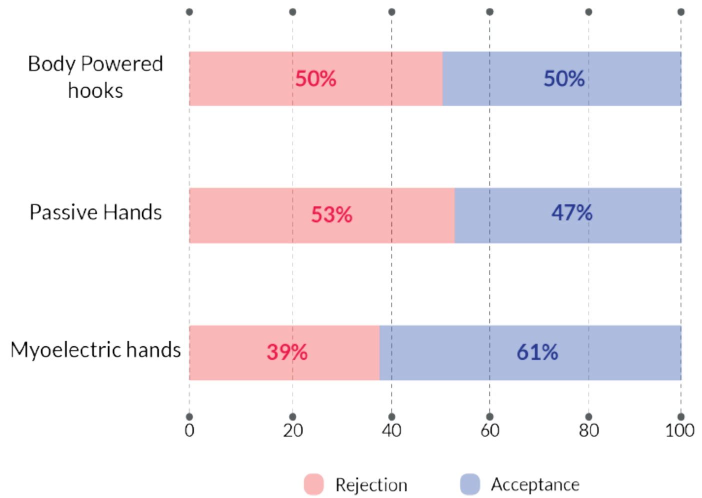


Fig 6 Prosthetic device acceptance-rejection rates

2.2.3 Prostheses' rejection factors: cases of study

On one side, psychological and psychosocial factors can affect the level of patient acceptance of the prostheses. However, this influence has not been well documented and its scientifically supported just by few statistical surveys with a short range of sample. Psychological influence includes negative reactions of other people, low self-esteem, lack of acceptance of disability, unrealistically high expectations regarding prosthetic function and poor initial prosthetic experience [5]. Furthermore, patients with prostheses or adaptative appliances were rarely use it for dressing tasks [13].

Patients who suffered amputation due to a traumatic event, are exposed to high level risk of any psychological adjustment disorder.

Figure 7 Pyschological factors

On the other hand, the wearing relationship patient-device, creates a sort of microenvironment on the stump, that with the increase of the temperature may lead to an excessive sweeting phenomenon. A warm and moist environment, it is the perfect scenario for bacterial growth and the appearance of odors, infections, pressure ulcers or pain. Skin problems (rash, boils, folliculitis) [14] generated by using some prosthetic devices, are in some cases a reason to discontinue the use of prosthetically equipment.

Figure 8 Stump skin problems

2.3 PHYSICAL ARM DESCRIPTION

A human arm is composed by three major joints - shoulder, elbow and wrist- plus a series of minor joints - phalangeal articulations- that control entirely the interaction with external objects.
In the develop of this project, will be analyze just the biomechanics of the elbow, having into account that trans-radial amputation, will be the level of amputation to study.

The elbow is a complex joint that functions as pivot point for the forearm lever system that is responsible for positioning the hand in the space [17].

2.3.1 BONES AND JOINTS

The elbow is composed by the humerus (the upper arm bone), the ulna (the larger bone of the forearm, on the opposite side of the thumb), and the radius (the smaller bone of the forearm on the same side as the thumb).

At the end of the bones, these are cover by articular cartilage. Physically described, cartilage is white shiny and has a rubbery consistency, and allows and easy sliding among the surfaces in contact plus a high shock load absorption. In high weight support joints, cartilage can reach a thickness of near 6 to 7 mm. In the case of the elbow joint – low load case - cartilage can be thinner than that.

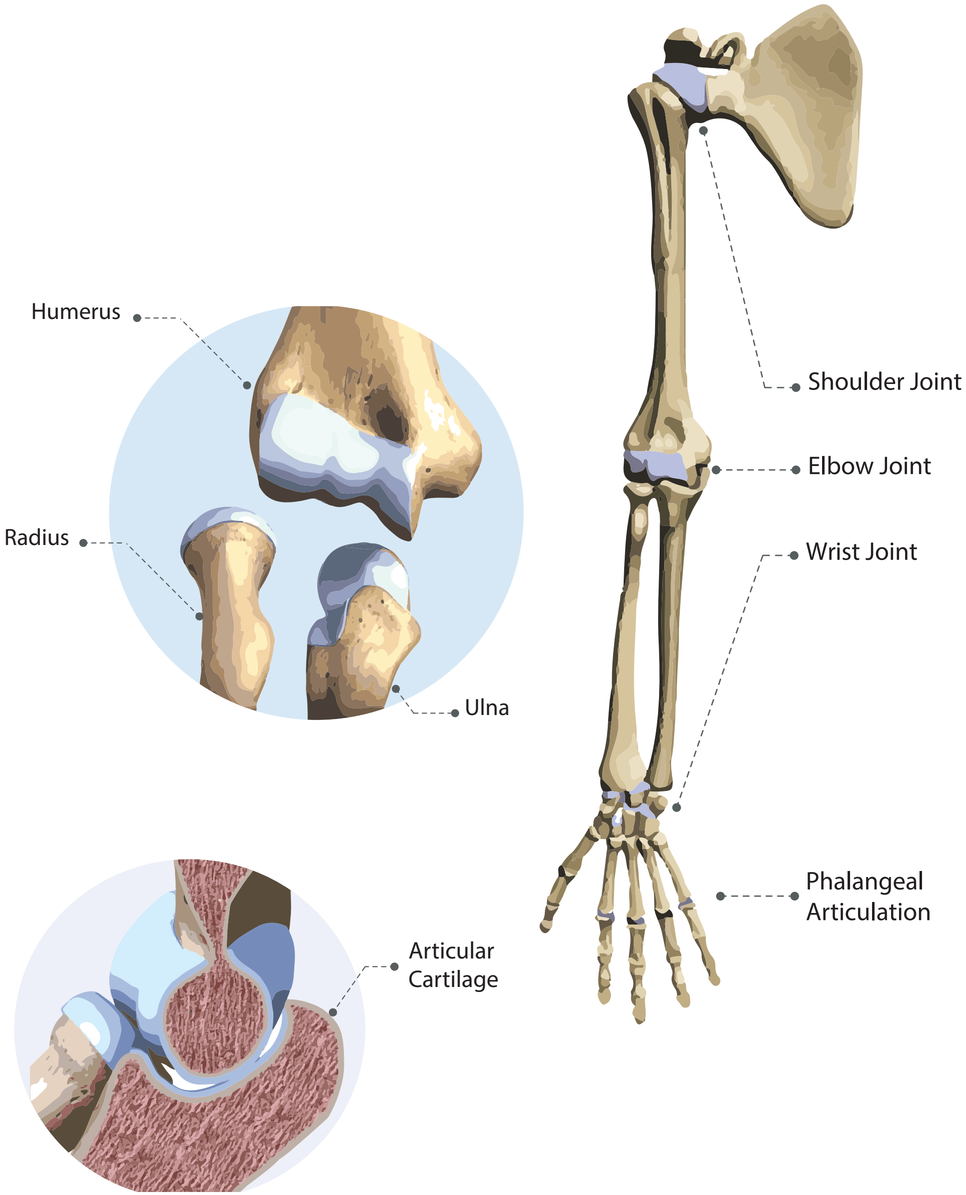


Figure 9 Arm articulation

2.3.2 Ligaments and Tendons

Bones are connected through ligaments, a sort of soft tissue structure. Around a joint, combined ligaments form a watertight joint capsule or sac that contains synovial fluid, lubricating fluid that facilitates the movement of the articulation.

Two of the most important ligaments in the elbow are the medial collateral and the lateral collateral ligament, located on the inside and the outside edge of the elbow, respectively. They fulfill the function to connect the humerus and the ulna and keep it tightly in place. These ligaments are responsible of much of the elbow's stability.

The annular ligament hat wraps around the radial head and holds it tightly against the ulna. Holding it in place forming a kind a of ring around the radial head.

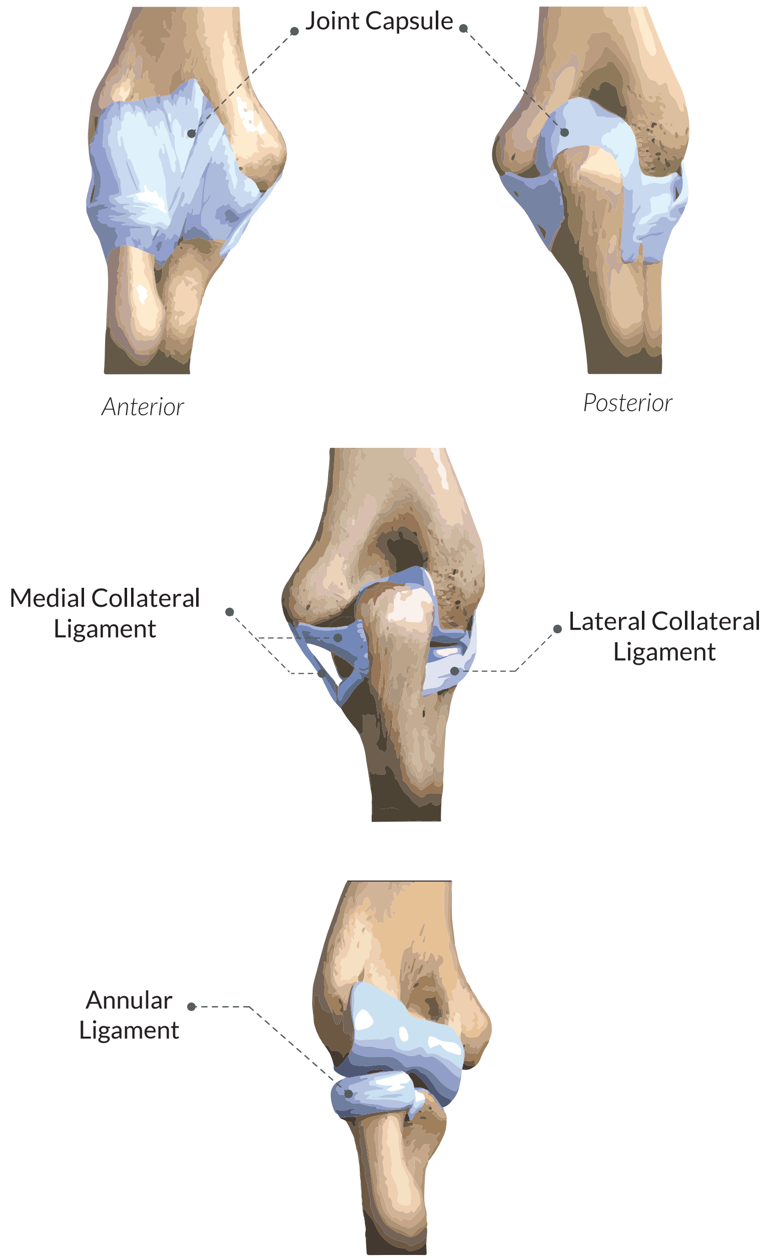


Figure 10 Elbow ligament schema

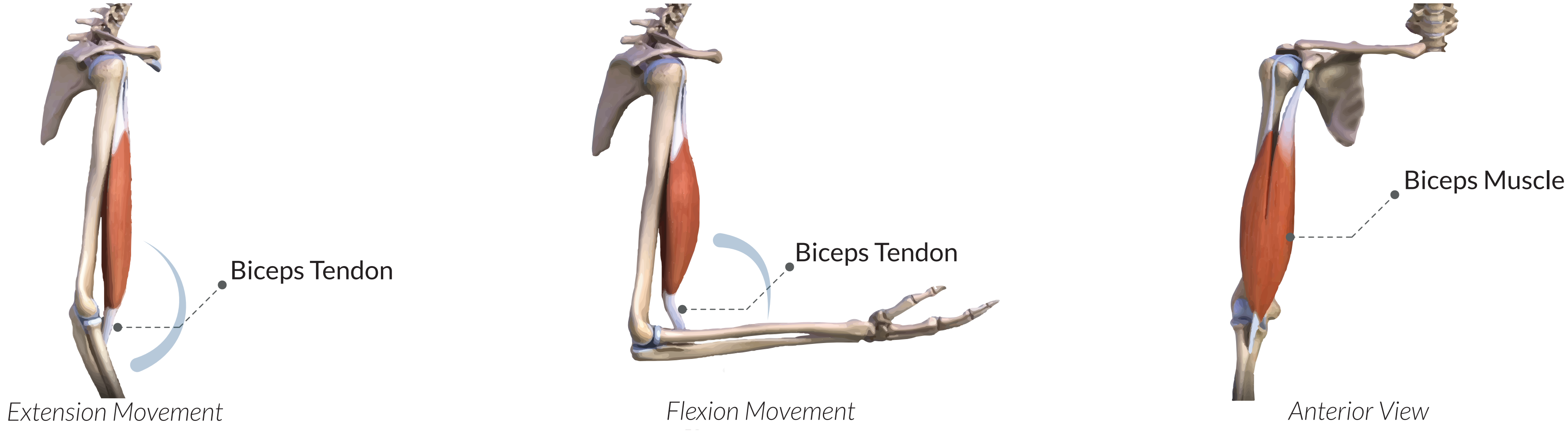


Figure 11 Biceps muscle

Equally important, tendons fulfill the function to attach muscles with the bones. Biceps tendon attach the large biceps muscle to the radius and is the direct responsible to allow the elbow bending with force.

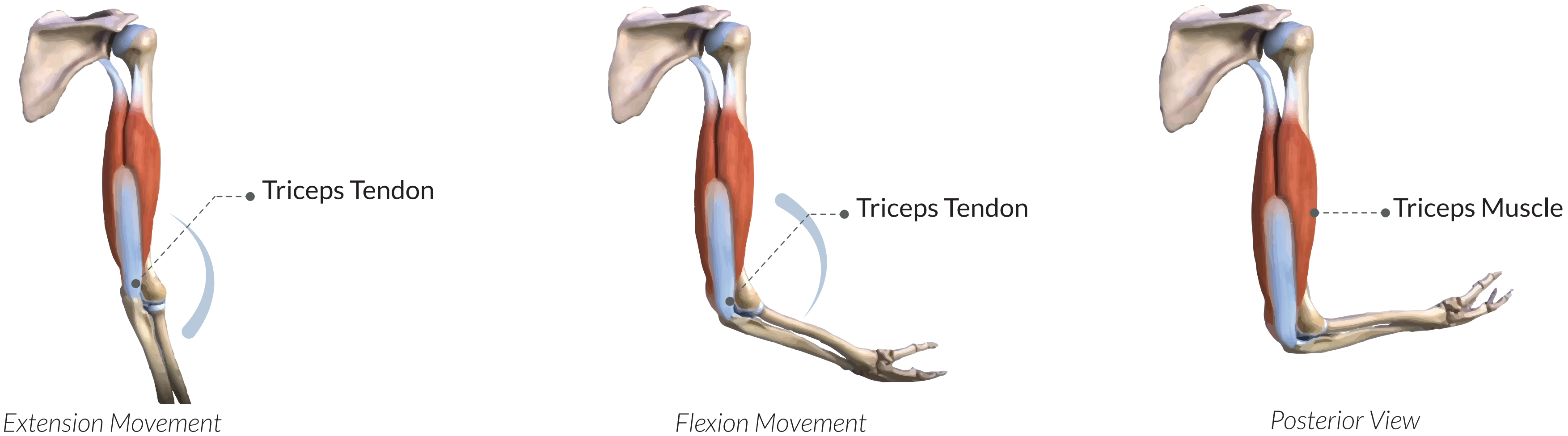


Figure 12 Triceps muscle

Triceps tendon connects the triceps muscle on the posterior part of the arm with the ulna, allowing the elbow to straighten with force.

2.3.2 Muscles

The muscles of the forearm cross the elbow and attach to the humerus. The lateral area bump just above the elbow is called the lateral epicondyle. Most of the muscles that straighten the fingers and wrist all come together in one tendon to attach in this area. These set of muscles are called wrist extensors.

The inside, or medial, bump just above the elbow is called the medial epicondyle. Most of the muscles that bend the fingers and wrist all come together in one tendon to attach in this area. These set of muscles is called wrist flexors.

Electromyography is the discipline responsible to analyze the generation and measurement of electrical signals emanated from the muscles. [18]
In what concerns the medical applications, electromyography (EMG) it is used to study the neuro-muscular activation related to human ergonomic activities, functional movements and rehabilitation or orthopedic task.
In the case of the prosthesis, EMG is used like control input of the electronical components, taking the signals of the muscles with higher levels of electric activity.

The electrical activity of the muscles that compound the system humerus-elbow-forearm are characterized [17] as follows:

- The brachialis is active through flexion and is considered the workhorse of that movement
- The brachioradialis also is active during flexion and the potential of the electrical activity increase when the forearm is in a neutral or pronated position.
- Biceps are less active in full pronation of the forearm
- The triceps electrical activity increases as much as the elbow flexion increases (because stretch reflex)
- Anconeus is active in all positions

The precise value of electrical potential for each muscle, change from person to person, and must be analyzed before to be used like control input for an external powered prosthesis.

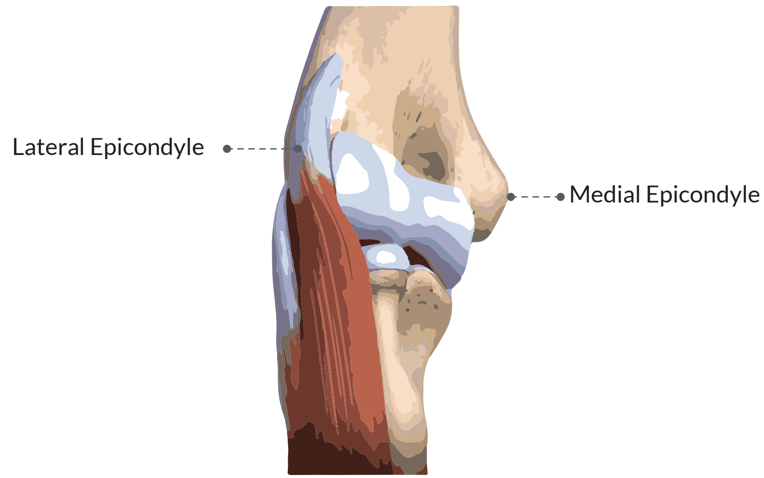


Figure 13 Elbow muscle Epicondyles

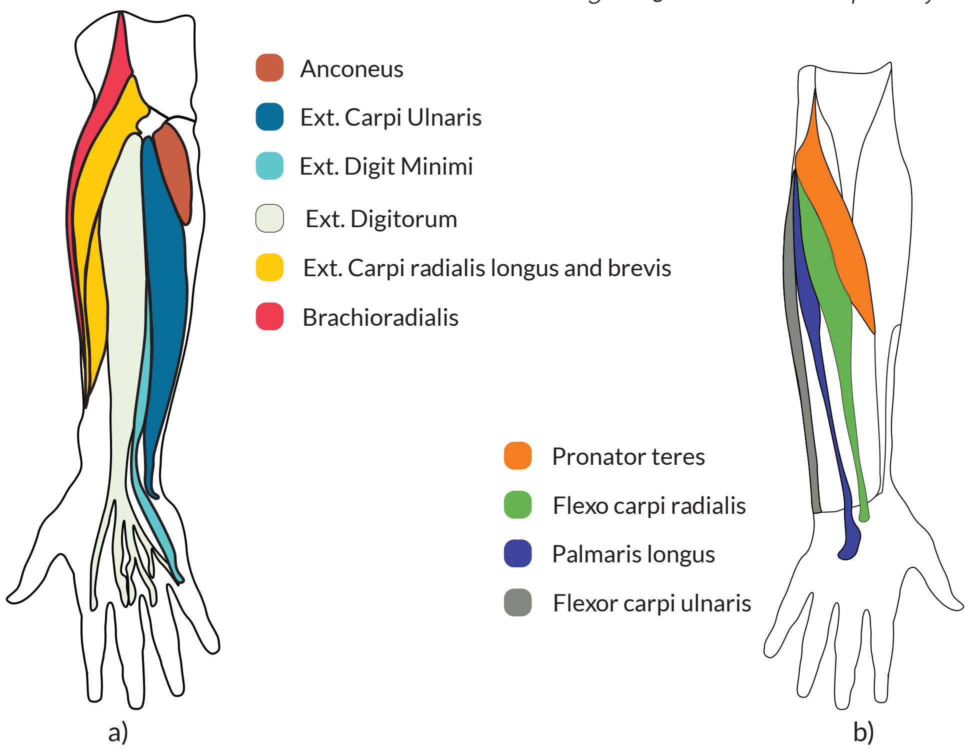


Figure 14 Arm muscles a) Posterior view b) Anterior view

2.3.4 Kinematics

Because meets the interaction among humerus, radius and ulna, the elbow has three types of movement: flexion-extension, pronation-supination and abduction-adduction.

Elbow flexion and extension take place at the humeroulnar and humeroradial articulation. The normal range of flexion-extension is from 0° to 146° with a functional range of 30° to 130°.

The normal range of forearm pronation-supination is approximately from 71° of pronation to 81° of supination. Most activities are accomplished within the functional range of 50° pronation to 50° supination and is generated because the proximal radioulnar articulation.

From a simplified point of view, trochlea's center could be considered the axis of rotation for flexion extension movement of the elbow, but what is true is that elbow has a changing center of rotation and cannot be represented as a simple hinge joint.

Pronation and supination take place primarily at the humeroradial and proximal radioulnar joints with the forearm rotating about a longitudinal axis passing through the center of the capitellum and radial head and the distal ulnar articular surface.

This axis is oblique in relation to the anatomical axis of the radius and ulna. During pronation-supination, the radial head rotates within the annular ligament and the distal radius rotates around the distal ulna in an arc outlining the shape of a cone.

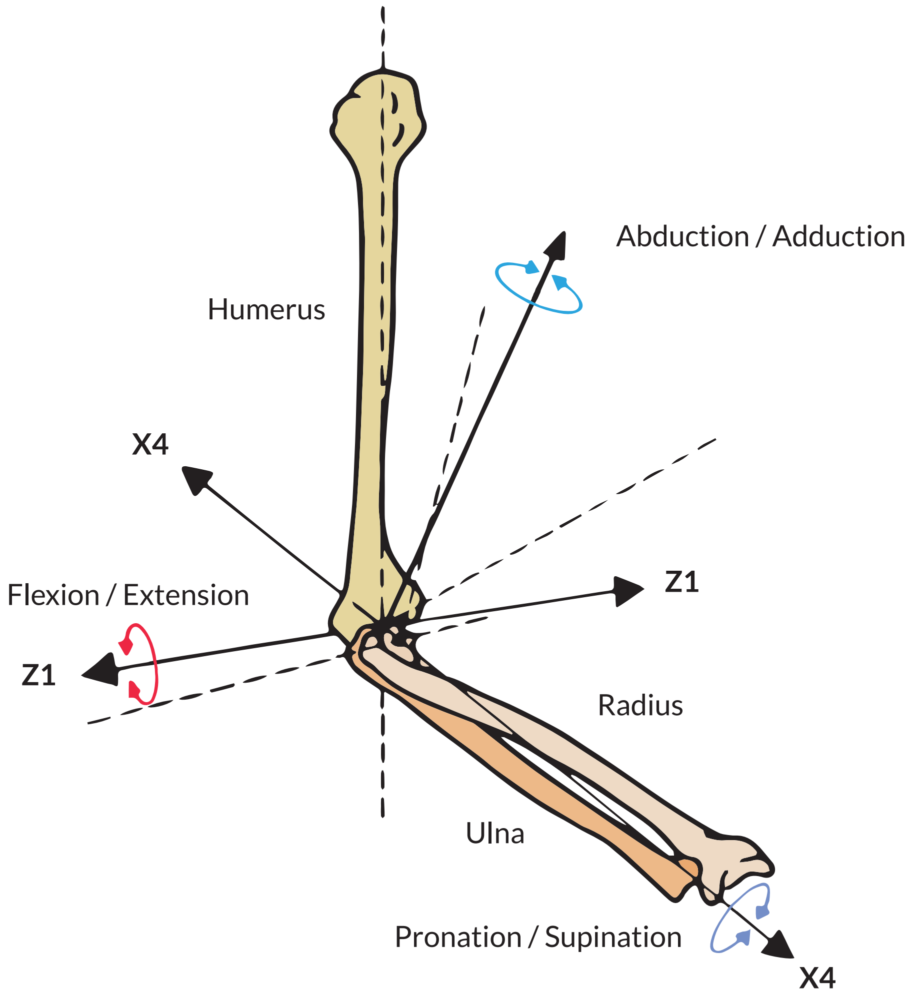


Figure 15 Elbow Kinematic movements

2.4 UPPER LIMB PROSTHETIC DEVICES

Prosthetics devices can be classified according the way they are made, in exoskeletal and endoskeletal.

Up to now, most of rehabilitation devices used by amputees, belong to exoskeletal characteristics, called too conventional or crustacean prosthesis [19].

Some of the main characteristics of both types of prosthesis are explained as follows:

- ***Exoskeletal devices:*** Created like a laminated external shell (usually in wood or polymer) that meets the functional and cosmetic requirements (strength and aesthetics) to replace the limb lost. The hollow inner space is used to fit key elements that could compound the prosthesis (batteries, wires and electronical control cards).

With lamination as manufacturing process in most of the cases, high mechanical characteristics are provided, driving to highly durable and low maintenance prosthesis. Lamination allows an easier manage of the shape.

Some disadvantages are related with heaviness, difficulty to change alignment after final shaping, un-efficient stance phase and longer fabrication times.

Figure 16 Exoskeletal devices

- ***Endoskeletal devices:*** Created with an internal pylon that support the applied loads, connect the socket (upper or lower limb cases) with the terminal device. Shaped foam cover covered by custom made gloves enhance the final aesthetic and cosmesis.

A high level of wearing comfort is achieved because the reduction in weight. The increase in the range of movement (ROM) of the patient and an easy donning and doffing are characteristics related with the absence of straps, belts or any external suspension method.

With endoskeletal prosthesis, time required in the patient fitting phase is reduced, so is possible provide finished and functional prosthesis in shortest rehabilitation process [19].

External soft feel of prosthesis and the use of realistic external coverage encourage a better aesthetical acceptability from the patient. However, durability of external foams and coverage is limited, relating this kind of prosthesis for light to moderate duty applications.

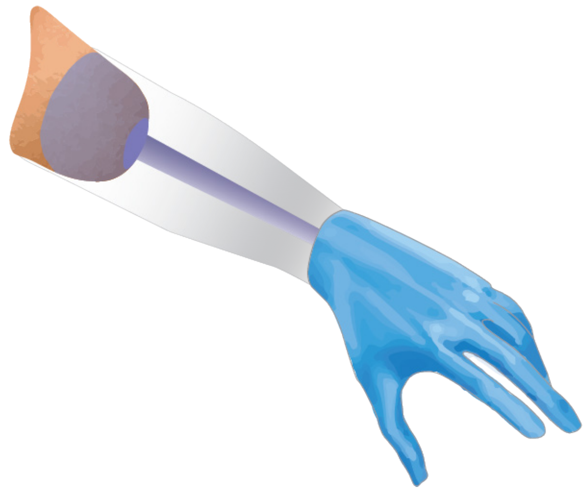


Figure 17 Endoskeletal devices

2.4.1 Upper Limb amputation treatment

In the treatment of patients with any level of amputation, it exists different solutions that could perform specifically in each patient and its particular health condition. Options for treatment are evaluated by professionals and relate external conditions as dairy activities intensity, age of the patient and in some cases, socio-economic conditions.

Some of the most common practices, offered by orthopedic and medical centers for upper limb amputees, are shown as follows:

- ***No prosthesis:*** Due to the lack of a complete biomimetic functionality, some patients decide not to wear any kind of external device. Several factors can promote this scenario, but some of the most remarkable are a longer transition time between amputation surgery and the beginning of rehabilitation therapies, a failure in training procedures or just funding limitations.

- ***Passive prosthesis:*** From a functional point of view, these devices allow to recover the body balance and the aesthetical symmetry. Just activities that do not require lateral grasping can be carry out through this way of treatment, therefore prehension is totally out of reach. Don and doff require a minimal level of harnessing without cabling. Social integration and psychological perception of the patient are the fundamental reasons to use these prostheses.

- ***Body powered prosthesis (BP):*** Taking advantage of specific body movements, the mechanical system is activated using wires. A mechanical translation of movement requires the use of a harness, to attach the prosthetic system to the amputee body, always encouraging the most effective transmission of power. The entire system became robust, durable and reliable, and because its functional simplicity, more affordable if its compare with another technologies.

- ***Externally powered prosthesis (EP):*** It makes use of portable batteries to power the motorized components of the prosthesis. The entire system can be activated through electrodes that collect electromyographic signals generated by the muscles, touch pad technology (force sensitive resistors) or in the simplest case, a mechanical switch.
  Because their functional components, the entire system became more complex in terms of maintenance and durability, therefore depending of the used technology, the device prices could be higher.

- ***Hybrid prosthesis:*** with components that are activated through body power, and electronical elements activated by an external source, this kind of prosthesis are common in elbow disarticulated patients. The significant restoring of the arm movements and hand functionality is the key idea of this combined system.

- ***Activity specific prosthesis:*** with design approaches that can go from professional sports practices, to specific working activities (farming, driving, etc.) these prostheses are designed with an entire functional purpose, leaving biomimetics in the background. Even prehensile characteristics are not considering in some designs.

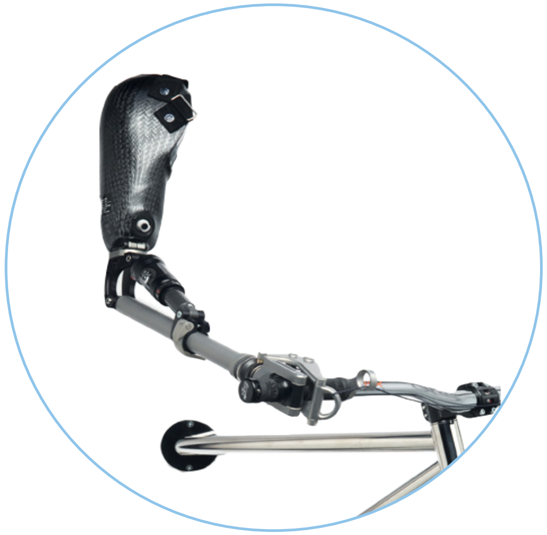
No prosthesis

Passive prosthesis

Body powered prosthesis (BP)

Externally Powered Prosthesis (EP)

Hybrid Prosthesis



Active Specific Prosthesis

Figure 18 Amputation treatments

As it was show before, it exists different ways to treat upper limb amputation patients. The ways to control the devices can vary from body to external power inputs, but because the technological characteristics of this project, it will be explained more in deep the available control input technologies for external powered devices

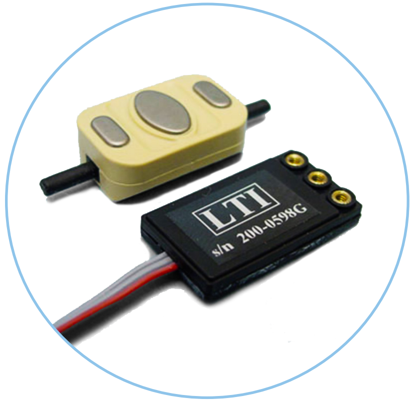
- ***Myoelectrode:*** Surface electrodes are installed into the socket to captured electromyographic signals (EMG) generated by the muscles. A high level of control is obtained when are used signals from opposite muscular groups. Signals are later processed to activate a power unit.

  The main advantage of this technology is the straightforward relationship between the muscular activity and the functional components. Sweating and moisture can affect the performance of the electrodes, so is require having a good isolation.

- ***Push switches:*** A button commands the movement of a motor that operates the device in single, dual position or selecting another function. Operation requires the use of the remain limb or another body surface.
  It is generally used when the patient requires to control multiple components (trans-humeral devices with elbow rotational joint for example). One of the main disadvantages is that some devices can have too many functions that became very unfriendly operated for the user.

- ***Pull switches:*** An electrical signal that controls the device is generated pulling on and small cable. The amount of force and excursion required in the operation its minimum.
  Used when the prosthesis requires a control of multiple components. The control of many functions can make it unfriendly for the user.

- ***Touch pads:*** Sensitive pads that generate signals with an intensity proportional to the level of applied pressure.
  These kinds of devices are available in customizable sizes and can be cheaper compared with electromyographic sensors.
  However, this technology can have a short durability and its constrained to flat surfaces.



Myolectrode

Push switches

Pull switches

Touch pads

Figure 19 Prosthetic's control systems

2.5 LEVEL OF AMPUTATION

In terms of classification, amputation in upper limb can be splitted in two principal groups:

- ***Major amputations:*** amputations through or proximal to the wrist joint
- ***Minor amputations:*** distal to the wrist joint

2.5.1 MAJOR AMPUTATION

Depending the level, are classified as follows:

- ***Forequarter amputation:*** Removal of the entire upper extremity as well as the scapula and a portion of the clavicle. Amputation is usually required for recurrent soft-tissue sarcomas or those bony lesions that fail induction chemotherapy. [20]

  Prosthetic to this level of amputation, need to include all joints. Shoulder prosthetic must be made to conform to the sound side, thus restoring the appearance and balance of the body.

  Due to the weight and the lack in effective functionality, most of the available prostheses are generally used for cosmetic purposes. Generally, just a shaped shoulder cap is used to restore the shoulder contour.

- ***Disarticulated shoulder amputation*** : Removal of the entire arm at shoulder level, and specifically an amputation through the shoulder itself.[22].

  Clavicle and scapula are remaining, characteristic that allows to the patient manage the weight of the prosthesis and reduce the possibilities of functional rejection. Whilst the control of terminal devices is possible, this remains difficult due to the absence of the humerus. [9]

- ***Transhumeral amputation***: Amputations of the upper arm between the shoulder and the elbow, where the patient retains use of their shoulder. This level of amputation opens the possibility to different methods of suspension and mechanic activation of the prosthesis. Movements like flection, extension, abduction* and adduction** allow the patient a straightforward control of the prosthesis -this include an appropriate operation of the terminal devices.

- ***Elbow amputation :*** Amputation that include the elbow and forearm. This level of amputation allows anatomic suspension and rotational control of the prosthesis and reduces rotational of the socket on the residual limb. The major disadvantages are the suboptimal cosmetic appearance and limited availability of elbow components. The external hinge elbow mechanisms for elbow disarticulations are not very cosmetically pleasing. [24].

  Due to the lack of space, is not possible to fit an elbow mechanism without increasing the length of the upper segment.

- ***Trans-radial amputation:*** Its related with the partial amputation of the arm below the elbow, at some point along the radial bone. Length of the remaining forearm varies in each amputee and can influence a greater effectiveness of the prostheses. The longer it is, the stronger lever arm will be, and the more completely pronation and supination will be preserved [25].

  The level of prosthetic socket's cosmesis increase as nearer the amputation is to the wrist (no less than 2 cm). This characteristic allows more space for all the elements that compound the prosthetic device. Because electronical components, myoelectric prosthesis used to be heavier than mechanical or cosmetic prosthesis. In this sense short residuals limbs can have problems tolerating its weight.

  In order to fit with prosthetic devices, proximal amputations – very short residual limbs - can have a minimum ulna dimensions of 3.8 cm to 5 cm. Conditions like that allow the preservation of the elbow joint

- ***Wrist amputation:*** Amputation that involves the removal of the hand and the wrist joint [26]. Because the full forearm length, pronation and supination movements are preserved providing a long lever arm. A long lever arm makes easier the use of the terminal device and facilitate to deal

** Abduction: The movement of a limb away from the midline of the body.*

***Adduction: Movement of a limb toward the midline of the body* with the weight of the prosthesis and external loads.

Active prosthesis for this level of amputation used to end up in a longer forearm. This issue could represent a minor disadvantage in terms of cosmesis, but not in functional capabilities.

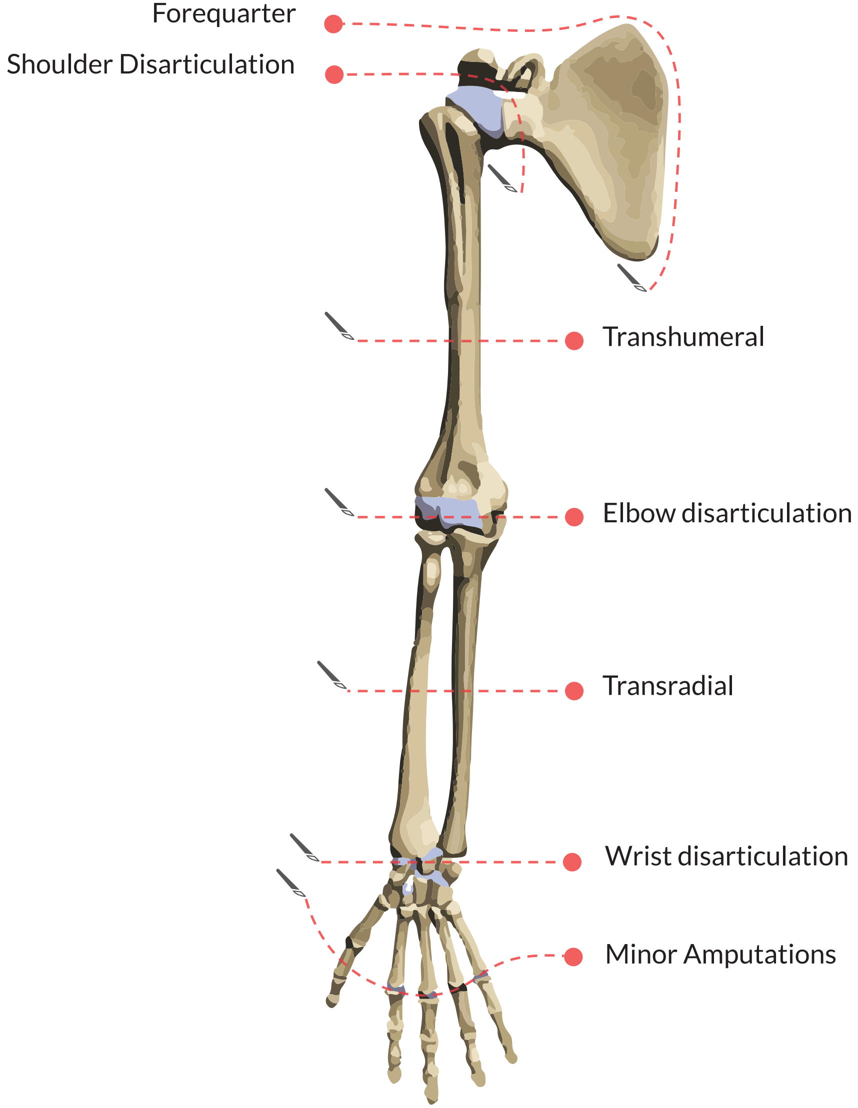


Figure 20 Arm amputation levels

2.5.2 Minor Amputation

Amputations that can include fingertips, and parts of the fingers. Being more precise, minor amputation can be related with the following levels of lack of functionality:

- ***Partial Hand:*** At least one metacarpal bone, accompanying a digit or digits.
- ***Metacarpal phalangeal disarticulation:*** Absence of metacarpal phalangeal joints of digits 2-5.
- ***Thumb amputation:*** Totally amputation of the thumb. This level of amputation is considered like one of the most common. Lack in thumb restrain the possibility to grasp, manipulate or pick up objects.
- ***Phalangeal amputations:*** Lack of all or part of phalanges 2-5.

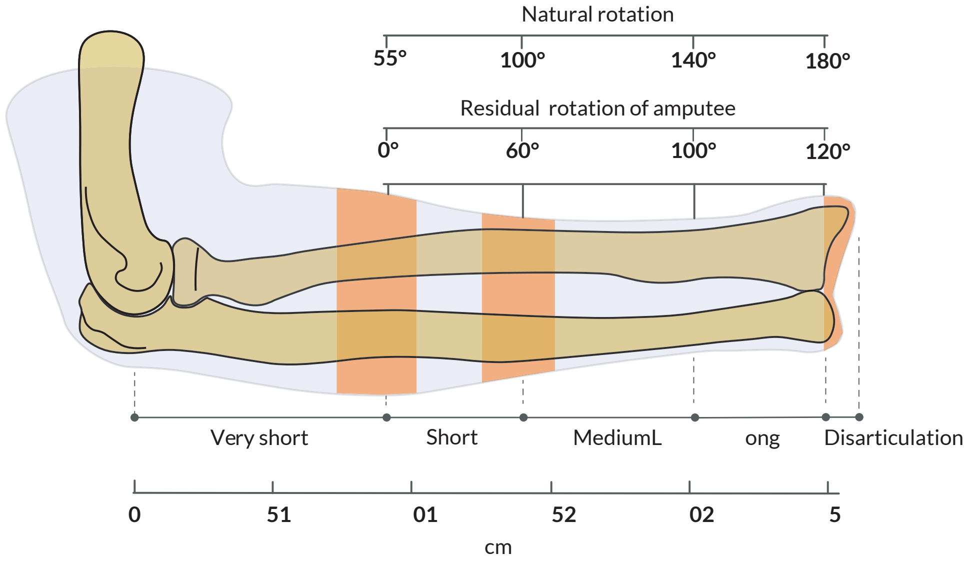


Figure 21 Transradial amputation level

2.6 Suspension Methods

In the arm, continuous suspension of the prosthesis is needed to overcome the tendency of gravity to disconnect it from the stump. [27]

To solve this, different methods to suspend the prostheses have been used along the time:

- Straps
- Prominent bones enveloping
- Silicone sockets
- Osseointegration

The design of the interface stump-prosthesis become a critical point in the functional conception of an entire prosthesis. In high fidelity interfaces, not only the elbow is used to anchorage, compression areas above the release tissue are used to improve the suspension conditions.

With the emergence of the myoelectric devices, the design of prostheses turned to the idea to avoid any kind of external suspension element to encourage an easier donning and doffing and increase the range of movement of the arm articulation.

2.6.1 Transradial Sockets

As is mentioned in the initially, the scope of this project will be related directly with the development of a trans-radial prosthesis. Therefore, all the medical and scientific definitions from now on, will be related directly with this amputation level.

In order to have a most precise description of the arm parts related with the design of the different kind of prosthesis sockets, will be used the following abbreviations:

- ROM : Range of motion
- A/P: Anterior - Posterior
- M/L: Medial – Lateral

- ***Muenster - type socket***
  Socket designed by Hepp and Kuhn in the mid-20th century, that was specifically designed for short trans-radial amputations.

  Its focused on anterior/posterior (A/P) compression stability at the proximal brim (in the cubital fold).

  This kind of socket is self-suspending with a supracondylar rim enveloping the epicondyles of the humerus. It is a full contact socket enveloping both epicondyles and fixed by muscle tension.[28]

- ***Northwestern University supracondylar suspension technique (NWU)***
  Designed by Billock in 1972, was specifically designed for longer residual limbs and is considered to obtain more medial/lateral (M/L) compression stability proximal to the epicondyles.

  This design relies primarily on compression in the M/L plane superior to the epicondyles with less restrictive A/P trim lines.

  This technique takes care to the biomechanics of socket design as it relates dynamically to the range of motion (ROM) of the residual limb.

- ***3/4 Socket design***
  Proposed by Sauter in 1986. Conceived by its creators recognizing the necessity to provide a socket that allows an easy release of the temperature in the stump area.

  The ventilation problem is overcome through the removal of proximal-posterior portion of the socket. The suspension characteristics and the flexion range movement are widely improved.

  Additional advantages are related with the increase in the ease of donning, greater range of movement and an enhance of proprioception*.

****Proprioception:*** *The ability to sense stimuli arising within the body regarding position, motion, and equilibrium. Even if a person is blindfolded, he or she knows through proprioception if an arm is above the head or hanging by the side of the body. The sense of proprioception is disturbed in many neurological disorders. It can sometimes be improved through the use of sensory integration therapy, a type of specialized occupational therapy.*

- ***High-performance variable suspension prosthesis (HPVSP)***
  Design by Radocy, is a trans-radial supracondylar socket -a modification of Munster design- that is combined with Icelandic Roll-On Silicone socket (ICEROSS) suspension technology.

  It works like an alternative for short to mid length trans-radial amputees who demand rigorous sporting activities and need increased the versatility.

  Combination of supracondylar socket and silicone liner, provide superior suspension, improving the functional performance.

- ***Wilmer open socket***
  Tubular open socket introduced by Prettenburg in 1998. Designed by Delft University of Netherlands, has a totally new fitting procedure that meet the disadvantages of the Muenster socket.

  It is made of soft-covered stainless-steel tubes and support the arm only at the minimal fitting areas that are required for a good socket fixation.This design is strong enough to transmit force and motion between the residual limb and the prosthesis. A good ventilation is provided to the skin caused because the open construction. Furthermore, an easy donning and doffing characteristics and the possibility of the elbow to have contact with its surroundings, complete the set of benefits of the design.

- ***Anatomically Contoured And Controlled Interface (ACCI)***
  Introduced by Alley in early 1990s, the ACCI increase the anterior-posterior (A/P) and medial-lateral (M/L) compression but focusing the pression in different areas.

  ACCI controls axial rotation by extending the medial and lateral stabilizers more proximally than in previous designs and adding supracubital fossae anterior and proximal to the humeral epicondyles. These characteristics avoid the often-reported discomfort in the standard designs that suspend directly proximal to the epicondyles.

  The ACCI design adds radial channels to the distal volume to help to increase the rotational stability and ensure sufficient soft tissue contact along the length of the entire limb throughout all ranges of motion.

  Compared with previous socket designs, ACCI differ in how well the interfaces perform under heavy loading, specially in the initial stages of flexion.

- ***Transradial Anatomically Contoured (TRAC)***
  Based on Muenster and Northwestern socket designs, TRAC socket has a more aggressive interface contouring the arm anatomy, with the idea of maximizing the load in the tolerant areas of the residual limb.

  Even it looks like a Muenster socket, differs in the fitting technique: TRAC socket counts with an inner shell made in flexible material.

  As biomechanics characteristics, TRAC use anterior-posterior (A/P) and medial-lateral (M/L) compression augmented by contouring of the musculoskeletal presentation distal to the cubital fold for enhanced comfort and stability.

  Another advantage of this design is an increase in the elbow's ROM, compared with the Muenster and NWU designs.

  TRAC addresses the deficits of previous designs by contouring five important areas:

  - Antecubital region
  - Olecranon region
  - Epicondylar region
  - Distal radial region
  - Wrist extensor and flexor musculature

  Later modifications based on 3/4 socket design, increased the stability and suspension, because a more aggressive supra-olecranon contouring.

- ***High Fidelity Radial Interface***

  Proposed by Randall Alley in 2011 makes use of the compression-release stabilization (CRS) technique, that is focused on control of the entire underlying bone along their entire length through alternating soft tissue compression and release.

This socket create longitudinal depressions added to the socket walls and open release areas between the depressions to receive the displaced tissue. To reduce the lost motion between the bone and socket wall, this technique correctly places three or more longitudinal compression areas along nearly the entire shaft of the bone, while the release areas allow for soft tissue to escape out of the fields of compression; compression should be a little larger in the center of the bone before a load is applied at the end of the socket to result in a uniform load along the residual limb bone.

Compression bar length should be adjusted in terms of each patient, to allow an adequate blood flow in the stump.

- ***International Transradial Adjustable Limb (ITAL)***

Proposed by Alwyn Johnson in 2009, provides an affordable and functional option for amputees in the United States and developing countries.

It makes use of a variable compression technique, adjustable below-elbow interface geometry, a new body-powered prehensor with adjustable pinch force, control harness and cable.

Also called Johnson-Veatch interface (JVI), incorporated variable compression and variable geometry with an open frame, in contrast to a full-contact socket. With modular two-component interface comprising a humeral cuff and forearm adaptor that can be manually adjusted with simple hand tools.

In terms of biomechanically characteristics the ITAL or JVI, provides its biggest suspension thanks to the humeral cuff, iteratively designed to be comfortable under considerable loads.

Interface stability is obtained by the cuff's three-point contact with the M/P (medial – posterior) condyles and olecranon process. The supracondylar cuff length can be adjusted medially and laterally to effectively minimize rotation and migration below the condyles and prevent point loading on the humerus.

ITAL/JVI suspension systems can suspend static axial load of up to 15.88 kg. Its low cost is related too, with the easy maintenance and fitting characteristics.

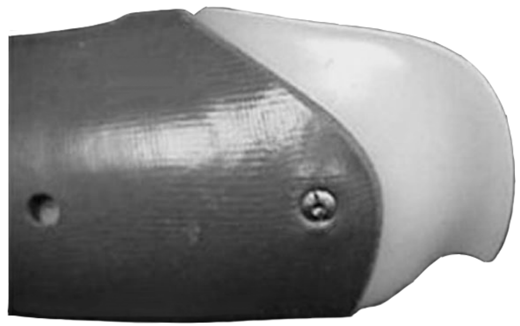
- ***Plastic Soda – Transradial Sockets***

Proposed by Wu in 2009, presents the possibility to design temporary low-cost trans-radial sockets using reusable material taken from soda PET bottles.

The manufacturing process takes the positive plaster model of the stump, modified in the interest areas (compression areas) for suspension, and use a heat gun to deform the thermoplastic over the mold. To form the socket, the shape is cut along the trim line. To adding comfort, a silicone pad can be inserted inside the socket.

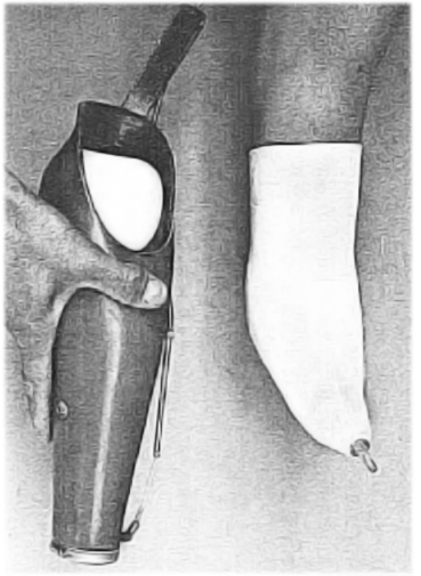
Offering light weight characteristics this proposal is suitable for use with cosmetic passive hand prosthesis, and as functional alternative for handicap people in third world countries. [29]

Muenster - type socket

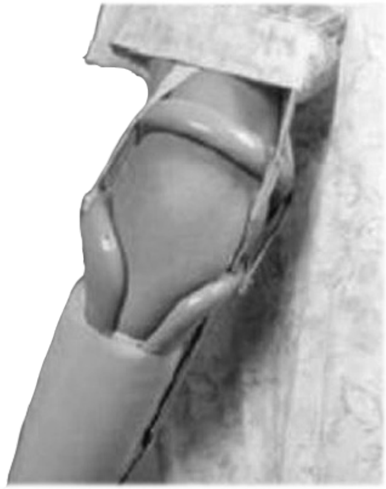


Northwester supracondylar suspension technique (NWU)

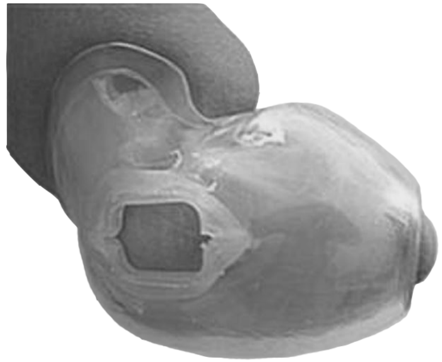
3/4 Socket design



HPVSP



Wilmer open socket



ACCI

TRAC

High Fidelity Radial Interface

ITAL

Plastic soda socket

Figure 22 Transradial Sockets

2.6.2 Silicon sockets

The introduction of silicone suspension methods in latest 80's, opened a new functional opportunity, taking advantage of the vacuum generated between the residual stump and the prosthesis socket wall. Rolled onto the residual limb, the silicone socket adheres to the skin by the vacuum and friction.

In addition to improving the suspension characteristics of prostheses, silicone sockets encourage the stability of the interface and provides a greater range of movement (ROM) for the prostheses, compared with the standard modes of suspension.

Over the time, several configurations of silicon sockets have been proposed but there are two basic construction methods that are particularly representative:

- Totally silicone molded (components molded inside the silicone)
- Hybrid construction (silicon interface attached to a laminated frame)

Devices that could include pin-locking mechanisms or small suction cups, are part of the different concepts generated because continue biomedical research works.

However, one of the most important issues related with the use of silicon socket is the body heat dissipation mechanism, and the effects of perspiration and sweating on the skin.

Amputees have less expose area to cooling down the body temperature. In this sense, natural body radiation, sweating evaporation and heat conduction become more complicated than usual with the use of silicon sockets. As a result, a notorious moisture increase in the stump area could carry out initially skin irritation and in the worst-case cutaneous infections.

Problems as folliculitis caused because poor or extremely precise fitting prostheses, soreness caused by the pulling action of the liner and allergic reactions like dry, rash or irritated skin generated from chemical adverse reactions with the liner fabrication materials, are the most common complications in patients that use silicone sleeves as prosthesis suspension method [30].

a) b)

Figure 23 a) Ottobock silicone arm liner b) Alpha Classic Willow Wood Liner

2.6.3 Breathable Liner

A continues develop in the science of materials, has allowed the design of breathable liners, that implement a combination of 3d fabrics with partial silicon coating for suspension [31]. Through this technology, the limb skin can regulate easily the temperature, thanks to the gas and humidity permeability characteristics of the material. An antibacterial effect is added to the inner part of the sleeve using fibers that include silver ions to prevent bacterial growth.

Peaks of pressure and shear forces in the limb are counteract thanks to the cushioning effect of the fabric layers.

Proper functionality of the arm liner is directly related with an appropriated prosthetic socket geometry.

Particularly, the use of open frame prosthetic sockets encourages an easy donning and doffing and could offer improvements in the limb ventilation. Hygienic conditions are overcome, thanks to the easy wash-ability of these kind of liners.

Figure 24 Breathable Liner

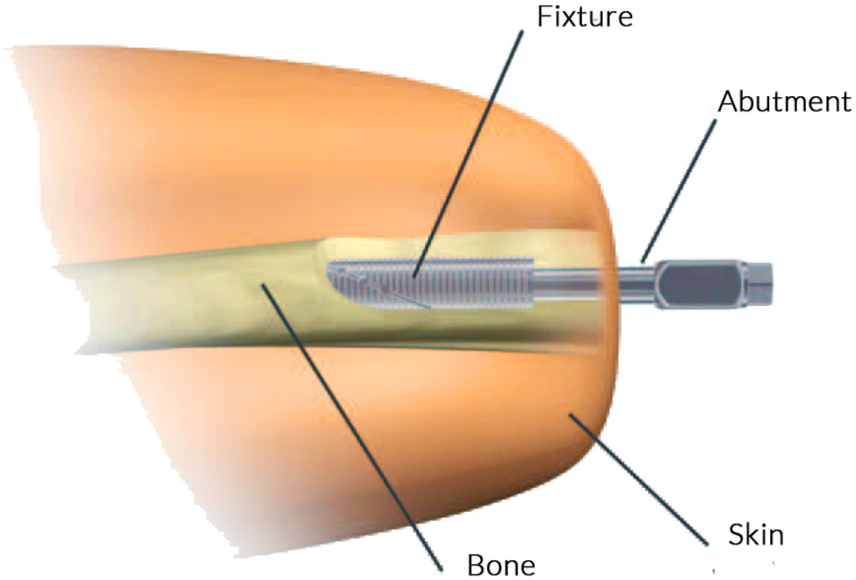


Figure 25 Osseointegration Suspension Method

2.6.4 OSSEOINTEGRATION

Based on the clinical dental procedures for maxillofacial implants, the osseointegration program for extremities, was born at the beginning of 90's in Sweden. Its involves the direct contact of titanium components with the bone tissue aiming a stable connection between the prosthesis and the residual limb [32].

Because with osseointegration the necessity of socket is eliminated, conventional socket problems like perspiration, heating dissipation and lose in range of movements are solved issues, becoming the breakthrough advantage of this technique.

Patients with different levels of amputation, have been treated with osseointegration procedures. For upper extremity absence almost all the levels of amputation can be managed with this method: trans-humeral, trans-radial and thumb amputation.

In the case of inferior limb amputees, transfemoral amputation is the type of amputation treated with this technique.

However, even osseointegration can improves substantially the entire performance of a prostheses system, medical conditions of the patients -as diabetes- combined with the sequence of surgeries carrying out by the specialist, can become reasons of procedure patient rejection.

In the worst of the scenarios, skin infectious reactions like marsupialization*, permigration** and avulsion***, can appear after the titanium components have been implanted. [33]

**Marsupialization:* *Epidermal downgrowth. The epidermis grows internally along the percutaneous post creating a sinus tract surrounding the implant.*

***Permigration:* *Marsupialization with porous percutaneous post. The implant extrudes as the post fills with cell debris.*

****Avulsion:* *The implant teating away of the soft tissue due to externally applied mechanical forces*

2.7 Customizable prosthetic devices

Taken from many projects that currently relate the use of 3D printing technologies with the biomechanical and prosthetic production sector, are presented below those that provide a representative conceptual contribution to the thesis topic to be developed.

2.7.1 Open Bionics – Hero Arm Project

Open Bionics is an English company, founded in 2014, based on Bristol – UK, focused in the develop of affordable assistive bionic devices.Their mission is provided a stylish and more beautiful solution to the market of upper limb prostheses, make them economically more accessible.As part of the Hero Arm Project, its products are centered in the following features:

- Integrated prostheses system (hand, frame and socket) all in one.
- Lightweight (less than 1 kg)
- Breathable stump sockets
- Removable sockets for maintenance
- Compressible and expandable sockets' materials
- Long lasting battery
- Multi-grip versatility
- Freeze mode (holding statics positions)
- Feedback suite tools (lights, sounds and vibrations) about the status of the prostheses.
- Custom covers
- Posable wrist and thumb
- Proportional control of the fingers' speed

Open Bionics offer 5 different concepts of prosthesis' cover, available for right and left hand. All the prosthesis' covers that company offers, are totally customizable (through the web site) in terms of color and textures. The materials in which are made these 3D printed covers are recycled PLA plastic or SLS Nylon, according the user requirement, and their weight turns around the 150 grams
In general, the bionic hand is divided in 3 segments in which it is possible to customize the color. The online store platform allows to choose the different color options and cover details.

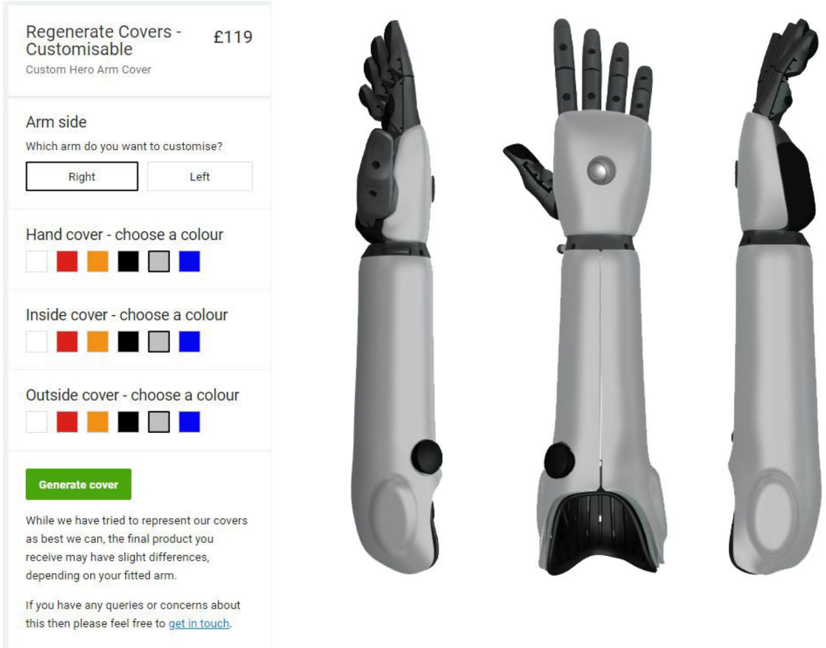


Figure 26 Open Bionics designs

2.7.2 Ottobocks – Michelangelo Prosthetics Hand & SIOCX TR Sockets

Ottobocks is a german company with almost 100 years of tradition in the market of orthopedic products. Founded in Berlin in 1919. Its mission has been provided to handicapped people the opportunity to have a better life quality in terms of mobility and independence.

In its beginnings Ottobocks started like a supplier of prosthesis to the World War victims, but with time became as one of the leader companies in the prosthetically market, introducing technological innovations and make them available for people.

Prosthetics division is the largest business unit of Ottobock (reference), and its distribution and services companies are in about 50 countries around the world.

Michelangelo prosthetic hand, in terms of upper limb devices, is the technological synthesis of knowledge about natural movement patterns and biomechanical relationships. Using myoelectric sensors, detects the muscles signals and allows the control of five movable fingers, including the thumb. Quick, precise and reliable movements are the characteristics of the grasping modes of the prostheses.

As part of the upper limb prostheses division, is comprised the area of Socket Technologies. This area deals with the way to connect the prosthesis to the human body, taking the best advantage of all the available technological resources. The right combination of liner and closure systems is considered essential for a successful prosthetic fitting.

In the last years Ottobocks has developed the SiOCX TR socket, design that meet the requirements of functionality, comfort and hygiene, enable the user to use the entire prosthesis for longer times than usual.

As part of Michelangelo hand prosthesis project, the characteristics of the socket are centered in the following features:

- Use of HTV silicone in the inner socket to encourage an excellent adhesion on the residual limb
- Different degrees of silicone hardness with integrated gel pads to reduce pressure in the stump sensitive areas
- Flexible sections for the inner and outer socket increasing the range of movement and adaptability.
- Easy to clean and maintain (hypoalleargenic and breathable material)
- Integrated electrode contact surfaces (electrodes do not have direct contact with the skin to reduce irritation)
- Individual and aesthetical customizable design
- Optimum hold thanks to the medical grade silicone inner socket

Figure 27 Michelangelo Upper Limb Prosthesis

Figure 28 Socket SiOCX TR

2.7.3 Glaze Prosthetics

*Glaze Prosthetics is a Polish company dedicated to the design of aesthetical upper limb prosthesis, with a futuristic concept of uniqueness in terms of finishing, color and textures. Its particular innovation lies in the introduction of external multifunctional gadgets (speaker, power bank and phone case), that transform the general idea of an orthopedic tool, to an element that become part of a personal identity.

Customizable in terms of shape and size, offer a quick way to put on and take off, replacing the way of how looks in seconds and depending the mood of the user.

Glaze Prosthetics designs offer:
- Matte, gloss, rough print, silicone or leather finishing
- Angular control
- Interchangeable mechanism
- Two aesthetical references: Sport and Smart model

Current designs are not biomechanically functional.

2.7.4 Fabrilab

**Fabrilab is a Colombian start up, created from the union of three companies dedicated to the develop of projects using 3d printing technologies, in Latino America. With more than five years of experience in Colombia are considered like pioneers in the use of these technologies in the country.

Using 3d print techniques, Fabrilab has develop projects in the healthcare area, where are included: myoelectric and mechanical hand and upper limb prostheses, and latest works for inferior limb prosthesis. Furthermore are dabbling in the conception of products for visual and rheumatism handicap's people.

Its essential philosophy lies in the develop of free-cost upper limb prosthesis for children that do not have the possibility to get these kind of technological devices, sponsored by crowd founding campaigns and particular donations.

Their aesthetical concept encourage a quick psychological acceptance of the patients, relating the prosthetic device with a cartoon or super-hero movie

Figure 29 Glaze Prosthetic designs

***Web site :** *https://glazeprosthetics.com/*

****Web site :** *http://fabrilab.com.co*

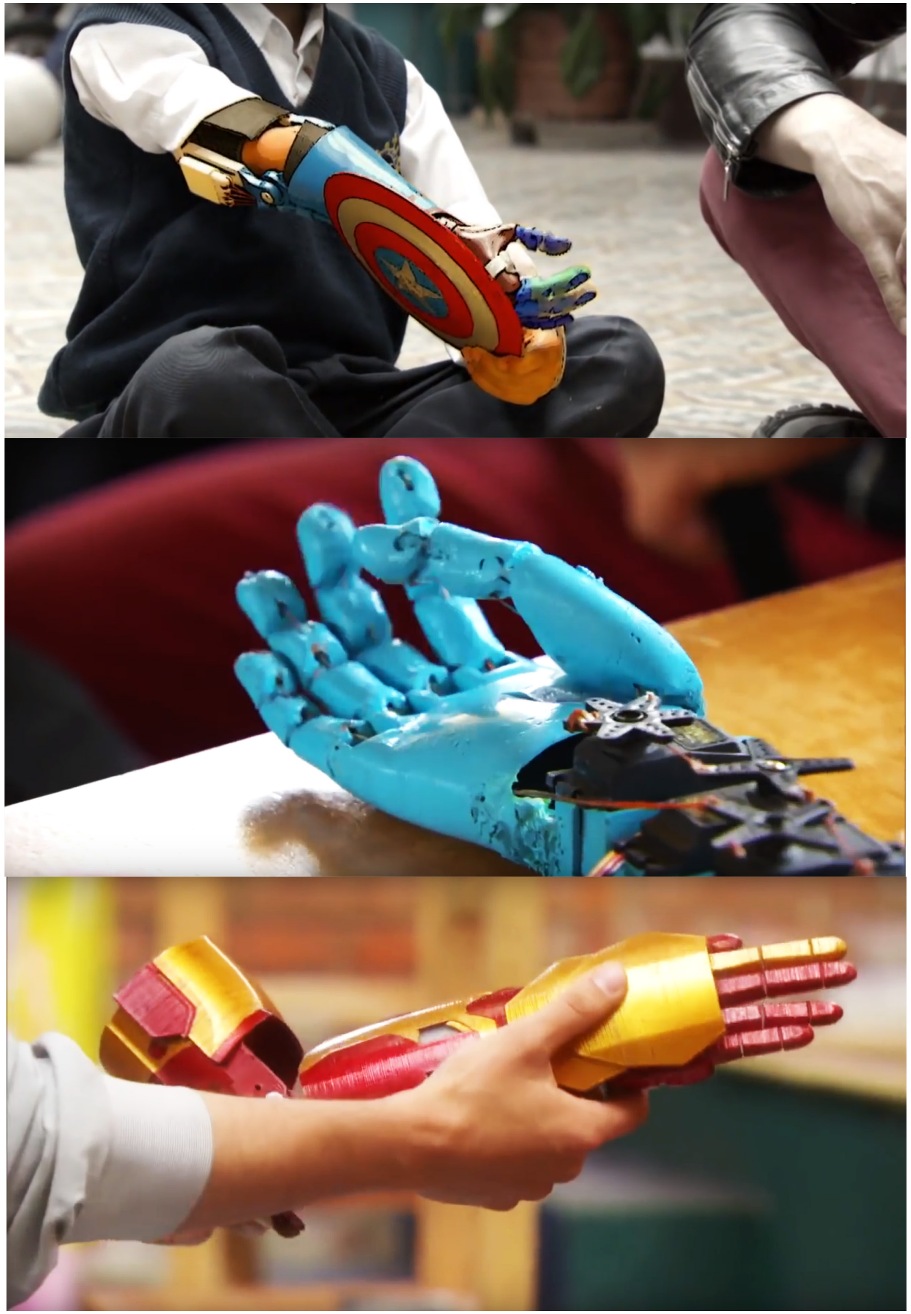


Figure 30: Fabrilab functional myoelectric prosthesis

character. Apart from that, the patient is guided through an entire process of orthopedically rehabilitation.

2.7.5 Exo Prosthetic Leg

Project carried out by ***Will Root, that propose a new way to make inferior limb prosthesis, using modern automated technologies, leaving aside expensive and laborious traditional “handcrafted” processes.

By replacing the complexity of traditional prosthesis – regard quantity of parts- for a single 3D printed exoskeleton, the leg no longer becomes a robotic and inhuman compilation of parts but rather a customizable intimate addition to the body.

The Exo-Prosthetic use a combination between 3D scanner, 3D printer and complex 3D modelling software to automatize the entire process of production, customizing the final shape in terms of the user requirements.

According to the project, the Exo-Prosthetic is printed out of titanium, which offer lightness and long lasting characteristics in terms of wearing and mechanical stress.

Affordability and a breakthrough aesthetic device are considered like the innovative additional .

2.7.6 Alleles

Alleles is a Canadian design studio whose mission is related with help amputees to express their creativity, individuality, and confidence through providing cosmetic options for their prosthesis. Being influenced by the eyeglass industry, Alleles use fashion and design to transform prosthetic cosmesis from a medical device into a new stream of fashion [34].

Primarily, Alleles produced prosthetic cover for lower limb prosthetic devices, but recently had added into its portfolio the upper limb prosthesis cover, centrered specifically in Rivo, Symes and osseo-integrated type of devices.

Average prices of manufactured accesories, are around the 550 dollars, and are totally customized according the user requirement.

****Web site :** *http://willrootdesign.com/exo-prosthetic-leg*

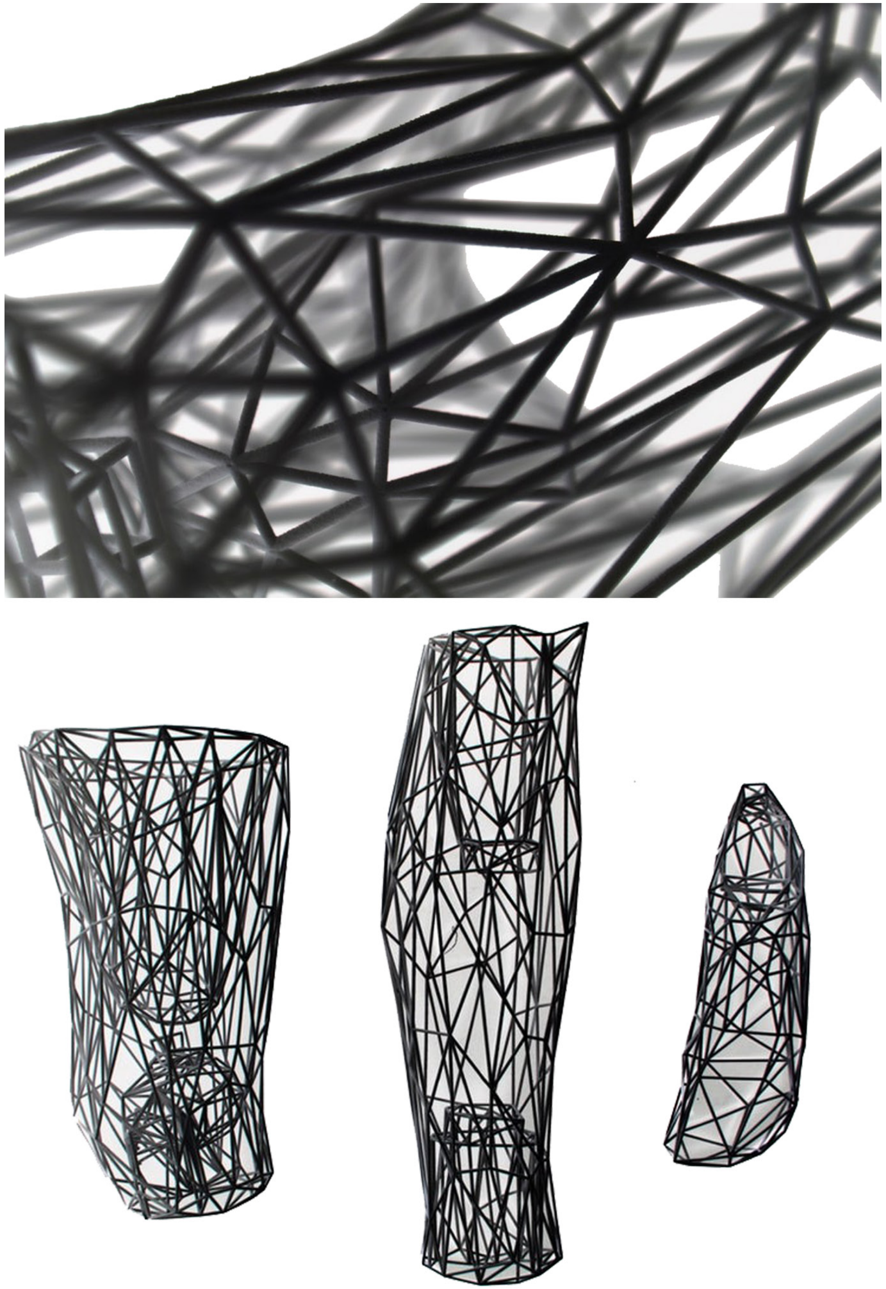


Figure 31: Exo Prosthetic leg

*Figure 32 ALLELES arm cover**

***Web site :** *https://alleles.ca*

3

CAD MODELLING TECHNIQUES

This chapter presents a brief review of software tools used during the project developing, and its relation with the specific approach faced to solve the problem initially raised. A special emphasis is dedicated to the use of generative CAD geometries and its inspirational bases along the design and architecture history.

3.1 REVERSE MODELLING

Reverse modelling is defined as the method that reconstructs CAD models from physical models [35]. The entire process follows a sequence of steps that start with the data acquisition, data preprocessing, surface fitting and making the CAD model. The application of this technique is used into the project as the initial point of the modelling process, because allow to take the geometrical constraints that relate the user with the final product.

Because the not availability of 3d scanner equipment on the field, data acquisition was implemented using photogrammetry, making use of standard photographic equipment and Agisoft Metashape Photoscan, as reverse modelling software compiler.

Owing to the fact the project is directly related with the human shape, a reverse modelling approach fits properly with the objective of start from and existing shape (patient stump), digitalizing the area of interest, and offering functional solutions based on a design concept.

Referring to the medical field, specifically in the areas of dentistry and orthopedics, reverse modelling works as an alternative way to work, that allows to reconsider traditional and time expensive processes (clay modelling, intrusive procedures, etc.). 3D model shapes generated by reverse modelling methods, can fit perfectly and be integrated into existing body structures, encouraging a new paradigm on manufacturing processability relied in a high percentage on CAD resources.

Several software products were analized to face the reverse modelling phase of the project. A selection between ReCap Photo from Autodesk and Agisoft Metashape Photoscan, tipped the scales in favour of Photoscan, because its powerful capacity to recognize mark points by itself, and the possibility to generate a good 3D cloud points even the quality of input data (pictures) did not fit with strict quality conditions. A short review of the software is shown as follows

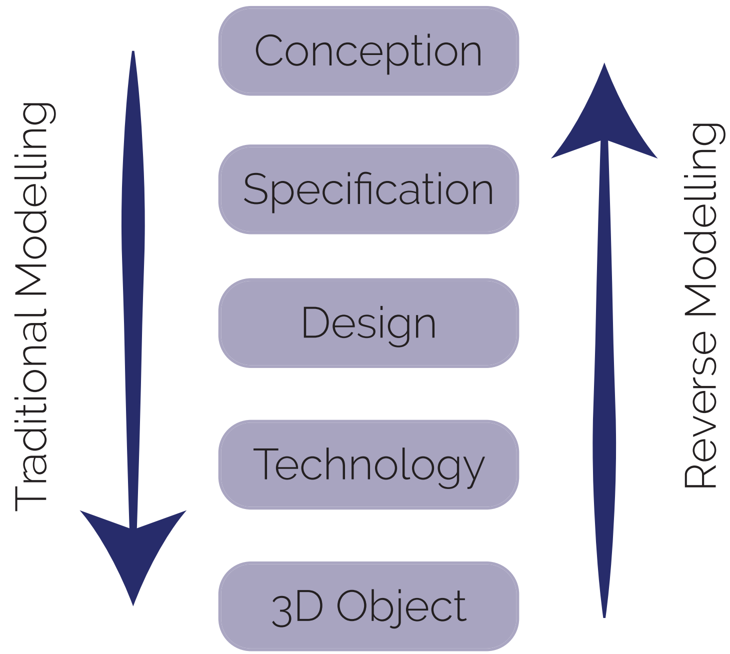


Figure 33 Traditional and Reverse modelling workflow

3.1.1 AGISOFT METASHAPE PHOTOSCAN

Agisoft Metashape is a software product that performs photogrammetric processing of digital images and generates 3D spatial data, possible to use in geographical information systems, cultural heritage documentation, visual effects and measurements of objects at different scales [36].

Photoscan allows to process images from RGB or multispectral cameras, including multi-camera systems, into dense point clouds and texture polygonal models

A standard version can manage photogrammetric triangulation, dense point cloud generation, panorama stitching, and 3D model generation and texturing.

This latter feature was used to rebuild the patient stump shape from a set of pictures taken on the field.

For more information about the product, you can visit its web site https://www.agisoft.com/.

Metashape

*Figure 34 Agisoft Metashape 3D modelling**

3.2 Generative design

Computational tools have introduced innovative form-finding techniques, that have come revolutionized the architecture, design and production world. These techniques are often described by terms such as "generative design", "parametric design" or "algorithmic design"[37].
Predictable relations between form and representation are broken, and a new paradigm in favor of computational complexities is open, encouraging the discovering of new topologies. Transforming the design based in "form making" to form finding.[38]
That design paradigm change, can be face from different perspectives, depending of the project characteristics, technological resources available or simply based in the designer approach. But are four widely distinguished approaches, whose had traced a path in what is called today generative design. These are:

- ***Design driven by nature:*** Inspirated in what is called nature-inspired architecture (rised up in 1920, and continuously developed at 60's and 70's). The idea is trying to translate living organisms' processes into architecture and design, not just as form and appearance inspiration but emulating its functional mechanisms. *Figure 35*
- ***Design driven by geometry:*** Based in the use of geometric proportion rules as tool to generate unexpectable form results. Architects as Louis Sullivan, Frank Lloyd Wright and Le Corbusier used into its projects, principles describe above. *Figure 36*
- ***Design driven by context:*** Based in the generation of geometries related with the morphological and typological characteristics of the place where will be located. Aldo Rossi and the use of basic shapes commonly found in Italian cities (octagon and colonnade) is a good example. *Figure 37*
- ***Design driven by performance:*** Approach that search the minimal possible form, base on material properties and structural performance. Context does not affect the final shape. *Figure 38*

*Figure 35 ICD-ITKE Research Pavilion**

*Figure 36 Expo 1958 Philips Pavilion***

*Figure 37 Teatro del Mondo - Aldo Rossi****

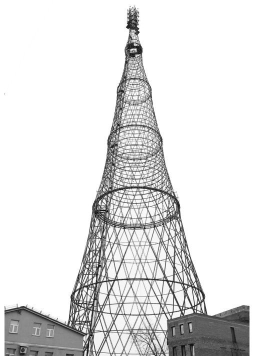


*Figure 38 Shukhov Tower*****

Today, more affordable digital modelling techniques besides an easier access to simulation software, dominate the creative scenario of generative design. Tools as Rhinoceros, Grasshopper, Netfabb and Fusion 360 for example, go through a base workflow that according to Lazzeroni, Bohnacker [39] stablish a continuous information feedback exchange between the computational tool and the designer.

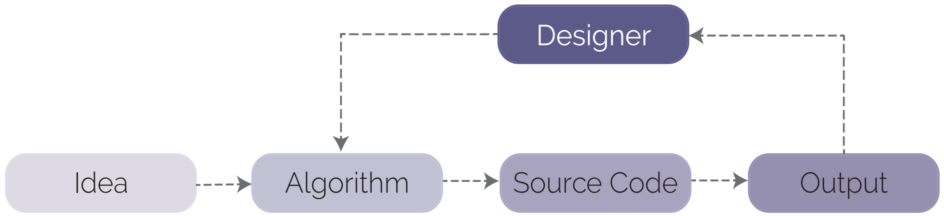


Figure 39 Workflow Generative Design (Lazzeroni, Bohnacker)

For the project, design and engineering input goals are setup along with functional loads, materials, and manufacturing methods as parameters. Software are not just in conditions to do the topological optimization, but to explore all the possible combinations for a problem solution, testing in each iteration which solution works and which not. Entirely driven by performance, the design conditions of the thesis project, fit better with the generative design plugin of Fusion 360. Some characteristics of the software are explained below.

3.2.1 Generative Design - Fusion 360

Generative Design's Fusion 360 plugin is a powerful tool that allows generate high performing design alternatives from a single set of conditions. The possibility to choose among hundreds of solutions brings to the designer the confidence to solve the functional requirements and choose the model that fits better into its needs.

Contrary to a traditional design process, where a design team starts with

Taken from:
***Web site :** https://icd.uni-stuttgart.de/?p=18905*
****Web site :** Own source, by Wouter Hagens*
*****Web site :** http://www.jmvvaloracion.com/2015/09/venecia.html*
******Web site :** https://archpaper.com/2016/09/moscow-constructivist-architecture-map/shukhov-tower/*

an initial design based just on form factor, generative design from Fusion 360, integrates important design values of a product as function and manufacturability process[40]. A comparative graphical shown as follows, can depict better a comparison in terms of time production, carrying out using both methods.

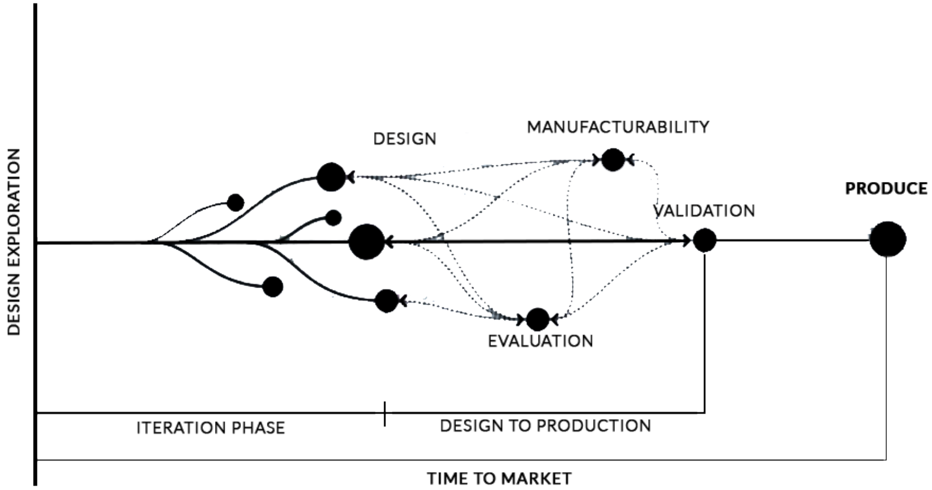


Figure 40 Traditional design method - From Autodesk Fusion 360

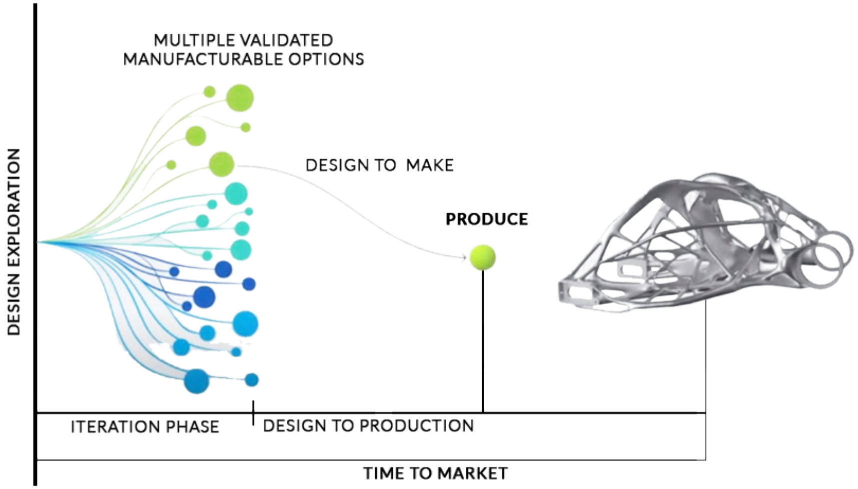


Figure 41 Generative design method - From Autodesk Fusion 360

A time production reduced, and a wide variety of performing options, give better decision tools to design teams, streamlining the whole design process from the beginning to the final market product.

Furthermore Fusion 360 promotes an effective and flexible workflow that is characterized by the setting of the following steps:

- *Loads definition:* What will the design do?
- *Material selection:* Which materials to use?
- *Manufacturing processes setting:* Which manufacture techniques are available?
- *Product performance:* How strong must it be?

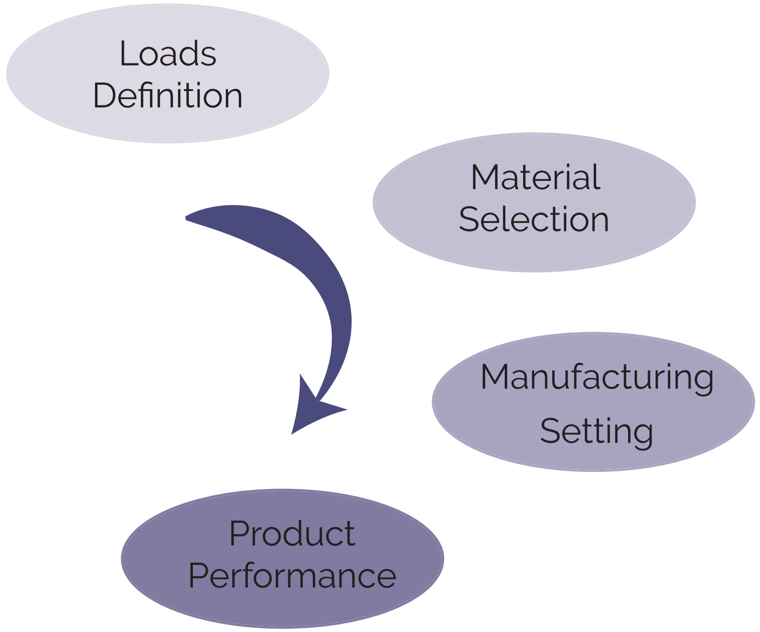


Figure 42 Fusion 360 Generative Workflow

Generative Design from Fusion 360 is applied in different technology fields. Some of the most outstanding areas are:

- *Automotive*
- *Aerospace*
- *Consumer goods*
- *Architecture and construction*
- *Industrial machinery*
- *Building products*

For the case of the project, a new set of application is open in orthopedics and prosthetics field and is specifically used in the modelling of a biomimetic bone structure, that supports the forearm prosthesis.

3.3 OTHER PARAMETRIC AND MESH DESIGN TOOLS

Apart from the previous software tools mentioned, the project makes use of additional software to accomplish the target of bring a design solution to the problem posed. These tools compressed the mesh modelling refining, the parametric CAD modelling and a later product final visualization.

For each of the mentioned phase were used respectively: Autodesk Meshmixer, ReCap Photo, Fusion 360 and Keyshot. A flow diagram describes better the tools used in each stage of the project realization. *Figure 43*

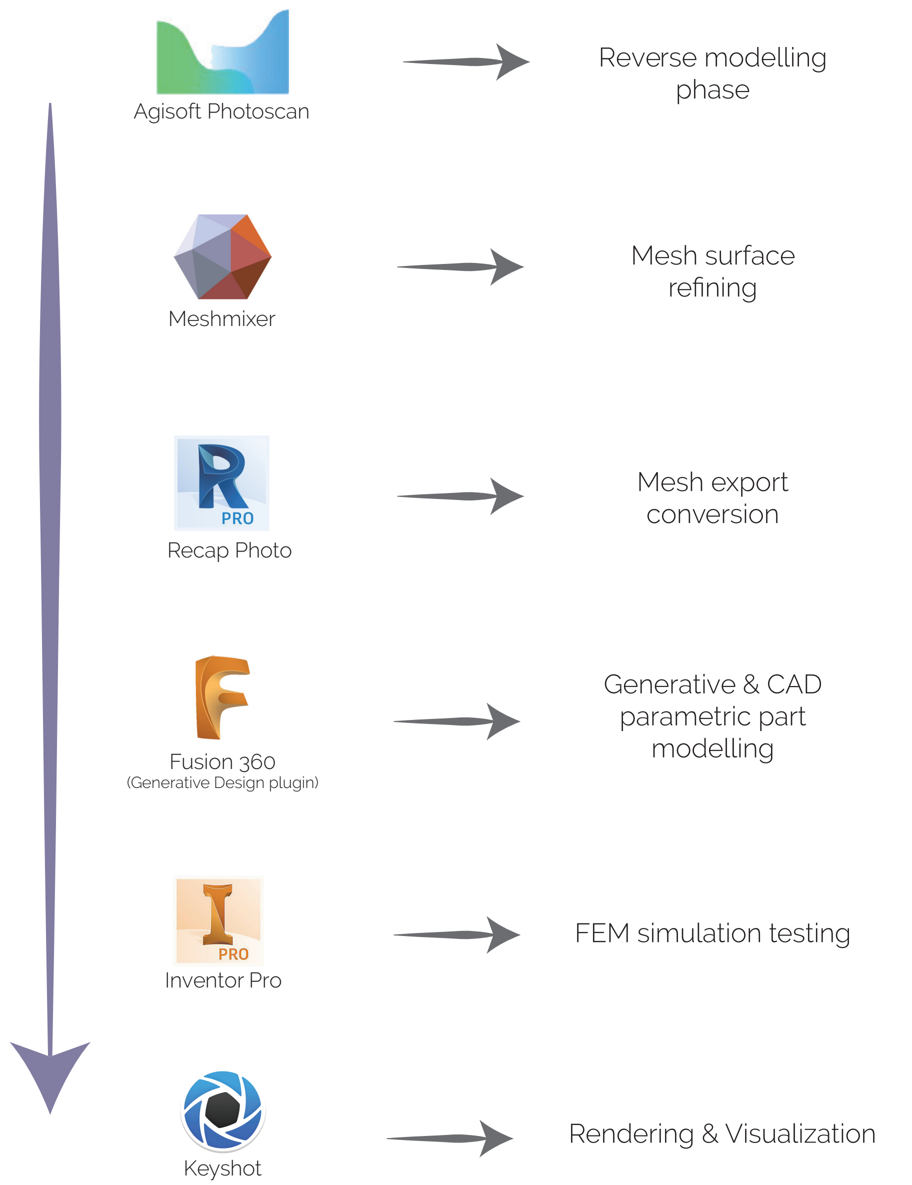


Figure 43 Software Design Routine

4

3D PRINTING TECHNOLOGIES

This chapter presents a general overview about 3d printing technologies, explaining the different developed techniques, additive manufacturing equipment available at Politecninco di Milano headquarters and the characteristics of material that can be printed in the equipment described .

4.1 GENERAL DESCRIPTION

Three-dimensional (3D) printing is defined as an additive manufacturing and solid freeform fabrication method used to fabricate high complex geometries without molds or tools. It involves a layer-by-layer raw material addition (liquid, powder, or sheets) fabrication process based on 3D computer aided design (CAD)[41].

The sequence of a typical 3D printing process starts with a CAD model (modelled by software or obtained through reverse modelling methods -3D scanning-). Then the model is converted in a stereolithography file to be read by a software that digitally slice the model in layers. The code generated will be follow by the 3D printer layer by layer to reproduce the part.

The schema in *Figure 44* explains graphically the sequence of steps, in a typical 3D printing manufacturing process.

Highly flexible, 3D printing can be scaled for low and mid manufacturing volume. But even the fact 3D printing is revolutionizing the industries as a rapid prototyping tool, the massive production of functional parts is not extended yet. However, some statistical surveys, shows that approximately more than 10% of parts could be manufactured with higher efficiency using this method[42].

A clear example of application of 3D printing technologies is the biomedical industry, where projects are constrained to conventional manufacturing processes, but it exists the necessity to reproduce complex biomorphically shapes, because the user. Additive manufacturing can arrive, with all its available techniques (rapid prototyping, reverse modelling, etc.) as an attractive and alternative way to solve that manufacturing issues.

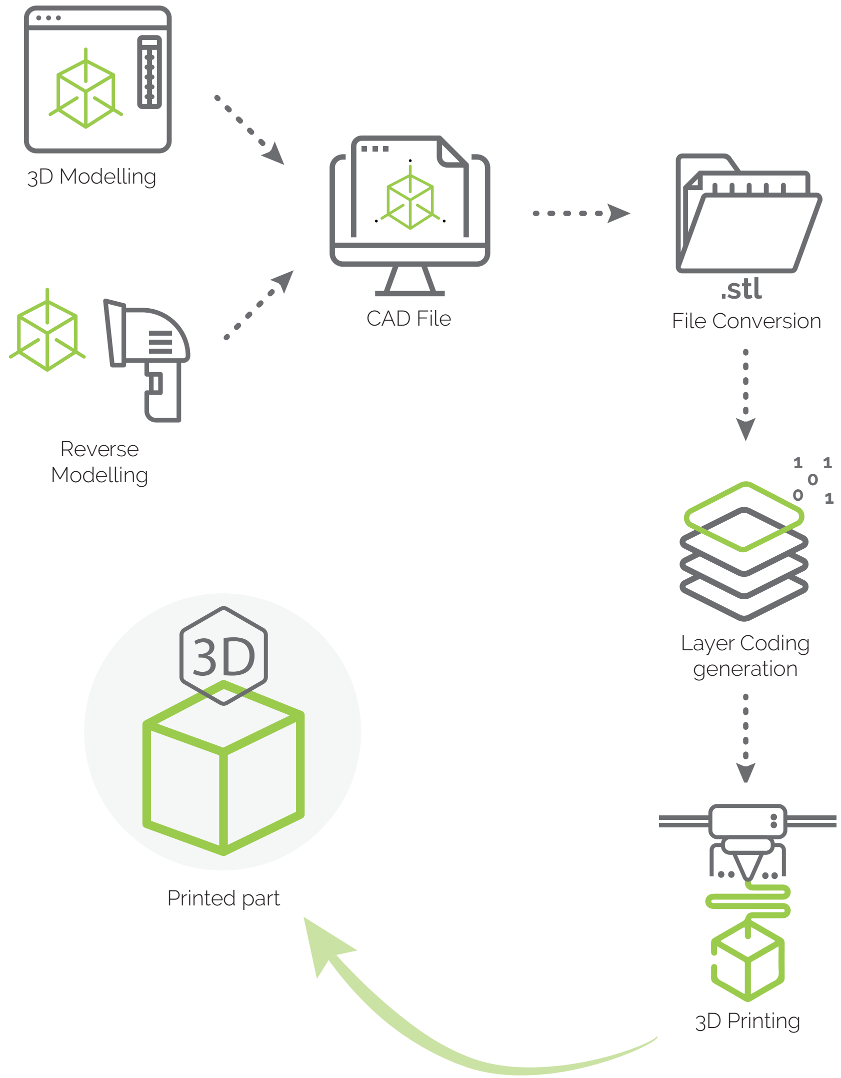


Figure 44 3D printing process sequence

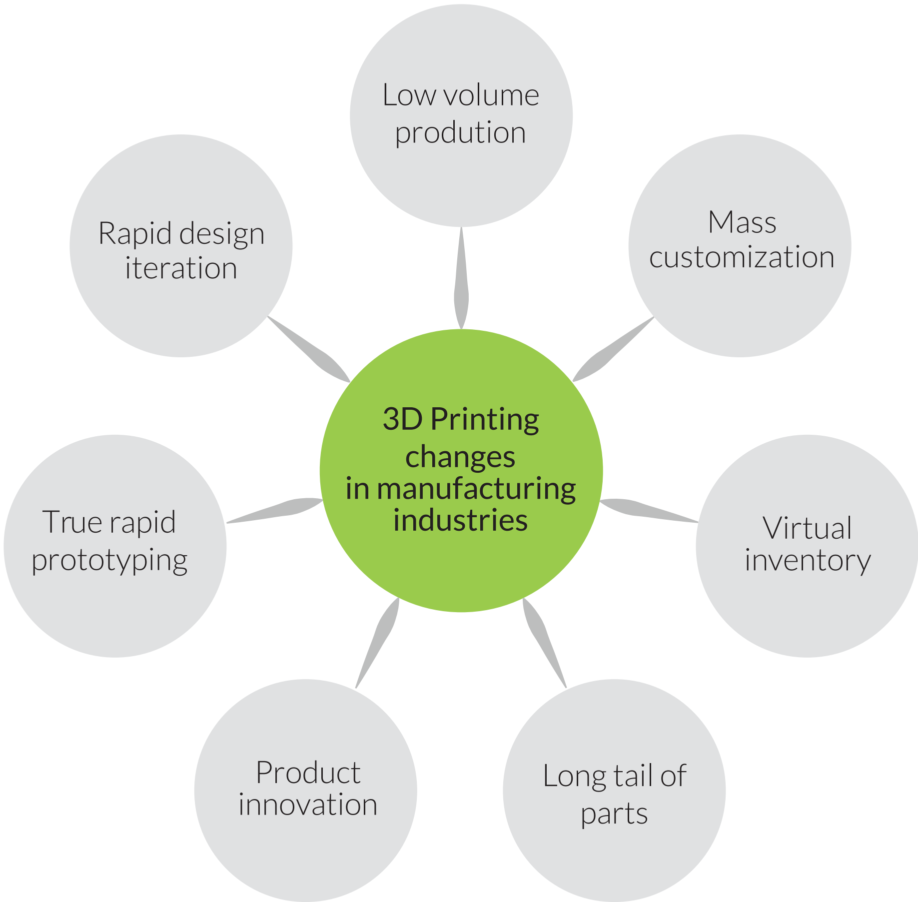


Figure 45 Transformations in manufacturability process

Key transformations in manufacturability process, that can be achieved using 3D printing, are presented in the schema on *Figure 45*.

Because the several technologies for additive manufacturing available in the industry, selecting the most suitable process, will depend of the functional characteristics of the product to manufacture. Material, dimensional constraints, surface finishing and postprocessing operations are part of the entire topics to analyze before choosing a certain process.

The best-known 3D printing processes and techniques can be found on the table. A general description of the characteristics of the widespread methods is presented, to clarify better each concept on *Table 1*.

CLASSIFICATION 3D PRINTING TECHNIQUES		
Material	**Classification of 3D Printing**	**Processing Method**
Vat Photopolymerization	Stereolithography (SLA)	Cured with laser
	Digital Light Processing (DLP)	Cured with projector
	Continuous Digital Light Processing (CDLP)	Cured with LED and oxygen
Material Extrusion	Fusion Deposition Modelling (FDM)	
Material Jetting	Material Jetting (MJ)	Cured with UV light
	Nanoparticle Jetting (NPJ)	Cured with heat
	Drop on Demand (DOD)	Milled to form
Binder Jetting	Binder Jetting (BJ)	Joined with bonding agent
Powder bed fusion	Multi-Jet Fusion (MJF)	Fused with agent and energy
	Selective laser sintering (SLS)	Fused with laser
	Direct Metal Laser Sintering (DMLS) Selective Laser Melting (SLM)	Fused with electron beam
	Electron Beam Melting (EBM)	Fused with electron beam
Direct energy deposition	Laser Engineering Net Shape (LENS)	Fused with laser
	Electron Beam Additive Manufacturing (EBAM)	Fused with electron beam
Sheet lamination	Laminated Object Manufacturing (LOM)	Adhesives are used for bonding

Table 1 Classification 3D Printing Techniques

- ***Vat Polymerization***

Resin based process where photopolymer resins are cured by UV light. Counts with a high level of accuracy and good finishing characteristics. It will require support structures and post-curing before the product can be subjected to structural loads. Layers in the process can have a precision from 0.025 to 0.5 mm. Not all polymer materials can be used as photo resins. Just UV curable photopolymer can fit into this process[43][44].

- ***Material Extrusion***

Method where a nozzle deposits material by extrusion on the cross-sectional area in accordance with the object slice. Material will be added continually on top of previous layer. A lack in dimensional accuracy, a low deposition speed plus the necessity of support material rake over, make part of the method´s restrictions. A high range of materials are suitable with this method: TPU, PS, PMMA, PC, HDPE, PP, PET, PPSF, ABS, PA, ASA and PEI[45].

- ***Material Jetting***

Material is jetted in droplets through either thermal or piezoelectric methods on a building platform to form the printing surface. Even droplets get solidified in contact with air, printing part will need support structures to be end up. Material jetting lend high levels of dimensional accuracy plus a reduction in waste of material, comparing with other methods. Materials that suits with this process are: PP, HDPE, PMMA, PC, PC, ABS and HIPS[46].

- ***Binder Jetting***

Materials in form of powder are spread and compacted in thin layers over a build surface using a roller. The binder is deposited through the printing head, according the piece geometry. Building surface moves down and a new layer of powder is spread for processing. The process is repeated time and time again until the end of the part. Not processed powder material works as support material and can be reused after a printing process. Suitable materials for this process are: stainless steel, PC, PA, ABS and ceramics[47].

- ***Powder bed fusion***

Materials in powder are layered on a bed to be fused selectively with a laser. Layer by layer the process is repeated until the part is finished. Surface finishes are constrained to the material granulometry and the range of speed in the process[48]. Powder based materials that suits with this promising technology are PA, alumide, carbonmide, aluminium, stainless steel and cobalt chrome.

- ***Direct Energy deposition***

A nozzle attached to a multi axis arm, deposits melted material on a defined area for its solidification. Different from extrusion process, the nozzle in DED, can move in multiple axial directions (4 or 5 directions). The material melting point is achieved through a laser or electron beam. Even can be used to manufacture pieces of polymer or ceramics, this process is typically used with metals (Cobalt Chrome, Titanium)[49].

- ***Sheet lamination***

Process in which a solid model is made by bounding layers each of them with the outline of the cross-sectional shape of a CAD model. Sheet lamination process are divided in two main process: laminated object manufacturing (LOM) and ultrasonic additive manufacturing (UAM). LOM make use of paper, plastic, cellulose, metal or fiber composites as working materials, with an adhesive backing to stick each layer. In contrast UAM uses just metal sheets that are bound using ultrasonic welding. UAM includes the use in aluminum, copper, stainless steel and titanium[50].

4.2 Equipments & Machines

Actual printing equipment make use of Extrusion Processing Material (FDM) and Vat Photopolymerization techniques. Description of the equipment is presented as follows.

4.2.1 Delta Robot Printer FDM

Delta robot printer is one of the most extended FDM (Fusion Deposition Modelling) DIY models of 3d printers and is basically a platform that is maintained by three pair of arms set in a triangle. The pairs of parallel arms maintain the horizontality of the platform and the movement of these arms displace the platform in the three dimensions[51].

Delta robot printer can be built under two displacement principles or configurations:

- The first where each arm pair is installed on a main articulated arm, where the movement is generated because the rotation of the main arm.

- A second, where arm pairs are attached to carriage sliding along parallel rails. This second configuration is one of the most extended machines around the world and is the kind of machine that will be use at laboratory to print under FDM process.

As DIY machine, its characteristics are not related with any standard model in the market. Features as temperature of extrusion, printing speed and printable volume, can be as customizable as the user prefers, constrained just by the characteristics of technological components (steeper's, nozzle extruder, thermal sensor and central controller shield) and by the material to print[52].

Because equipment characteristics, pieces printed with this technology, do not have a higher precision requirement in terms of geometry and structural performance, reason why the use of Delta robot printer, should be deeply analyzed if it is intended to be used in the development of fully mechanically functional prototypes.

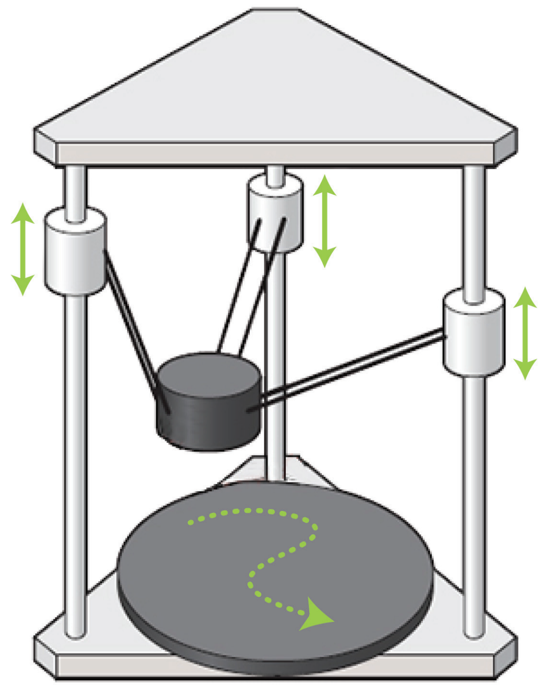


Figure 46 Schema Delta Robot

4.2.2 Form 2 - Formlabs

Formlabs 2 is considered one of the most advanced desktop 3D printers in the market and its based-on vat photopolymerization (stereolithography) 3D printing techniques.

The heart of the machine is composed by an optical engine, a high-powered laser that is guided by custom galvanometers creating each layer with exceptional detail.

A sliding peel mechanism removes the part from the print bed while a wiper glides across the optical window.

A responsive heating system warms the resin to a consistent temperature. This creates a reliable print process, producing well defined parts without sacrificing speed.

It features a 40% larger build volume and a smart resin system that automatically refills the tank when the levels are low.

To make printing simple, Formlabs 2 add wireless connectivity and a touch screen display. That connectivity features allows to upload .stl files over a Wi-Fi network, managing files in queue and receiving notifications when the print is completed.

Functional features are designed to work together with an own software platform and cutting-edge materials (from flexible to though materials) that open the possibility to create parts with professional results.

Formlabs 2 has a printing volume of 145 mm (length), 145 mm (width) and 175 mm (height) and a laser spot of 140 micron. The range of height is managed in a range of 25 to 100 microns. More specific printer characteristics can be found on the manufacturer website [53].

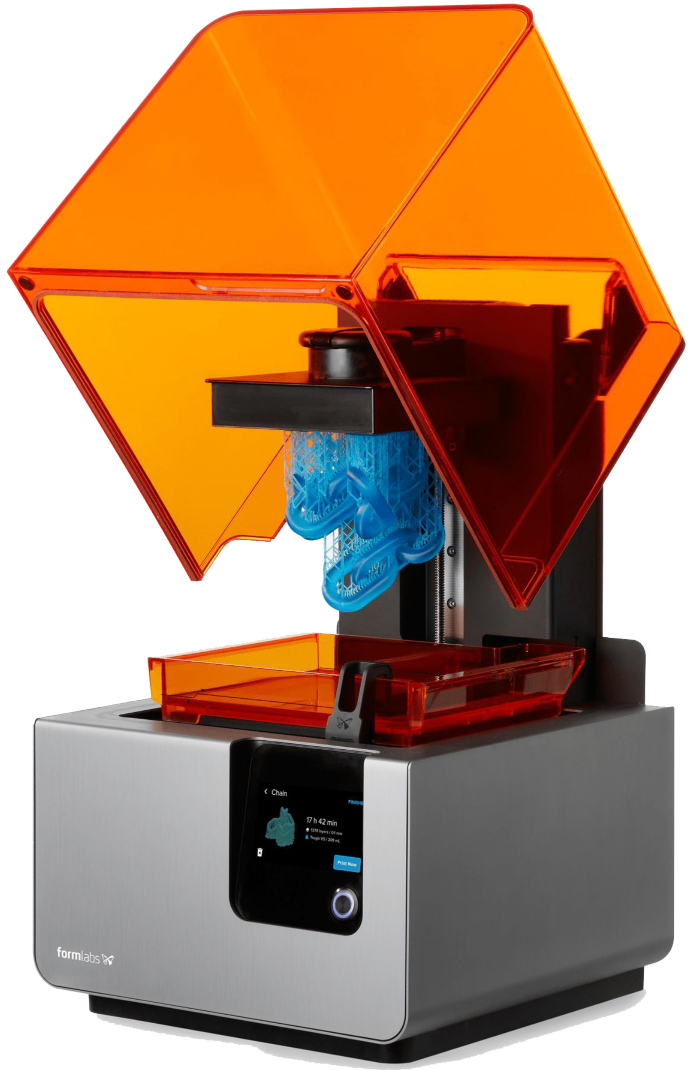


Figure 47 Form 2- 3D printer

4.3 Materials

Materials and 3D printing technologies used for the prototype development are linked with the characteristics of the printing machines available at the laboratory Sensibilab belonging to the Politecnico di Milano. Actual printing equipment make use of Extrusion Processing Material and Vat Photopolymerization techniques, reason why, just material characteristics related with these processes are presented below.

Materials for these two processes are classified based in the way are supplied into the 3d print machine as filament material and photopolymer resin, respectively.

Characteristics of others materials (metal powers and composed materials) are mentioned as reference point and will allow a later wider analysis regard design performance.

4.3.1 Filament Material

Material used in FDM (Fusion Deposition Modelling) is supplied as a filament and could be available in different diameters that goes from 3.0 to 1.75 mm. For 3d printing process, is required a circular transversal section with a constant diameter along the entire coil.

Fusion temperature as decisive factor in the process, is related with the material characteristics, but factors as the color, precise filament chemical composition, and external conditions as humidity or dirtiness can affect the equipment temperature setting point and the quality of the final print. Mechanical and thermal properties are shown in the *Table (2)(3)*

- ***ABS (Acrylonitrile Butadiene Styrene)***

Thermoplastic polymer with an amorphic structure, reason why ABS do not have a precise fusion point; ABS start to become soft around 90°C and melt to 105°C. For FDM extrusion is recommendable achieve a temperature of 230° but it exists some filaments that would need to arrive 260°C to get extruded[52].

A usual phenomenon that affects to ABS is the thermal retraction. To avoid it, is important to pre-warm the surface printing area in a range of temperature from 90°C to 110°C. If these considerations are not considered, retraction effect will be noticeable specially in the corners and in the areas far away from the printing plane. Because its temperature sensibility, ABS is not recommendable for high temperature applications.

ABS polymeric amorphous structure plus 3d printing model method (layer by layer modelling), makes printed parts to have a limited mechanical resistance specially for traction loads. High engineering performance applications are not recommendable for ABS printed parts. General properties are shown together on the table.

- ***PLA (Polylactic Acid)***

Thermoplastic polymer derivate either from corn or potato starch, and sugarcane. It is easily compostable, because its biodegradable properties, becoming an alternative for oil derivate polymers. Parts made with PLA, presents a higher fragility because a higher rigidity on the material – compared with ABS printed parts - reason why mechanical performance of PLA pieces is not the best for mechanical loads.

PLA can be extruded in a range of temperatures from 160°C to 220°C, and printing adhesion can be improving with a pre-warm on the printing surface of 60°C[52].

Because over a certain threshold the process of biodegrading starts in PLA, control of humidity is important in the preservation of the mechanical properties and in the control of the printer fusion setting point.

- ***Nylon***

Offers elevated mechanical performance in terms of strength and durability, when is used as 3d printing material. Offers high resistance to abrasion and heat with a low friction coefficient.

Nylon presents different behaviors depending the thickness grade in which is printed: flexible in thin printed layers, solid when layers become thicker.

In addition, Nylon offers and outstanding dimensional stability during FDM process[54].

It requires a fusion temperature in a range of 245°C to 300°C, and a slow printing process to avoid the delamination. A pre-warm of 100°C of the printing surface is recommendable to improve nylon adhesion to the plane [52].

- ***PET (Polyethylene Terephthalate)***

As 3D printing material, PETG (filament variation of PET with addition of glycol) has an intermediate characteristic between PLA and ABS, with more flexibility and durability than PLA and easier printability than ABS.

PETG gives the possibility to print translucid parts with a high mechanical resistance. Regard its functional behavior, PETG became sticky in the printing phase, so as support material it cannot be the best option. However, it works well for layer adhesion.

It requires an extrusion temperature in a range of 210°C to 220°C. A pre-warm of 60°C of the printing surface is recommendable[52].

- ***PC (Polycarbonate)***

Resistant to mechanical and thermal impacts, PC is highly resistant, moderately flexible and durable, characteristic that makes it a material of engineering applications quality. Commonly and because its transparency properties is used in products as bullet proof glass, electronic display screens and scuba mask[47]. Able to withstand temperatures up to 110°C, its functional constraint lies in the elevated temperature requirement for extrusion phase: up to 300°C[52]. This implies that not all 3d printers available in the market are able to print Polycarbonate.

- ***TPU 95A***

Material option specifically for parts that require rubber and plastic characteristics (flexibility). TPU filament have semi-flexible characteristics and outstanding chemical resistant capabilities, allowing the use of this material in long term UV exposition, moisture conditions and industrial oils/chemical agents [56].

TPU filament printing, requires low speeds and extrussion temperatures around 195°C to 230°C. Preheating of the printing bed is reccomendable at 70°C [57].

Figure 48 PolymerExtrusion Filament (Ultimaker)

MECHANICAL PROPERTIES - 3D PRINTED POLYMERS

Material	Tensile Modulus Young's Modulus ISO 527	Tensile stress at yield ISO 527I	Tensile stress at break SO 527	Flexural strenght ISO 178I	Flexural modulus SO 178	Izod Impact strenght ISO 180	Hardness	Specific gravity
ABS	1681.5 MPa	39.0 MPa	33.9 MPa	70.5 MPa	2070.0 MPa	10.5 kJ/m$_2$	97 (Shore A)	1.10
PLA	2346.5 MPa	49.5 MPa	45.6 MPa	103 MPa	3150 MPa	5.1 kJ/m$_2$	83 (Shore D)	1.24
TPU 95A	26 MPa	8.6 MPa	39 MPa	4.3 MPa	78.7 MPa	34.4 kJ/m$_2$	95(Shore A)	1.22
Nylon	579 MPa	27.8 MPa	34.4MPa	24 MPa	463.5 MPa	34.4 kJ/m$_2$	74 (Shore D)	1.14
PET	2264MPa	40.9 MPa	39.9 MPa	76.7 MPa	2280.8MPa	12.4 kJ/m$_2$	71.4 (Shore D)	1.34
PC	2134 MPa	MPa	76.4 MPa	111MPa	2410 MPa	4.1 kJ/m$_2$	82 (Shore D)	1.18

*Table 2 Mechanical Properties-3d Printed Polymers**

THERMAL PROPERTIES - 3D PRINTED POLYMERS

Material	Melt mass-flow rate (MFR)	Glass Transition	Melting Temperature
ABS	41 g/10 min	97°C	225°C-245°C
PLA	6.09 g/10 min	60°C	145°C-160°C
TPU	15.9 g/10 min	-24°C	220°C
Nylon	6.2 g/10 min	50°C	185°C-195°C
PET	20.02 g/10 min	62°C	210°C-220°C
PC	32-35 g/10 min	112°C-113°C	260°C-300°C

*Table 3 Thermal Properties - 3D Printed Polymers**

** From material datasheets: https://ultimaker.com*

4.3.2 Photopolymer Resin

Form 2, 3D printer machine, makes use of stereolithographic vat photopolymerization technique using methacrylate photopolymers, commonly referred as resin. Resins comes in many types, including options for mechanical performance and aesthetic value. In the project, photopolymerization is used to print just the flexible parts, due the printing good level of precision (compared with FDM process) in the final product and the functional characteristics of the printed material. In the comparative graphic presented, are shown the characteristics of two resins compared with the behavior of classic rubber. In any case, 3d printed elastic/flexible materials never will have the same characteristics of classic elastomers but can works as good emulators in the application of additive manufacturing techniques. Information about flexible resins material properties is widely explained below.

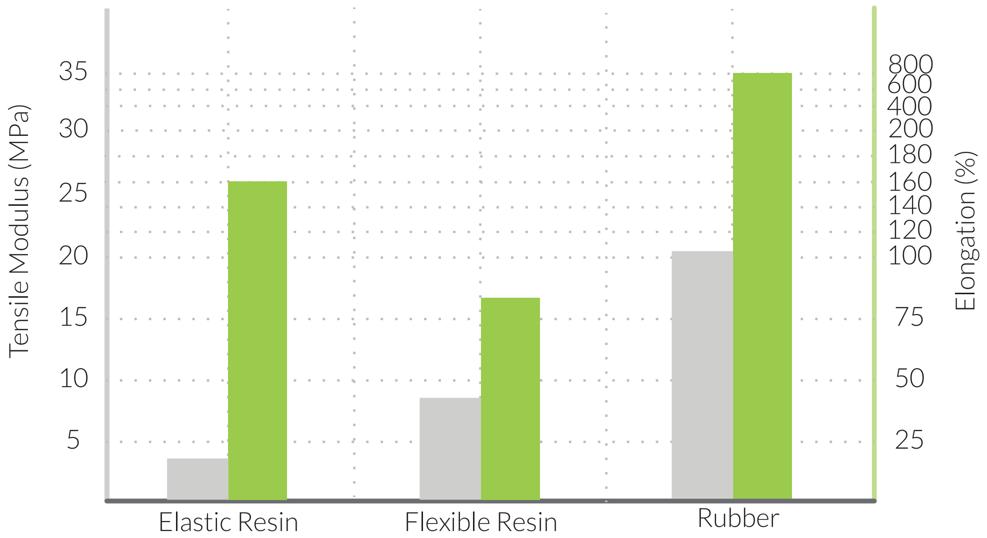


Table 4 Comparative Functional Behavior

- ***Formlabs Elastic***

Resin: Used as emulator of silicone, is an elastomeric material designed for applications with high elongation and high energy return. Parts that are usually bend, stretch, compress and hold up in repeated cycles, can be molded in this material without problems of tearing. Elastic resin is transparent and can be printed at 100 microns.

The use of this material is recommendable for wearable and consumer goods prototypes, medical models, and flexible features for robotics. It's not recommendable for parts with high dimensional accuracy and high surface detail, and for parts that requires to keep a particular shape[58].

Figure 49 Elastic Resin Printed Parts

** * From material datasheet: https://formlabs.com*

- ***Formlabs Flexible***

Used as emulator of rubber, is an elastomeric material designed for bendable and compressible parts.

The use of this material is recommendable for functional prototypes that are under cushioning or damping loads, parts with an ergonomic purpose (handles and grips) or to simulate soft-touch materials. It's not recommendable in simulation of parts with high elongation requirements and pieces with reduce thickness[59].

Figure 50 Flexible Resin Printed Parts

MECHANICAL PROPERTIES - ELASTIC RESIN

Properties	Green	Post-cured
Ultimate tensile strength	1.61 MPa	3.23 MPa
Stress at 50% elongation	0.92 MPa	0.94 MPa
Stress at 100% elongation	1.54 MPa	1.59 MPa
Elongation at failure	100 %	160 %
Compression set at 23°C for 22 hrs	2%	2%
Compression set at 70° Cfor 22 hrs	3%	9%
Ultimate tensile strength	8.9 kN/m	19.1 kN/m
Ultimate tensile strength	40A	50A

*Table 5 Mechanical Properties - Elastic Resin***

MECHANICAL PROPERTIES - FLEXIBLE RESIN

Properties	Green	Post-cured
Ultimate tensile strength	3.3 - 3.4 MPa	7.7 - 8.5 MPa
Elongation at failure	60%	75%-85 %
Compression Set	0.40 %	0.40%
Tear Strength	9.5 - 9.6 kN/m	13.3 - 14.1 kN/m
Shore Hardness	70-75 A	80 - 85A
THERMAL PROPERTIES		
Ultimate tensile strength	231 °C	230°C

*Table 6 Mechanical Properties - Flexible Resin***

***From material datasheet: https://formlabs.com*

4.3.3 Other Materials

The following materials are mentioned, with the purpose of generate a wider comparative scenario, related with the final characteristics of the design and its performance. Even, this materials can not being implemented at laboratory headquarters because the lack in technological resources and the elevated price of base printing materials, are considered important to arrive to more integral conclusions.

- ***Carbon Fiber PEEK 3D Filament -CarbonX™***

With an aerospace-grade performance, *CarbonX™* is made using Kepstan PEEK and Toray Aerospace- Grade T800 24K chopped carbon fiber, and was created for applications with exceptional thermal, mechanical and chemical resistance requirements [60].

With a glass transition temperature near the 162°C, is 20°C higher than PEEK, CarbonX™ melts at approximately 335°C. Its extrusion temperature point is set up between 355°C to 385°C

Outstanding mechanical properties, make of this polymeric composite an interesting option for parts subject to heavy duty applications where lightness became a fundamental requirement, and where technological equipment is related with FDM printing technique.

- ***Aluminium alloy $AlSi_{10}Mg$***

Alloy that comprises aluminium alloyed with silicon of mass fraction up to 10%, a percentage of magnesium plus other elements. Silicon provides the alloy harder and stronger characteristics than pure aluminium, due the formation of Mg_2Si precipitates [61]. Properties involved as a low density, a high specific strenght and a well response to post process finishing treatments, make AlSi10Mg ideal for automotive applications, aerospace, electronic cooling and general consumer products.

Mechanical properties of both materials are presented in the table as follows.

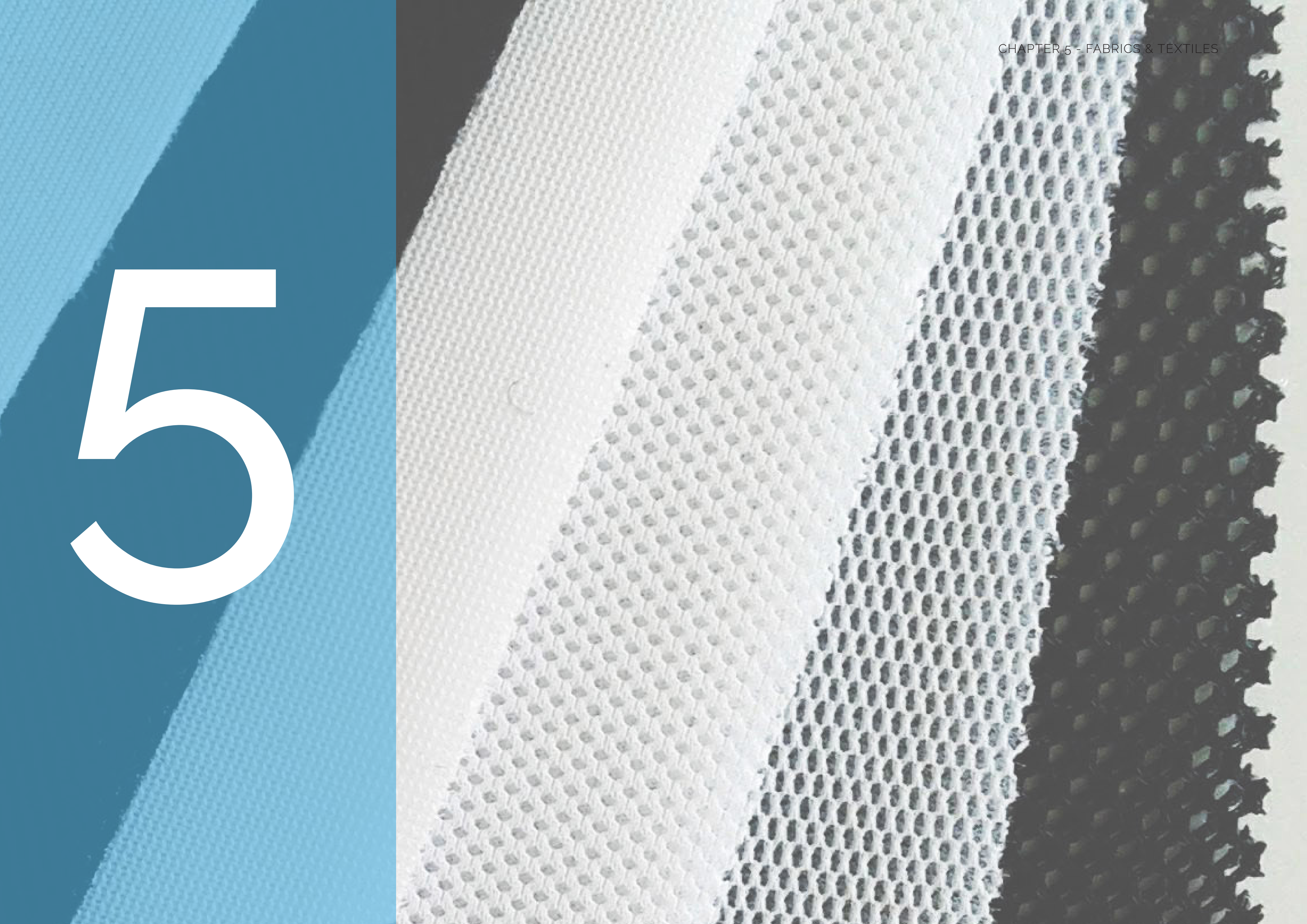
MECHANICAL PROPERTIES - CARBONX FILAMENT	
Properties	Typical Value
Tensile Strength, Break	105 MPa
Tensile Modulus	8100 MPa
Tensile Elongation Break	3 %
Flexural Strength	136 MPa
Flexural Modulus	8300 MPa
Density	1.39 g/cc

Table 7 Mechanical Properties - CarbonX™ Filament

MECHANICAL PROPERTIES - AlSi10Mg	
Properties	Typical Value
Tensile Strength, Break	442 MPa
Tensile Modulus	71 GPa
Yield Strength	264 MPa
Elongation at break	9%
Hardness (Vickers)	119 HV

Table 8 Mechanical Properties - $AlSi_{10}Mg$

5



FABRICS & TEXTILES

This chapter presents an state of art about the several fabric structures available for textiles, their different properties and applications. Explaining the different manufacturability process, it clarifies the definition of 3D fabrics and present a range of market possibilities to be used in the project.

5.1 FABRIC CHARACTERISTICS

A set of multiple characteristics must be analyzed, when a project pretends to make use of textiles, specifically when the action field is related with smart wearable technology. The analysis, principally, must be focused in the intended end use. Some fabric's characteristics to consider can be:

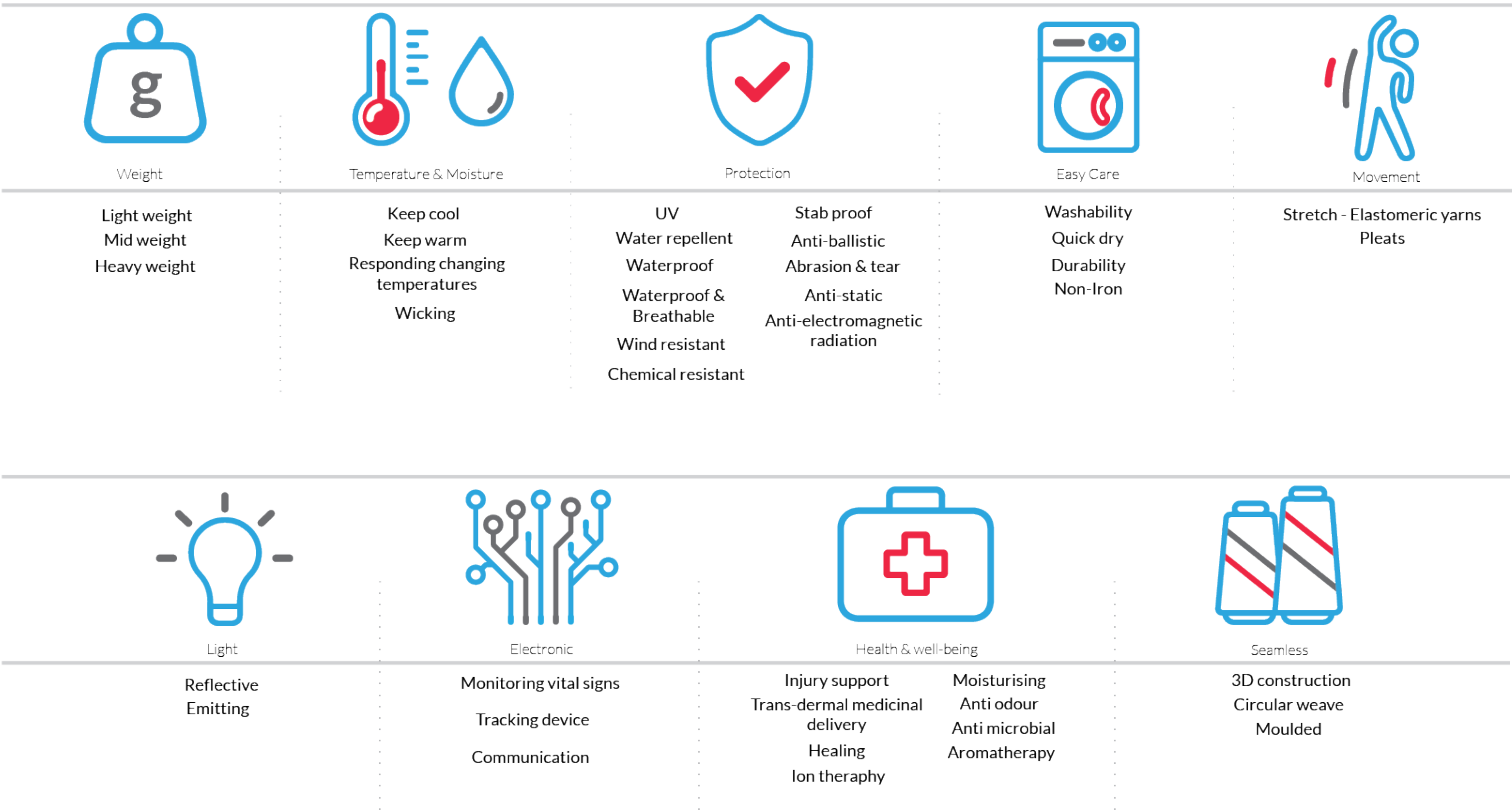


Figure 51 Fabrics Characteristics

5.2 PRODUCTION TECHNIQUES

There are several ways to made fabrics, all of them, add functional characteristics to the textile. Two of the most common techniques, that will be explained deeply, are the knitting and the woven. A knit structure allows a longitudinal and lateral stretch of the garment meanwhile woven fabrics are more stable and have more strength. A third technique, defined as non-woven fabric, will be mentioned and briefly explained.

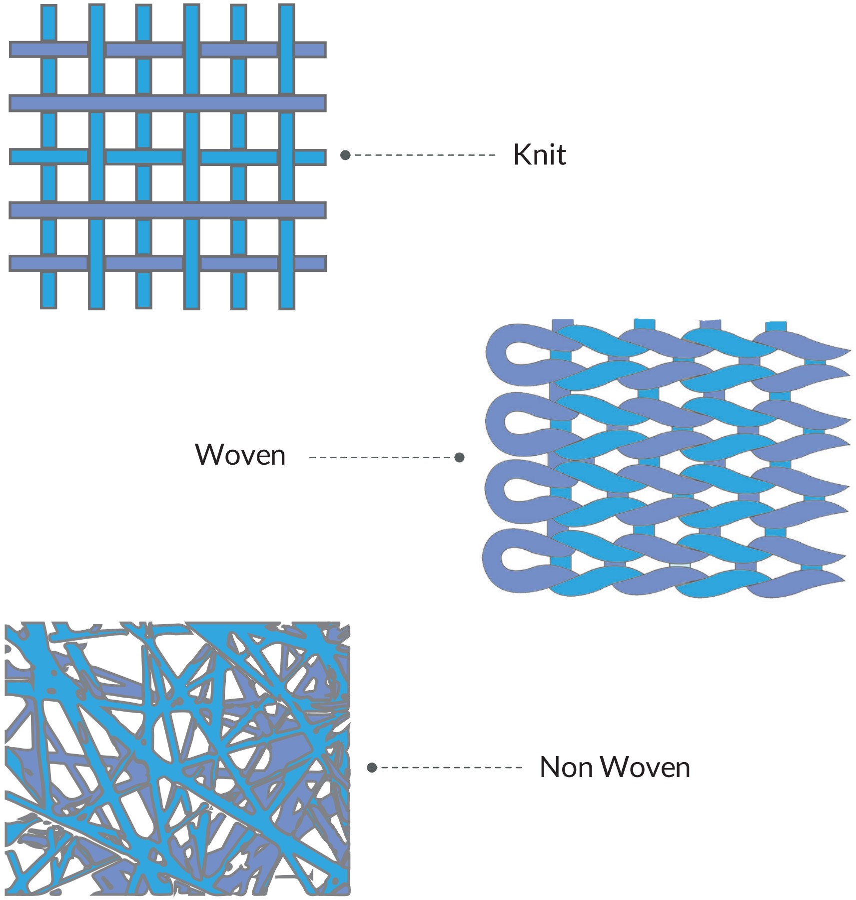


Figure 52 Production techniques fabric structrures

Factors to take into consideration when a fabric pretends to be used in a design, are correlated to the final user requirements. Characteristics as “the fiber, the yarn, the weave structure, the thread density” [62] and the finished treatment, can defined the entire performance of the textile. Some of the most relevant key points to analyze in a fabric selection process, are shown as follows:

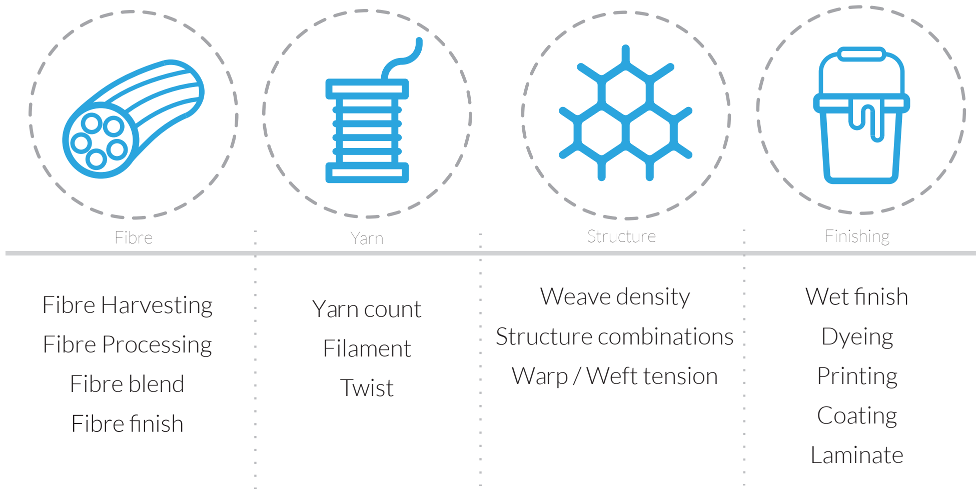


Figure 53 Factor selection key points

5.2.1 Knitting Fabrics

Knitting is the construction of an elastic, porous fabric, created by interlocking yarns by means of needles[63]. Intermeshing the loops of yarns, one loop is drawn through another, forming loops in horizontal or vertical direction[64].

There are two basic forms of knitting technology: weft and warp knitting, explained as follows:

- ***Warp knitted fabrics***

The most important advantage of warp knitted cloths is that, unlike weft knitted fabric, it is not easy to unravel. However, these fabrics are not as elastic as weft knitted fabrics. Warp fabrics are most often used in swimwear, intimate apparel and sportswear.[62]

- ***Weft knitted fabrics***

These types of fabric are more stretchable in the horizontal direction than in the vertical direction. The main benefit is a maximum stretch placed around the body. The fabric appears to be bulkier than the yarn from is knitted from, improving insulation characteristics. Because the air and space into the textile, the fabric can be water and air permeable.

	Structure	Attributes	Uses
Weft	Fabric formed in loops in one continuous thread	Highly elastic and highly droppable porous and comfortable	Ideal for apparel outer and under garments
Warp	Structural threads of fabrics running along the lenght of the fabric	Durable, run resistant, insulating properties, good surface resitance	Sportswear, automotive, industry, military

5.2.2 Woven Fabrics

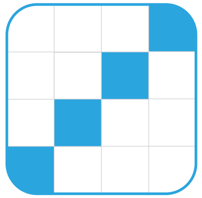
Manufacturing process of fabrics that consists in the interlacing systems of yarn[65]. An interlacing modification allows a wide variety of fabric constructions. For this project, most common woven structures and their properties were consulted. The following infographics summarize their properties and usual uses.

Plain weave

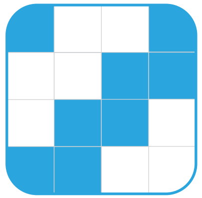
Yarns interlace over one, under one

- *Firm*
- *Stable*
- *Tears easily*
- *Frays less*
- *Creases easily*
- *Lightweight*
- *Minimum yarn slippage*
- *Less absorbent*
- *Poor drape*
- *Thin*

Twill



1/3 twill

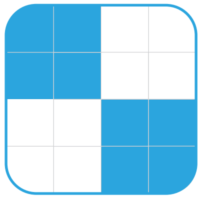


2/2 twill

Yarns interlace with diagonal lines on the fabric surface. Generally used in denim clothes

- *Geometrical diagonal line*
- *More dense woven*
- *Strong & stable*
- *Durable*
- *Good abrasion resistance*
- *Medium tear strenght*
- *Creases less*
- *More dirt resistance*
- *Pliable and flexible*
- *Snag resistant*

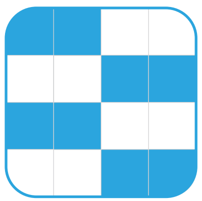
Hopsack & Basket weave



Hopsack

Yarns interlace over two, under two

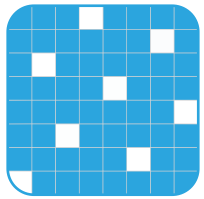
- *Frays easily*
- *Flexible*
- *Not durable*
- *High yarn slippage*
- *Biased to strech*
- *Good tear resistance*
- *Breathable*



Basket weave

Yarns interlace over one, under two

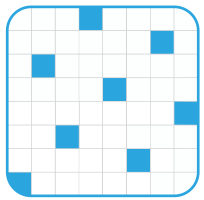
Satin & Sateen



8th end Satin

The weft will float under one warp end over seven to make the repeat.

- *Very densely woven*
- *Snagging*
- *Stable & strong*
- *Durable yarn*
- *Wind repellent*
- *Yarn slippage*
- *Lustrous*
- *Water resistance*
- *Smooth with good drape*
- *Very pliable*
- *Smooth with good drape*
- *Frays easily*
- *Good tear resistance*

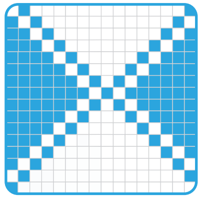


8th end Sateen

The weft will float over seven warp ends and under one to make the repeat.

It corresponds to the opposite of a satin

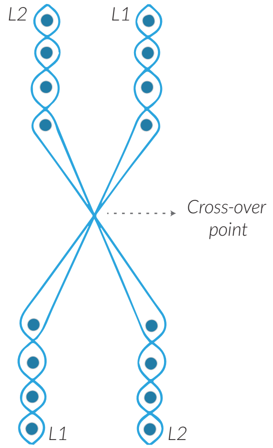
Honeycomb



Structure from eight warps increasing up to sixteen. Usually used in towels and blankets

- *Good insulation*
- *3D structure*
- *Poor abrasion*
- *Poor durability*
- *Breathable*
- *Very absorbent*
- *Textured surface*
- *High bias strech*

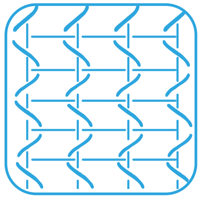
Layered Weave



Two layers of cloth interlinked, where each have their own set of warp yarns and are woven independently yet simultaneously.

- *Insulating*
- *Heavy weight*
- *Thick*
- *Reversible*
- *Durable*
- *High thread count*
- *More time consuming to weave*
- *Stable*
- *Firm*
- *Can be 3D*

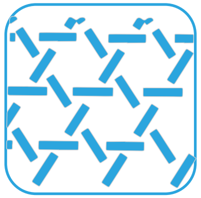
Leno



Twisting of adjacent warp threads around each other. Usually used in blankets for hospitals.

- *Very stable*
- *Lightweight*
- *Open*
- *Breathable*
- *Strong*
- *Reduced yarn slippage*
- *Reduced warp content*
- *Firm*
- *Reduced distortion*
- *Good shear resistance*

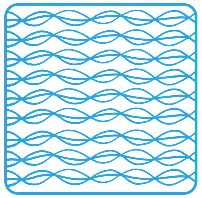
Triaxial



3 ways construction with the threads running at sixty degree angles to each other.

- *No bias stretch*
- *High tear*
- *Shear resistance*
- *Very strong*
- *Stable*
- *Lightweight*
- *Breathable*

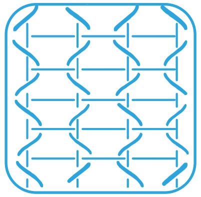
Pile Weaves



Structure that can be loop pile (terry cloth) and cut pile (velvet and corduroy)

- *Durable*
- *Firm*
- *Dense*
- *Insulating*
- *Surface texture*
- *Absorbent*
- *Abrasion resistant*
- *Strong*
- *High yarn content*

Counter Leno



Twisting of adjacent warp threads mirrored repeated across the fabric width as opposed to a regular block. Usually used in bandages

- *Stable*
- *Lightweight*
- *Open*

5.2.3 Non-Woven Fabrics

Non-woven textiles are defined by the British Standards as a manufactured sheet, web or batt of directionally or randomly oriented fibers, bonded by friction, cohesion or adhesion [66]. Fibers in non-woven fabrics can have a natural or industrial origin. The way as they are formed could be through basic or continuous filaments or be formed during the process.

Making production processes of non-woven fabrics, are related with technological used for paper and plastics manufacturing, and usually have the following sequence of steps:

- Web formation
- Web bonding
- Finishing

Each of these processes and its subsequent variables, are generally explained through the following schema:

WEB FORMING	**Dry -Laid**	**Wet - Laid**	**Polymer - Laid**
	Manipulation of fibres in their dry state	Fibres are dispersed in water to form fiber dispersion. *Modification of paper making process	Formation of webs directly from molten polymers in one continuous process
WEB BONDING	**Mechanical**	**Thermal**	**Chemical**
	Needlepunching Hydroentangling Stich bonding	Calenderering Air bonding Ultrasonic	Coating Spraying Printing
FINISHING	**Mechanical**	**Chemical**	
	Drying Shrinking Embossing Moulding Cutting	Dyeing Printing Impregnation Coating Lamination	

Table 9 Non-Woven manufacturing process

Non-woven fabrics are classified by their production process and can eventually being made of almost of all types of fiber. Polypropylene it's one of the most used materials under this textile production technique[67].

- ***Applications on Smart Textiles***

Widely used in the production of smart textiles, non-woven fabrics fit properly for functional requirements as:

- *Support materials:* used for garment interlinings and insulation features and for footwear components.
- *Outer garments:* like outer shell of garment and clothes
- *Medical purposes:* for high sterilized environments (surgical stuff and sterilizable packaging)
- *Protective clothing:* linings for chemical protection, micro-organism barrier, radioactivity, thermal or mechanical wearing.

5.2.4 Three Dimensional Fabrics

Three dimensional fabrics can be defined as the type of textile that have a considerable dimension in the thickness layer. Fibers or yarns are intertwined, interlaced or intermeshed in the X (longitudinal), Y (cross) and Z (vertical) directions [68].

Textile technology has been one of the few approaches that can organize unidirectional materials into 2-D and 3-D assemblies with the desired shape, dimension, and, to some extent, material orientation [69].

Because of this, 3-D textiles characteristics as light weight, structural integrity is considered as high-performance advantages in the conception of advanced composite materials, becoming a breakthrough in engineering and fashion design contexts.

Currently, 3-D woven fabrics are basically made through two routes: one by using the conventional weaving technology and the other by using specially developed weaving devices or heavily modified conventional looms [69]. Because the technological constraints, conventional weaving machines, continued being the most used technological method for 3D textiles manufacturing, so 3d textiles could be considering, an extension of woven fabric techniques.

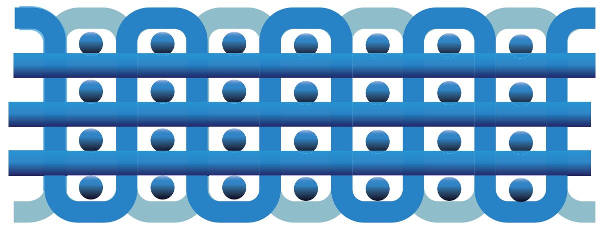
Because the several forms of 3D textiles existing in the market, it can be a difficult task trying to be classified it. Different criteria have been used by distinct authors, having into account methods of manufacturing.

On one side, Fukuta and Aoki [70] classified 3d fabrics starting from parameters as yarn dimensions, dimensions of the structure and fabric architecture.

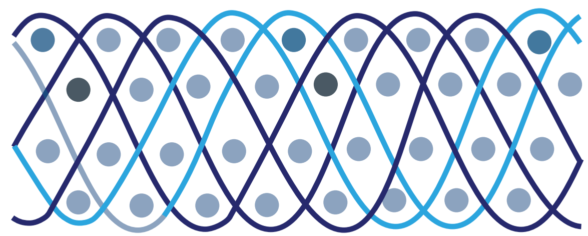
On the other side, Chen [71] makes a classification based on the geometric configurations of the 3d woven fabrics. Four main categories describe the textiles as: solid, hollow, shell and nodal.

Table 10 and *Table 11* states clearer the two previous classifications.

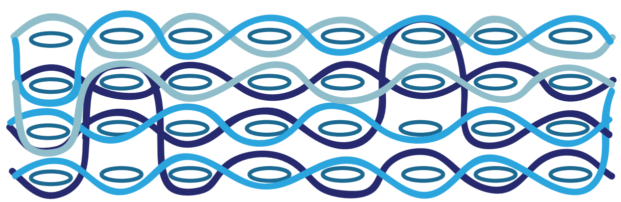
However the most widely used fabric architectures used for 3D woven textiles manufacturing are orthogonal weave, angle interlock weave and multilayer weave. Orthogonal weave has the need to use specific 3D weaving machines, whereas angle interlock and multilayer can be produced with traditional 2D weaving machines. The following graphic scheme exemplifies the mentioned architectures.



Orthogonal weave



Angle interlock weave



Multilayer weave

Figure 54 Weave architectures [56] [63][64]

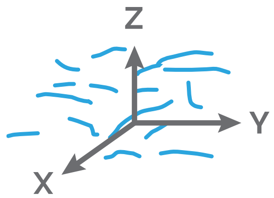
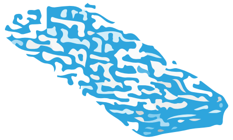
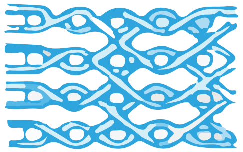
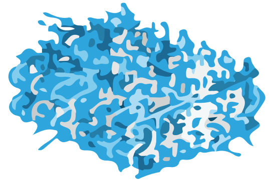
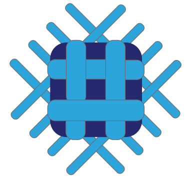
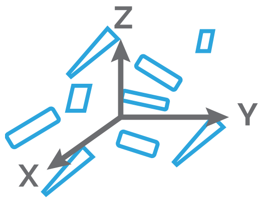
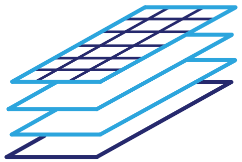
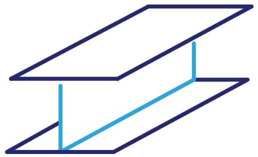
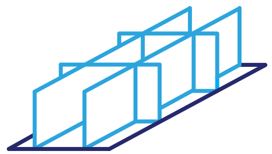
Axis	Non-Axial	Mono-axial	Riaxial	Triaxial	Multi-axial
Linear Element		 3D Braid	 Multiply	 Triaxial 3D weave	 Multi- axial 3D weave
Plane Element		 Laminate type	 "H" or "I" Beam	 Honey Comb	

Table 10 Fukuta and Aoki 3D Fabrics classification

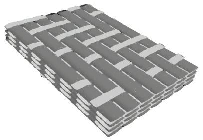
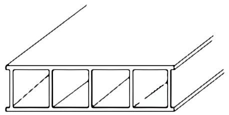
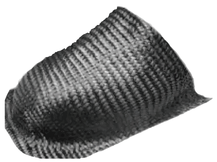
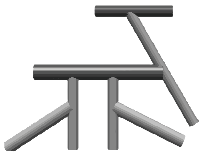
Structure	Architecture	Shape
Solid 	- Multi-layer - Orthogonal - Angle interlock	Compound structure with regular or tapered geometry
Hollow 	- Multi-layer	Uneven surface, even surfaces, and tunnels on different levels in multi-directions
Shell 	- Single-layer - Multi-layer	Spherical shells, and open box shells
Nodal 	- Multi-layer - Orthogonal - Angle interlock	Tubular nodes and solid nodes

*Table 11 Chen 3D fabrics classification****

Structure where three sets of yarns are perpendicular to each other (X, Y and Z coordinates). Z yarns, often interconnect all individual warps, filling directional yarns and solidifying the textile.[77]

Some mechanical properties, investigated by Chen, define the behavior of this architecture with the following characteristics

-Tensile stiffness and strength values, are directly proportional with the number of layers

-Breaking elongation its not affected by the number of layers and binding weaves. Elongation depends mostly on the yarn's material.

-Shear rigidity increase proportionally with the number of layers involved

-Tighter binding weaves will produce higher bending stiffness

Structure that have at least two sets of yarns such as warp and weft. Stuffer yarns are added in order to increase the fiber of each volume fraction.

Angle interlock textiles are divided in two: "through thickness" arrange, where warp yarn travels from one surface of the 3D fabric keeping together the layers, and "layer to layer" structure where warp yarns travel from one layer to the adjacent layer and come back.

Compared with the mechanical properties of laminated composites, angle interlock weaves do not have a good performance, nevertheless impact/ fracture resistance and dimensional stability [78] are achieved, when angle interlock are used as part of composite layers.

Weave structures that consist of multiple layers with its own sets of warp and weft yarns. Existing yarns or external sets of yarns allows the connection among the layers.

Mechanical behavior of this structure is defined by the following characteristics

-As much the number of layers, higher will be the strength of the fabric structure and its structural stability.

-A reduction in the strength of the structure can be generated by the increase in stitch density

Obtained from
Picture "Solid" TexEng Software Ltd.
Picture "Hollow" [72]
Picture "Shell" [73]
Picture "Nodal" [74]

5.2.5 PRODUCTS IN THE MARKET

- ***3Mesh Smart spacer fabric – Müller Textil Group***

Versatile spacer fabric, with excellent touch characteristics and structure that allows a high air circulation with or without load conditions and a good live durability. Its lightweight guarantees a good ventilation, breathability and a proper air distribution into the space.

Mechanical capabilities as high-pressure distribution and rebound elasticity make it an adequate material for isolation and space refilling. As a result of this, 3DMesh from Müller became an interesting alternative to replace any kind of foam and foam laminates

It has a high level of process manufacturing flexibility, allowing being processed through different joining, molding and cutting techniques (punching, thermal contact welding, warping and hardening)

A most complete summary of the technical properties, is supplied by the producer web site under the following schema in the *Figure 55* [79].

- ***Douplex /3A Threespace - TessilGiada S.R.L***

Italian company, specialized in the production of maliwatt and malivlies, and in the recent years, innovative leader in spunbond and knitted textiles fabrication [80].

Douplex knitted fabric, appears as a product solution in the area of mattresses, sport clothing and shoes.

Made 100% in polyester, the breakthrough point of the company, its to have the possibility to change the knitting patterns, according to the client requests.

A complete schema of the different patterns offered by the company it's presented.

- ***Tessiltoschi S.R.L***

Italian company founded in 1968 with the aim of satisfied its client request regard the production of fabrics with high technological properties [81]. Technological processes carried out by the company involved since hotmelt lamination, latex lamination (fabric softening technique), waterproofing coverings, antistatic and antibacterial treatments.

3D-mesh fabric and textile nets, for the special case, are the products considered as part of the interest for the project.

Different textile characteristics, from the brands described before, are found in the following pages, and will be part of the selection criteria in the final concept.

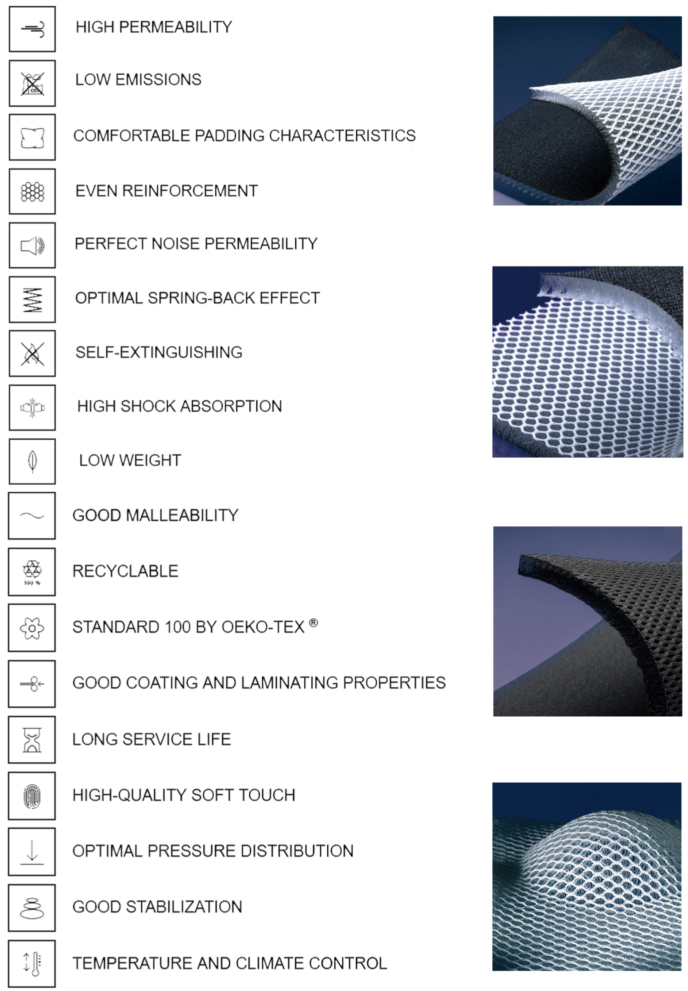
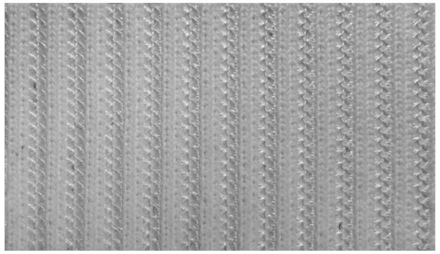
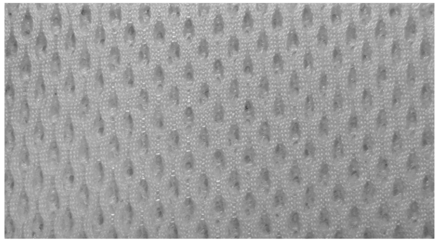


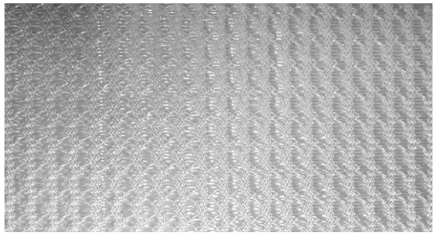
Figure 55 Müller Textil Group



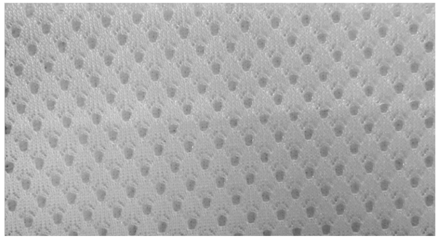
Douplex /928
GR250MQ H140CM
100% PL



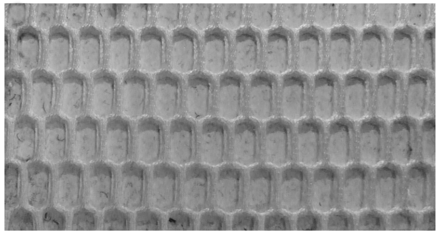
Douplex /Soft
GR240MQ H150CM
100% PL



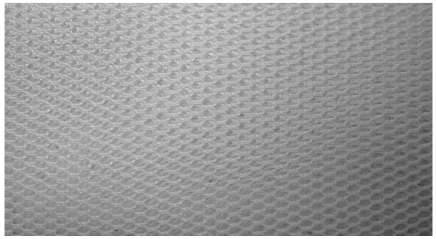
Douplex /504S
GR250MQ H150CM
100% PL



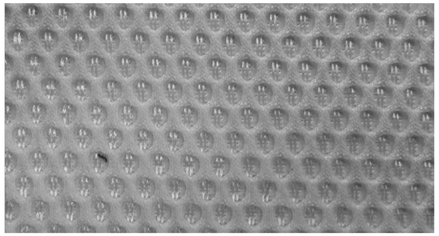
Douplex /659
GR330MQ H140CM
100% PL



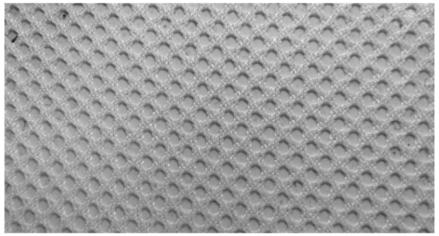
Douplex /R
GR260MQ H150CM
100% PL



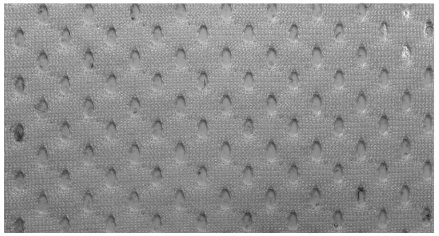
Douplex /189
GR300MQ H150CM
100% PL



Douplex /DF102
GR280MQ H150CM
100% PL

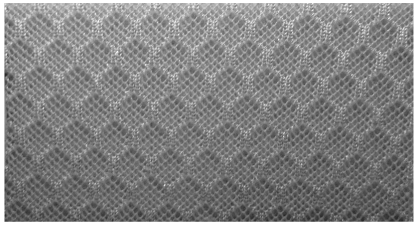


Rete
GR250MQ H150CM
100% PL

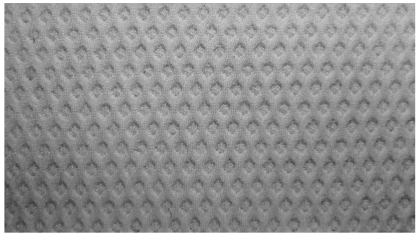


Douplex/101
GR180MQ H150CM
100% PL

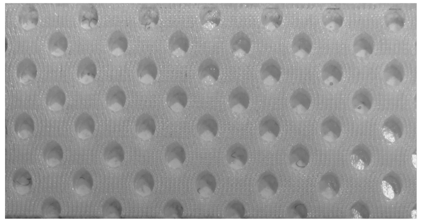
Figure 56 Douplex /3A Threespace-1



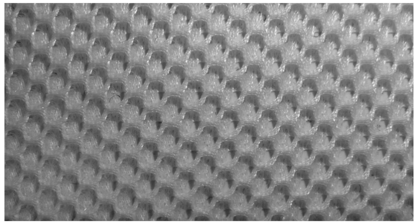
Douplex /070
GR380MQ H150CM
100% PL



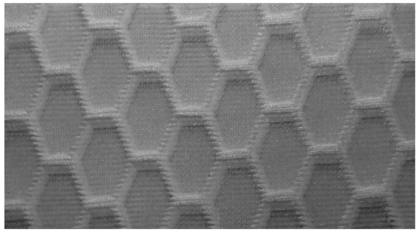
Alveare
GR180MQ H150CM
100% PL



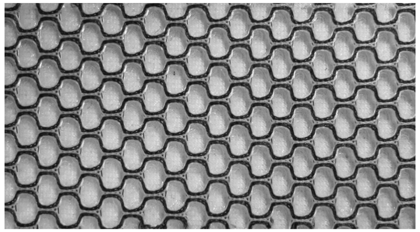
Douplex /636
GR230MQ H150CM
100% PL



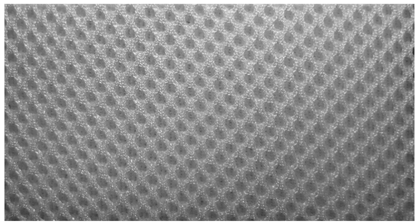
Douplex /039S
GR250MQ H150CM
100% PL



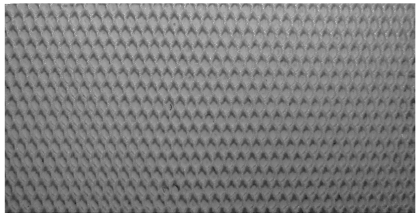
Douplex /Air
GR210MQ H150CM
100% PL



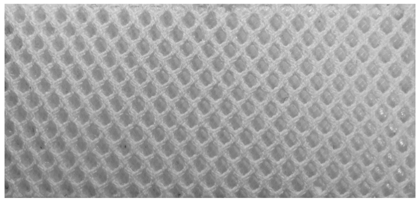
Douplex /1039
GR245MQ H150CM
100% PL



Douplex /3A
GR220MQ H160CM
100% PL

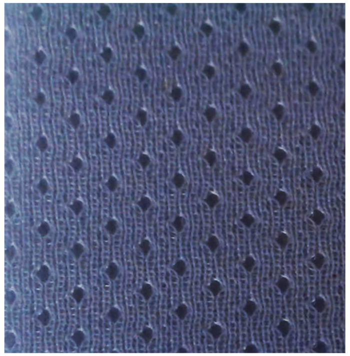


Douplex /522
GR130MQ H140CM
100% PL



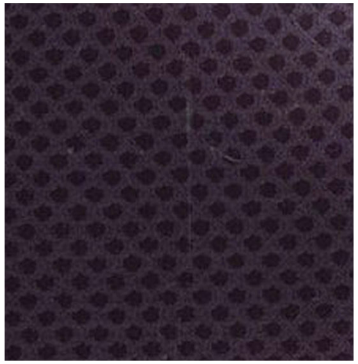
Douplex/COT
GR220MQ H160CM
90%COT -10% PL

Figure 57 Douplex /3A Threespace-2

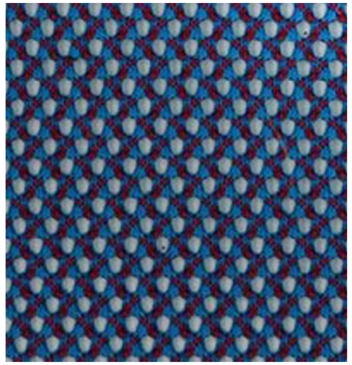


Asterix
GR330MQ
100% PL

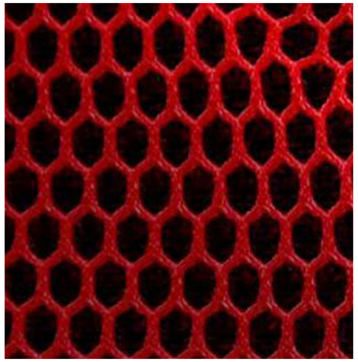
Mikedue
GR330MQ
100% PL



Complet
GR640MQ
100% PL

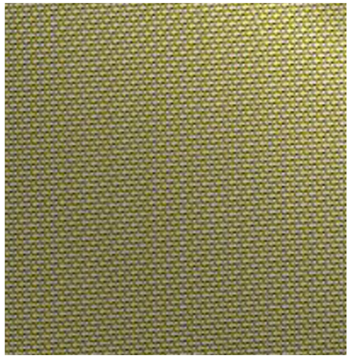


Mikeforty16
GR650 MQ
81% PL 19 PA



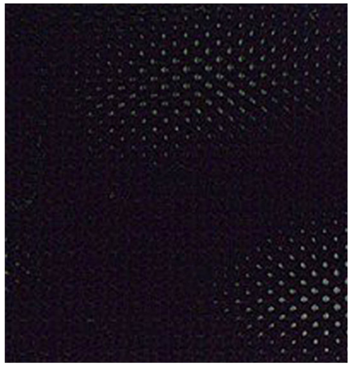
Miketre
GR525 MQ
100% PL

Minimike
GR350MQ
100% PL



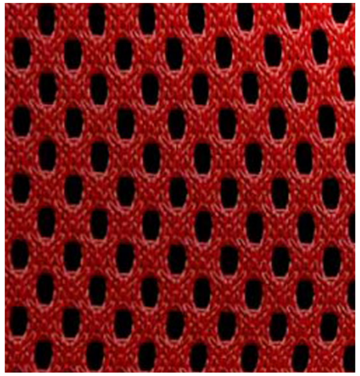
Mosquito Lame
GR220MQ
100% PL

Figure 58 3D Mesh Tessiltoschi

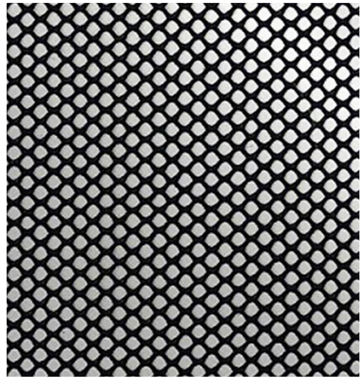


Army
GR320MQ
100% PL

Atala
GR370MQ
100% PL



Nadal
GR490MQ
100% PL



Tony
GR180 MQ
100% PL

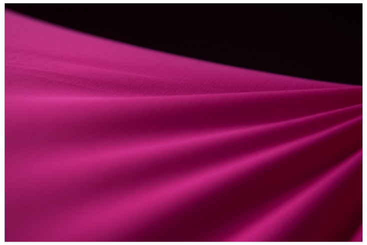
Figure 59 Textile Nets Tessiltoschi

- ***Sensitive Fabrics***

Founded in 1960, EuroJersey is a reference point in the sector of Italian-made warp knit fabrics. Its patented technology called Sensitive Fabrics, it used by most brands for sportswear, ready to wear, intimate apparel and swimwear markets [82].

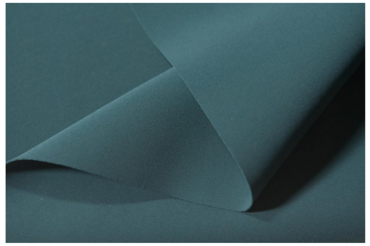
Classified by applications, the range of products is quite broad and cover the sectors of underwear, swimwear, sportswear and ready to wear. In the develop of the project will be choose the material, searching technical conditions of waterproofing and keep or release of temperature.

Just for now, the products will be shown with its basic's distinctive characteristics.

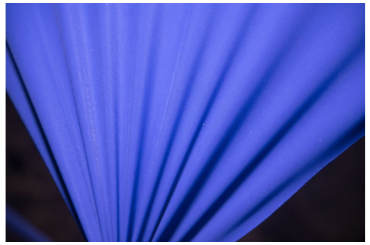


Sentitive® Fit
GR213MQ - H150CM
68% PA - 32% EA (Lycra)

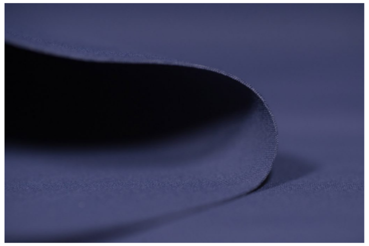
Sentitive® Power
GR230MQ - H160CM
80% PA - 20% EA (Lycra)



Sentitive® Sculpt Bonded
GR340MQ - H135CM
72% PA - 28% EA (Lycra)



Sentitive® Sculpt
GR218MQ - H140CM
59% PA - 41% EA (Lycra)



Sentitive® Plus bonded
GR250MQ - H135CM
73% PA - 27% EA (Lycra)

Sentitive® Bonded Bicolor
GR340MQ - H135CM
72% PA - 28% EA (Lycra)

Underwear Swimwear Sportswear Readytowear

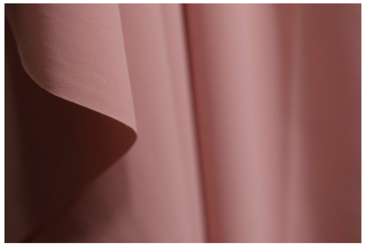
Figure 60 Sensitive Fabrics-1

Sentitive® Grace
GR80MQ - H140CM
74% PA - 26% EA (Lycra)

Sentitive® Ultra Light
GR143MQ - H140CM
78% PA - 22% EA (Lycra)

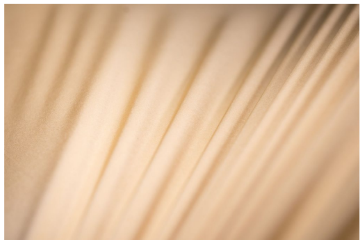
Sentitive® Sculpt Light
GR167MQ - H145CM
59% PA - 41% EA (Lycra)

Sentitive® Plus
GR117MQ - H140CM
73% PA - 27% EA (Lycra)

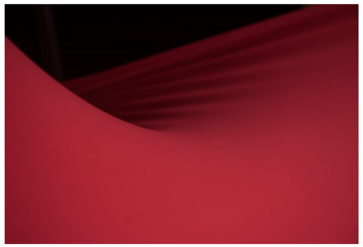


Sentitive® Sand
GR150MQ - H150CM
73% PA - 27% EA (Lycra)

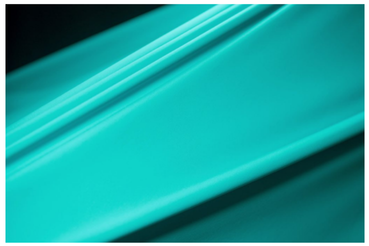
Sentitive® Poliestere
GR180MQ - H150CM
74% PL - 26% EA (Lycra)



Sentitive® Seric Plus
GR120MQ - H140CM
80% PA - 20% EA (Lycra)



Sentitive® Classic
GR164MQ - H140CM
72% PA - 28% EA (Lycra)



Sentitive® Life
GR185MQ - H150CM
71% PL - 29% EA (Lycra)

Underwear Swimwear Sportswear Readytowear

Figure 61 Sensitive Fabrics-2

5.2.6 Conductive fabrics

Conductive fabrics are defined as textiles structures that can conduct electricity. As typical uses, these fabrics are used as antistatic textiles, electromagnetic (EM) shielding, and e-textiles for flexible electronics[83].

These kinds of textiles can be obtained through different technological process [84] as follows:

- Dispersion: conductive carbon or metal particles are dispersed into synthetic polymers before or during fiber spinning.
- Coating: the textile surface is cover with a thin layer of electronically conducting materials such as silver, copper, aluminum or gold.
- Blending: nonconductive textile fibers are blended with conductive fibers.
- Threading: using conductive metal fibers (stainless steel, aluminum, copper and carbon) the fabric is produced.

However, the most versatile methods considered to manufacture nonmetallic electroconductive fibers are: melted spinning and metal's powder coating. These techniques are widely used for the industry.

The following table summarized the type of process, depending on the production phase of the fabric.

	Fiber	Yarn
During Fabrication	- Spinning - Wire drawing - Melt spinning - Wet Spinning	- Spinning - Twisting
Post-treatments	- Coating - Ink-jet printing	- Coating

Table 12 Overview of fabrication methods to produce conductive [71]

Because the nature of the project, the analysis will be focused on the use of e-textiles as basic component in applications as sensors and data transfer clothing.

Essential characteristics to consider in the design of wearable gadgets, using non-metallic conductive fibers and yarns, are related with its levels of flexibility, soft handling, drape and wash ability of the textiles.

Figure 62 Conductive fabrics considerations

Considering the previous requirements, a market research was done, aiming to find higher performing fabrics as possible options to the project.

Three important suppliers were found.

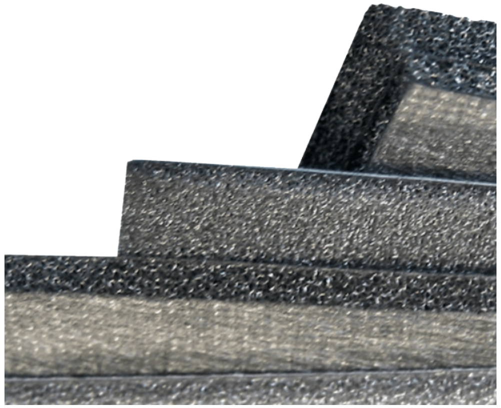
- ***Holland Shielding Systems BV***

Holland Shielding Systems BV is a Dutch company, mainly focus on research and development of high-tech functional industrial textiles for electronic shielding (EMI), and experts on the fabrication of Faraday's cages. Its portfolio of products includes, for the particular interest of the project, the manufacturing of conductive non-woven fabrics, conductive foam and conductive mesh.[85]

However, Holland Shielding Systems does not still produce any conductive textile with flexible characteristics.

Holland shielding
Conductive non-woven

Holland shielding
Electrically Conductive foam



Holland shielding
Electrically conductive mesh

*Figure 63 Holland Shielding Products**

***Obtained from:** hollandshielding.com*

- ***Statex***

German company based on Bremen that produce flexible metalized textiles and yarns. Its target market its focused on technical applications for the automotive industry and high-performance sensors for robotics [86]. Antibacterial fabrics for medical purposes, and EMI shielding are part of its production too.

Breakthrough Statex technology is based in the perfect combination of polyamide with silver filaments. On one side polyamide allows elasticity and strength, and silver filaments add part of the following properties to the textile:

- Antimicrobial
- Fungicide
- Odor- inhibiting
- Kind to the skin
- Thermal & Electrical conductor
- Anti-static
- Ductile
- Lightweight

Shieldex®, as registered denomination of Statex fabrics, can be manufactured under different industrial techniques: woven, knitted and non-woven fabrics. Selection will depend of specific applications.

*Figure 64 Statex Products***

*****Obtained from**: https://www.statex.de*

- ***Noble Biomaterials: Circuitex ®***

Global leader in conductive solutions for smart textiles applications, has collaborated with Bemis Associates (American company) to develop a seamless conductive advanced material that could allow a simple and durable integration of electronics into apparel [87].

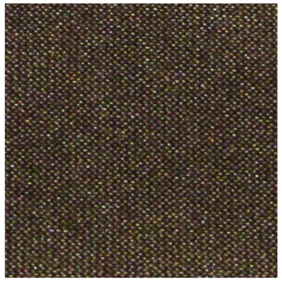
This technology called Circuitex® provides and easy detection, transmission and protection of electronic signals in a soft and flexible format.

A permanently pure silver bonding, that a add the conductive and antimicrobial characteristics to the fabric, are not a limit to the high level of flexibility, comfort and durability of the textile.

Data transmission as ECG, EMG signals, body monitoring and power delivery (basic power, lighting, electro-muscle stimulation) are the kind of applications for which Circuitex® can be widely used.

Just stretchable materials, it will be considered from the Circuitex® catalogue, because the characteristics of the project.

Series 5640862
Strech: 2 way
GR302MQ
95% Silver Nylon -5% Spandex

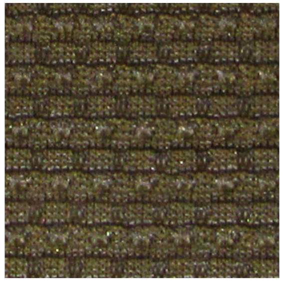


Series 5240560
Strech: 1 way
GR193MQ
87% Silver Nylon -13% Spandex

Series 57600654
Strech: 4 way
GR339MQ
93% Silver Nylon -7% Spandex

Series 5161068
Strech: 2 way
GR346MQ
89% Silver Nylon -11%

Series 5560553
Strech: 2 way
GR146MQ
76% Silver Nylon -24%



Series 562704DG57
Strech: 1 way
GR193MQ
75% Silver Nylon -20% 1604DG/13
- 5% Spandex

Series 54256-S
Strech: 1 way
GR220MQ
71% Silver Nylon -21% Polyester-
8% Spandex

Figure 65 Circuitex Catalogue

5.2.7 JOINING PROCESS

Finishing process can be as important as the internal structure of the garment, in the final user performance. Depending of the needs several methods could be chosen. Everything will depend of the functional requirement, the technology available and the final product's price. Some of the most used methods are presented as follows [62]:

- ***Unit method***

The entire piece is knitted in just one piece. Shortest manufacturing process and lowest prices is the main benefits.

- ***Linking***

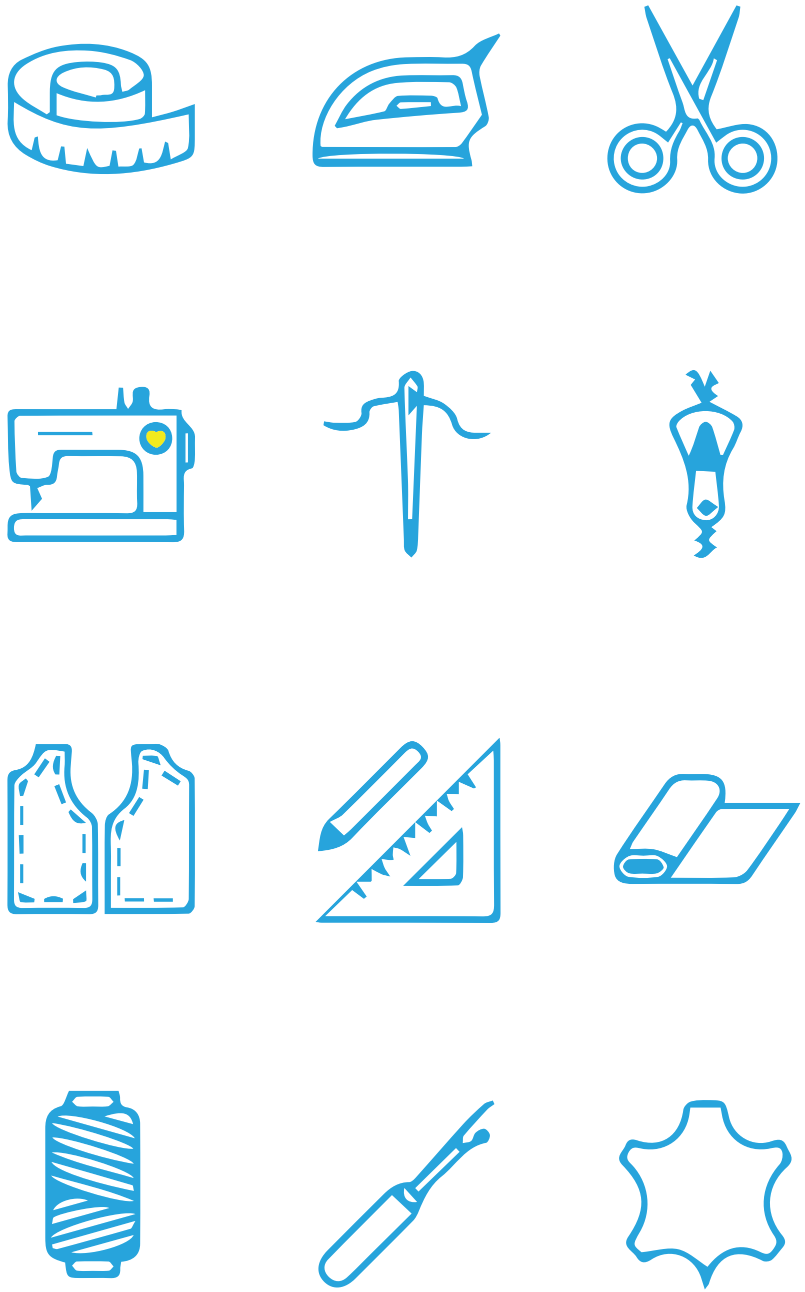
It is achieved by joining two fabrics together, loop by loop along the wale (vertical direction) of the fabric. Commercially high-end garments use this method.

- ***Cut and sew***

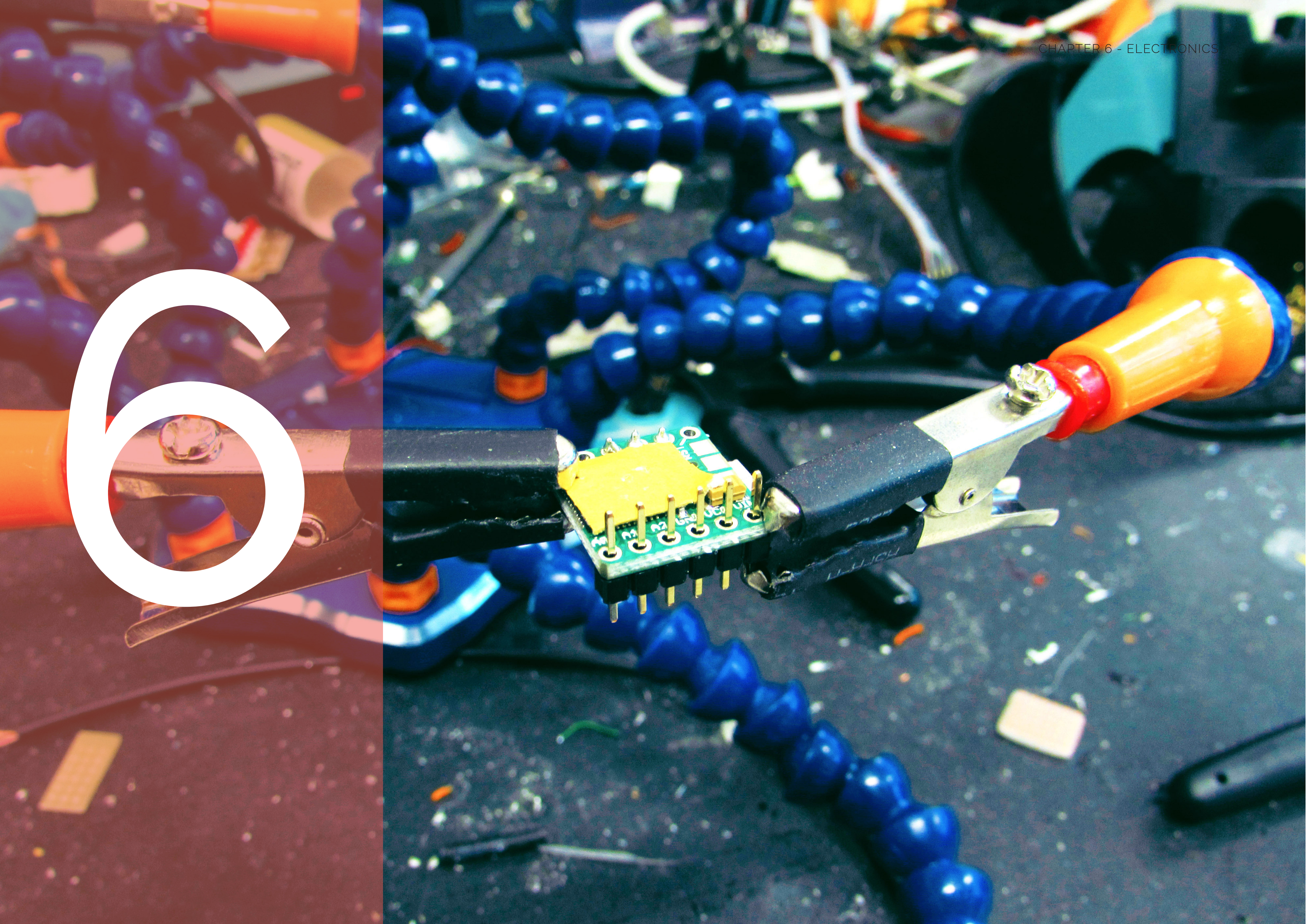
Cutting out the patterns of the garment and sewing them together. Commonly used in mass production.

- ***Ultrasonic bonding***

Seams joined with ultrasonic radio frequency. Can be used to cut, seal and sew synthetic materials as far as they have 60% of thermoplastic elements. Applications like sportswear and outwear take part of this method, because provides a durable lightweight fabric.



6



ELECTRONICS

This chapter shows the electronic devices to be used in the project, explaining their functional characteristics, requirements and constraints. Electronic arrangement and the use of Arduino shields in the project is presented as a functional prototype proposal, not scalable at commercial production level because its DIY characteristics.
However, the methodological structure developed, allows to understand the the operation sequence defined for the product.

6.1 General description

The explanation about the electronic components of the project is focused in the technology used for the construction of the functional prototype. A functional prototype is produced in order to show the integration and functionality of available hand prosthesis models with the interface socket – forearm developed during this research as thesis topic.

Searching about the electronics state of art, it was found that mass manufacturing techniques can allow high levels of miniaturization in electronics at a low-cost production. As a result, reduction in size components implies a reduction in weight and encourage a better user performance in any type of electronic device.

But due to the manufacture impossibility to develop an own PCB (printed circuit board), the project implementation is carried out taking advantage of DIY cutting-edge technology (Arduino board, Myoware chips, micro servomotors etc.). The breakthrough point of the project, will be the use of Arduino Pico board, as an alternative of miniaturization in projects of these characteristics.
Based on this, a general description of each of the devices used in the project, is shown below, and a final arrangement of the functional implemented circuits will be presented too.

6.2 Arduino uno R3

Used to during the project to build prototypes in preliminary phases, integrates versatility in the arrange of electronic circuits taking advantage of a hardware microcontroller and a simplified programming language based on C++, that substitute complex wire connections by computational routines.

As part of its operational features, Arduino UNO R3 allows to use 14 digital pins as input or output, using the code functions pinMode (), digitalWrite(), and digitalRead(). All of them operate at 5 volts providing or receiving a maximum of 40 mA and with an internal pull-up resistor of 20-50 k Ohms[88].

Another 6 analog inputs can provide 10 bits of resolution (i.e.1024 different values) for this kind of signals. By default they are measured from ground to 5 volts, though is it possible to change the upper end of their range using the AREF pin and the analogReference() function.

Arduino UNO R3, counts with two microcontrollers that based the performance of a versatile board. The most relevant characteristics of both microcontrollers are shown below. Further and detail information can be consulted at product datasheet[89].

ATMEGA328P-PU - Specifications

- Microcontroller with flash memory that reach to 32KB.
- High performance, Low power AVR
- 256/512/512/1K Bytes EEPROM (electrically erasable programmable read-only memory)
- 512/1K/1K/2K Bytes Internal SRAM (Static Random-Access Memory)
- Write/Erase Cycles: 10,000 Flash/100,000 EEPROM
- Data retention: 20 years at 85°C/100 years at 25°C
- 23 Programable I/O lines
- 28 Pin PDIP
- Operating voltage: 1.8 -5.5 V
- Temperature range: -40°C to 85°C
- Speed grade: 0 - 4 MHz@1.8 - 5.5V, 0 - 10 MHz@2.7 - 5.5.V, 0 - 20 MHz @ 4.5 - 5.5V
- Power consumption (at 1MHz, 1.8V, 25°C)

Active mode: 0.2 mA

Power-down mode: 0.1 μA

Power-save mode: 0.75 μA.

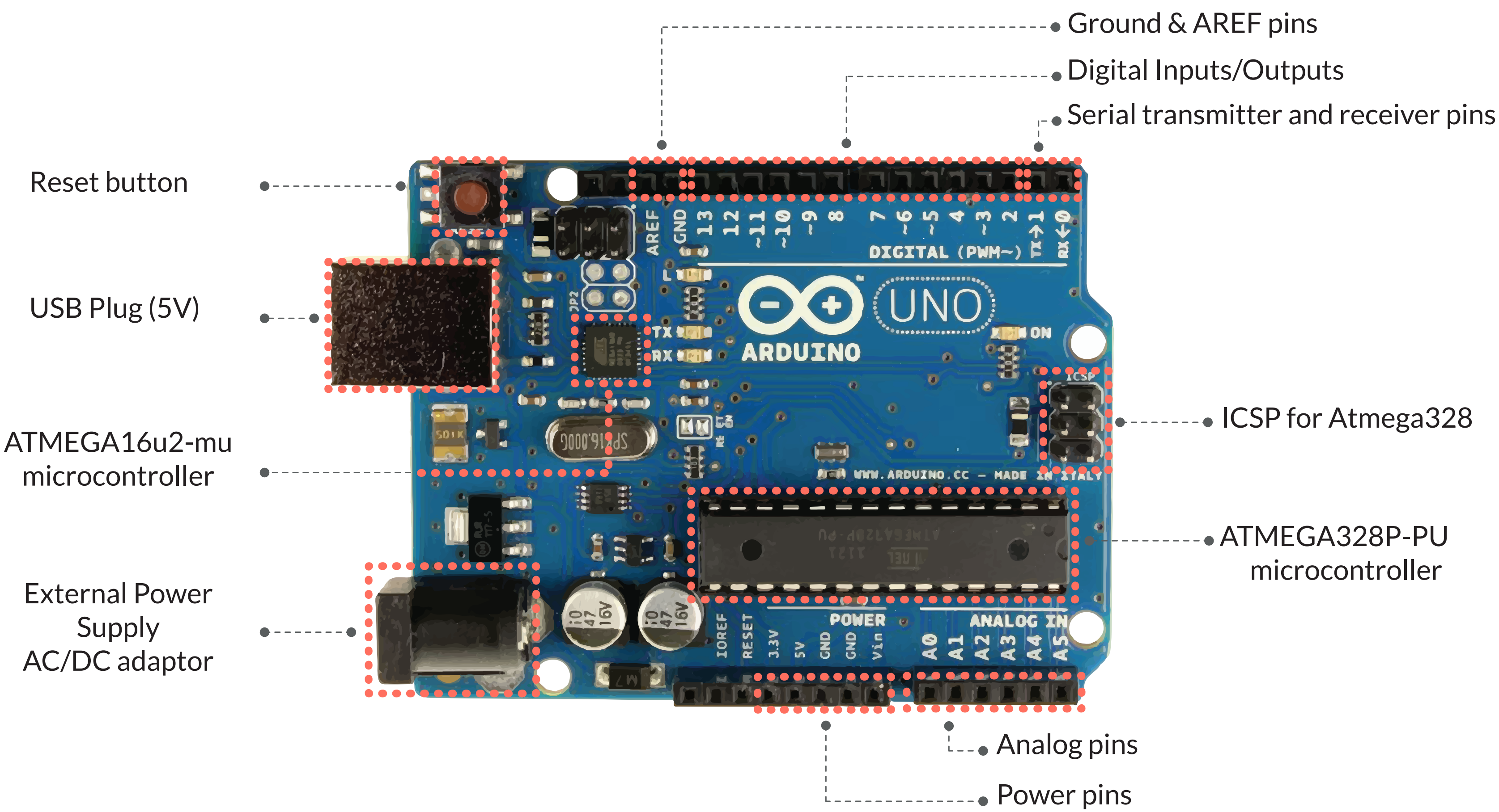


Figure 66 Arduino UNO R3 board

ARDUINO UNO-TECH SPECIFICATIONS	
Microcontroller	ATMEGA328P
Operating Voltage	5V
Input Voltage (suggested)	7-12 V
Input Voltage (limit)	6-20 V
Digital I/O pins	14 (of which 6 provide PWM output)
PWM Digital I/O pins	6
Analog Input Pins	6
DC Current per I/O pin	20 mA
DC Current per I/O pin	50 mA
Flash memory	32 KB (ATMEGA328P) of which 0.5 KB used by bootloader
SRAM	2 KB (ATMEGA328P)
EEPROM	1 KB (ATMEGA328P)
Clock Speed	16 MHz
LED_BUILTIN	13
Length	68.6 mm
Width	53.4 mm
Weight	25 g

Table 13 Arduino UNO Technical Specifications

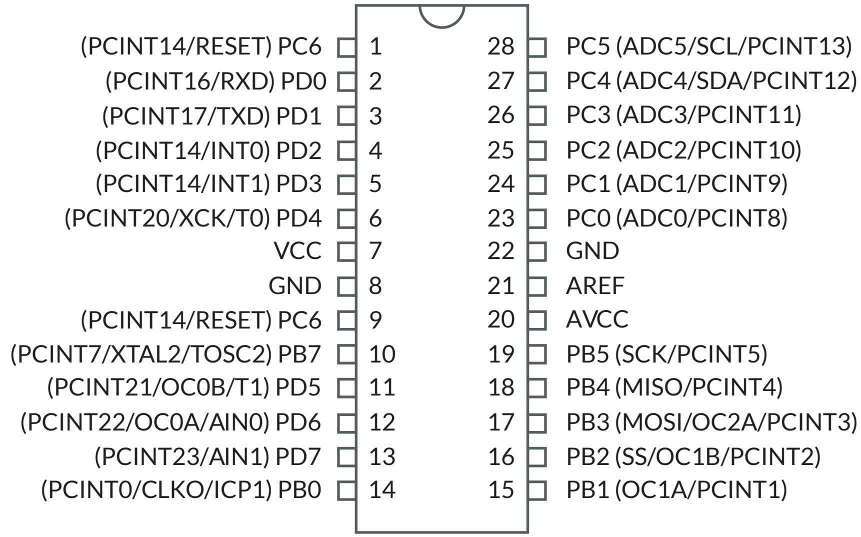


Figure 67 Pin configuration ATMEGA328P-PU

ATMEGA16u2-mu -Specifications

- 8-bit microcontroller used as USB driver.
- High performance, Low power AVR
- 8K/16K/32K Bytes of In-System Self-Programmable Flash
- 512/512/1024 EEPROM (electrically erasable programmable read-only memory)
- 512/512/1024 Internal SRAM (Static Random-Access Memory)
- Write/Erase Cycles: 10,000 Flash/ 100,000 EEPROM
- Data retention: 20 years at 85˚C/ 100 years at 25˚C
- 22 Programable I/O lines
- Operating voltage: 2.7 -5.5 V
- Temperature range: -40°C to 85°C
- Speed grade: 8 MHz@2.7V, 16 MHz@4.5V

6.3 Arduino Pico

Arduino board, actually in kickstart period, is considered one the latest innovative DYI products in terms of size and weight performance.

Based on the ATmega32u4 microcontroller, it has into its features 5 I/O pins, 3 analog inputs and 3 SPI enabled pads on the bottom side of the board [90].

With its tiny dimensions 15,25 x 15,25 mm, Arduino Pico allows to set aside limitations caused by the size and flexibility, opening the possibilities of applications related with wearable devices[91].

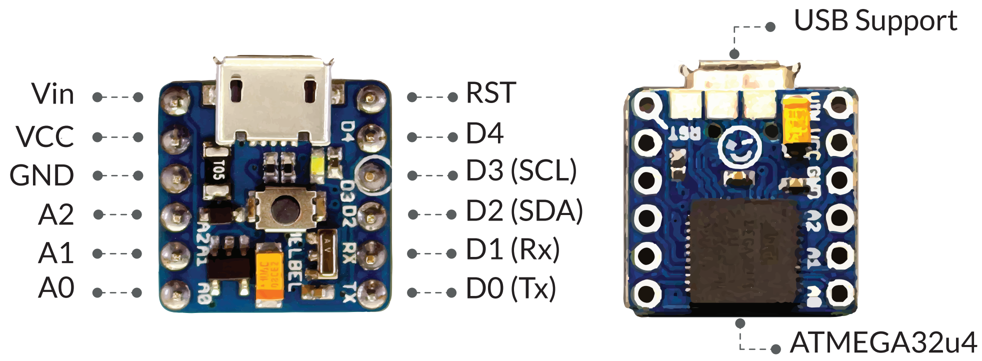


Figure 69 Arduino Pico board

Arduino PICO, counts with a low-power microcontroller (ATMEGA32U4) that allows executing powerful instructions in a single clock cycle with a working performance range of 1 MIPS per MHz, optimizing power consumption versus processing data speed[92]. Some specific microcontroller features are shown below. Further information can be consulted in the product datasheet.

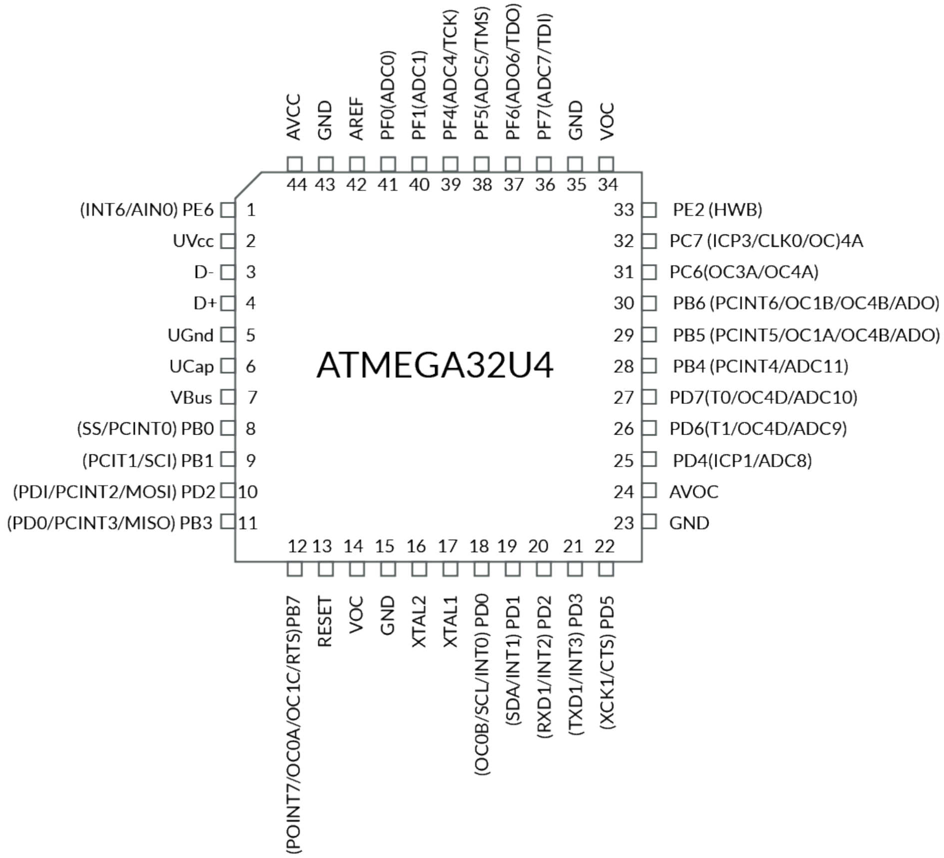


Figure 68 Pin configuration ATMEGA16u2-mu

***Obtained from:**https://store.arduino.cc/arduino-uno-rev3*

ATMEGA32u4 -Specifications

- Microcontroller flash memory: 32KB.
- High performance, Low power AVR
- 1024B EEPROM (electrically erasable programmable read-only memory)
- 2KB Internal SRAM (Static Random-Access Memory)
- Write/Erase Cycles: 10,000 Flash/100,000 EEPROM
- Data retention: 20 years at 85°C/100 years at 25°C
- 26 Programable I/O lines
- 44 Pin
- USB module 2.0 full speed/low speed
- Operating voltage: 2.7 to 5.5 V
- Temperature range: -40°C to 85°C
- Speed grade: 16 MIPS at 16 MHz@2.7 - 5.5V

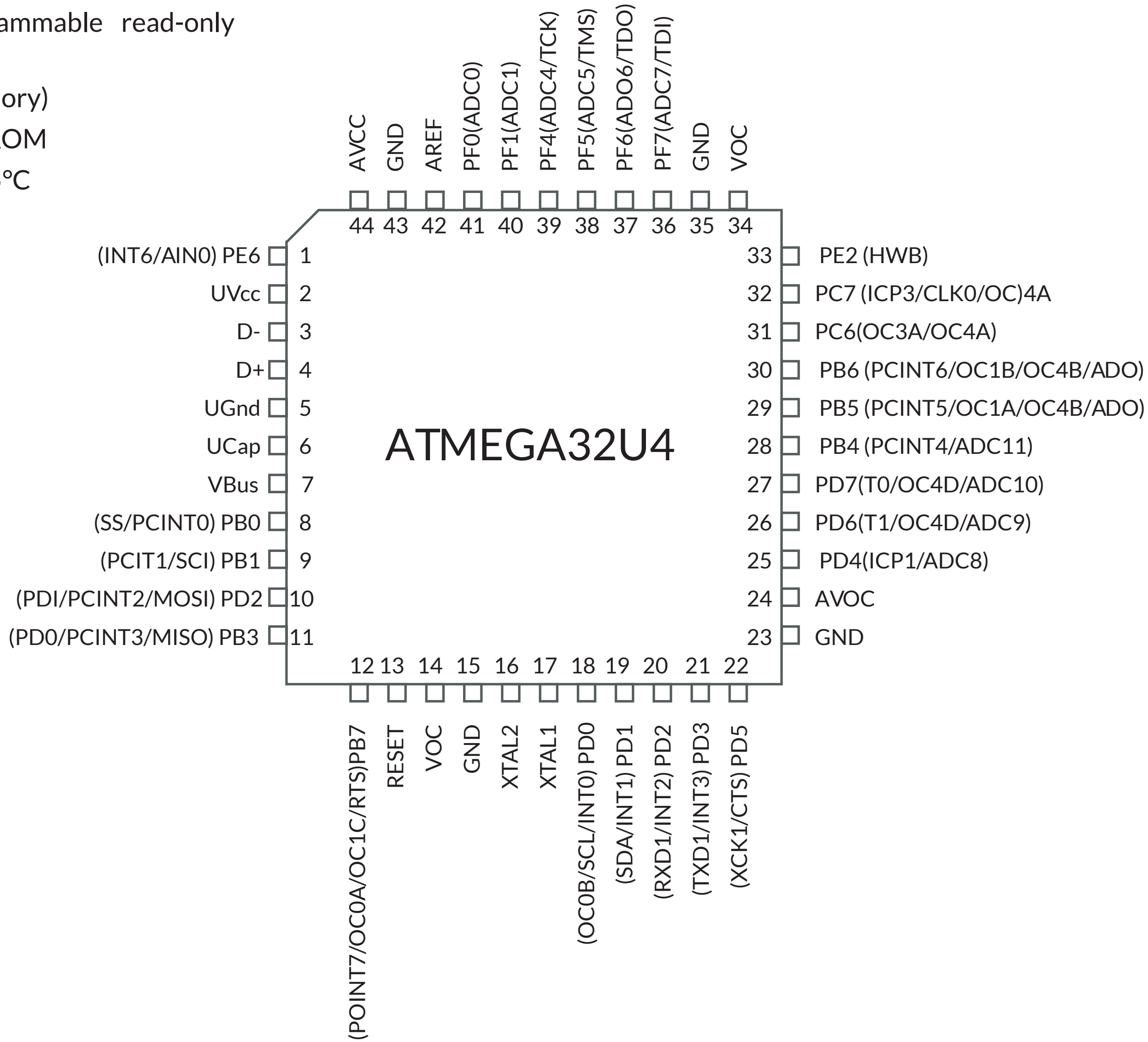


Figure 70 Pin configuration ATMEGA32u4

The application of Arduino Pico represents the use of just the 6% of area of an Arduino UNO board beside a weight reduction in 95%. Speed in data transmission, rise up because the improved characteristics of the microcontroller. Comparative schema clarifies better the geometric characteristics of Arduino board in the market.

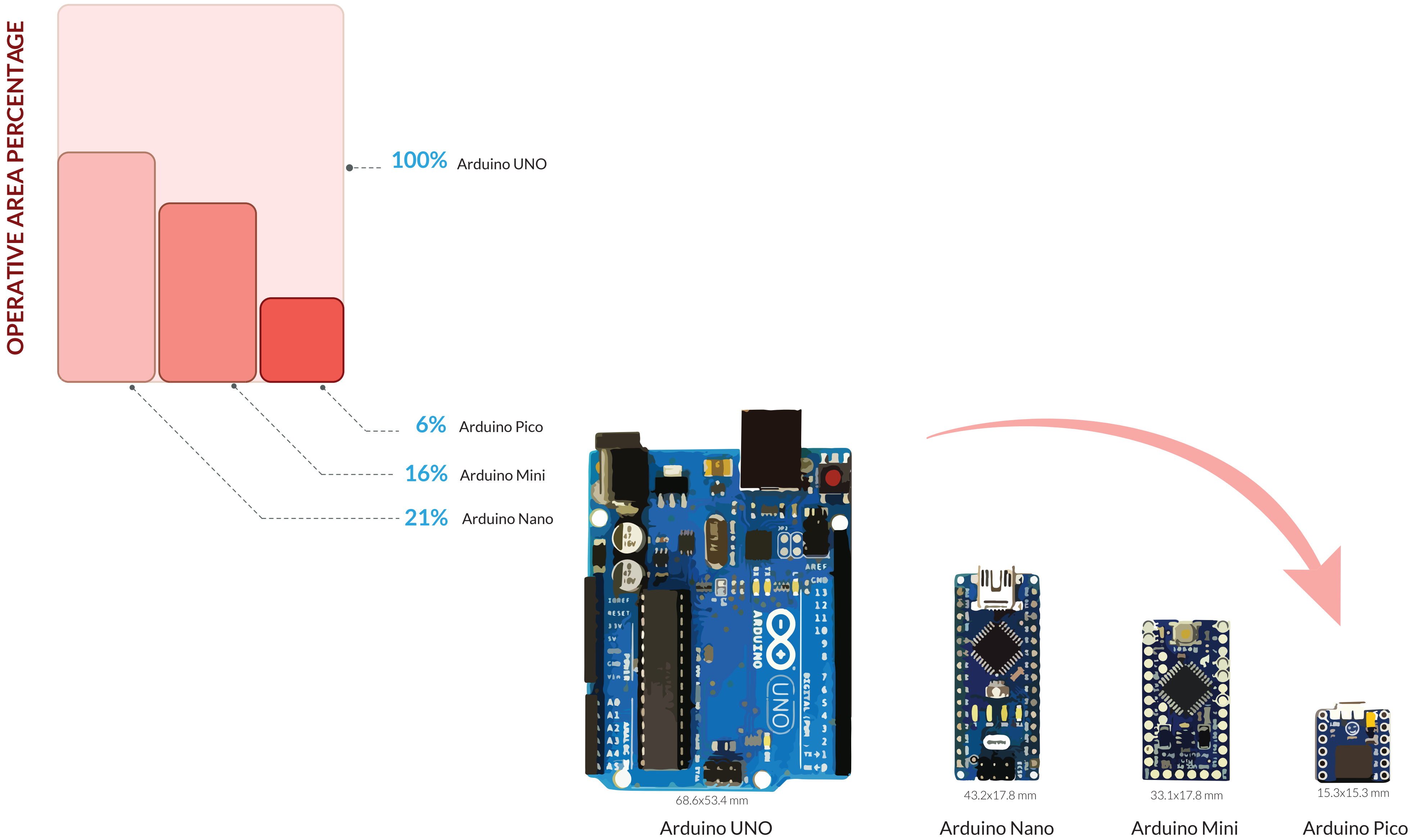


Figure 71 Arduino Board Operative Area Percentage

6.4 Myoware™ muscle sensor (AT-04-001)

Part of the technological evolution of integrated circuits, has led to EMG sensors can be used as an alternative element of control in robots, prosthetics and some other systems, allowing new applications beyond the traditional use in the medical research. Advancer Technologies in its last EMG chip release, reduced the size in an important percentage, making its chip adjustable and adaptable for wearable applications.

The possibility to attach biomedical sensor pads to the board, reduce complicated arrangements of wired connections, and simplified its implementation.

Myoware sensor, measure the muscular signals, filtered and rectified the electrical activity, allowing its post-processing in some Arduino, Raspberry Pi, or any other similar microcontroller board. Includes single-supply voltage of +3.1V to +5V, RAW EMG output, polarity protected power pins, indicator LEDs, and an On/Off switch [93]. Detail electrical specifications are found on the table.

MYOWARE™-ELECTRICAL SPECIFICATIONS

Parameter	MIN	TYP	MAX
Supply Voltage	+3.1 V	+3.3 V or 5 V	+6.3 V
Adjustable gain potentiometer	0.01 Ω	50 kΩ	100 kΩ
Output signal Voltage			
EMG Envelope	0 V	-	+Vs
RAW EMG (centered about +Vs/2)	0 V	-	+Vs
Input Impedance	-	110 GΩ	-
Supply current	-	9 mA	14 mA
Common mode rejection ratio	-	110	-
Input Bias	-	1 pA	-

Table 14 Myoware Electrical Specifications

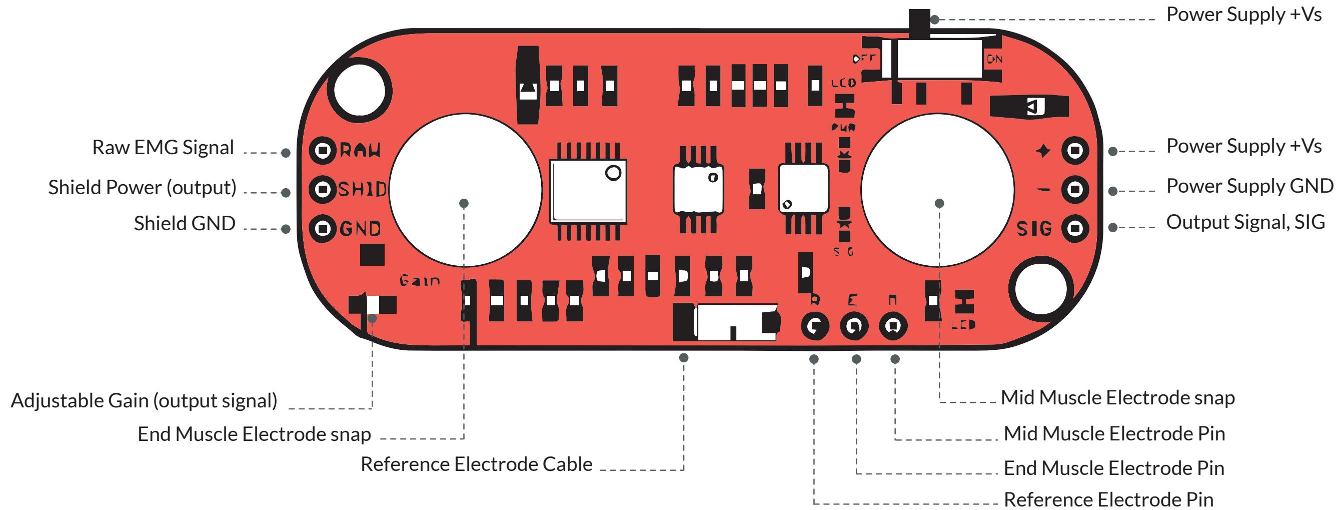
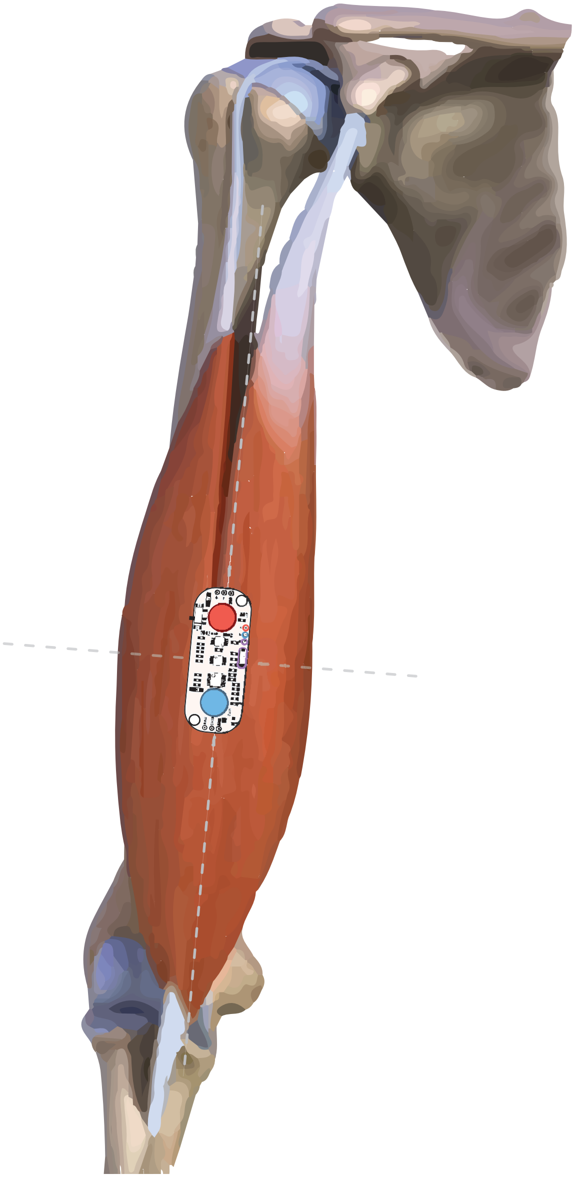


Figure 72 Myoware Pin configuration

6.4.1 Mode of Use

Myoware™ AT-04-001 sensor has integrated in the board a series of 3 electrode snaps, that replace the used of cables. However, if the application does not require the snaps use, external wired can be set up to the hole pins shown in the picture.



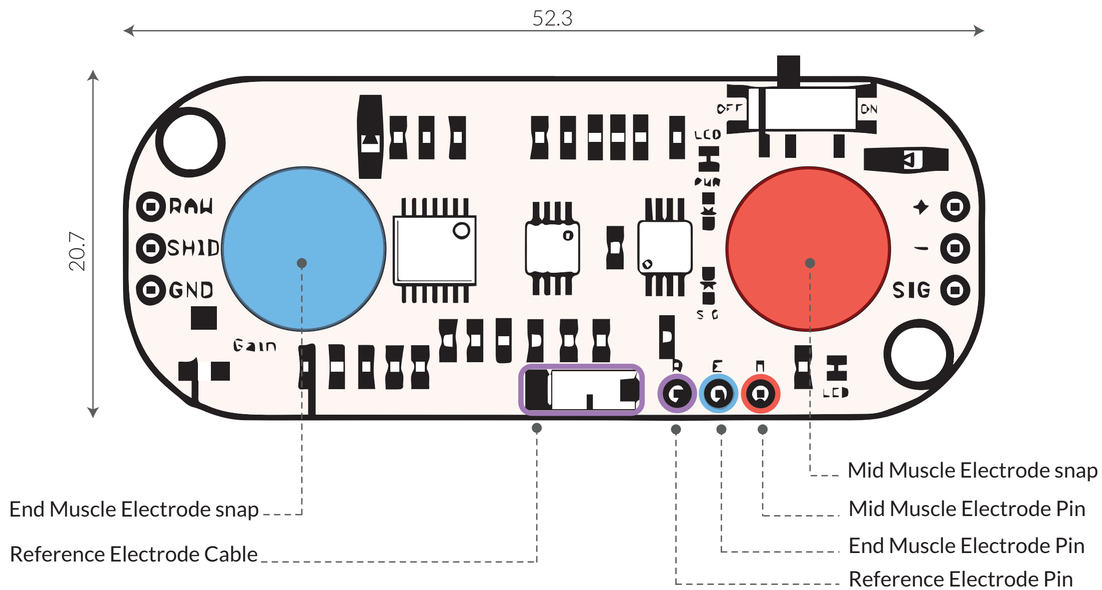


Figure 73 Myoware Mode of use

Correct position of the sensor is key for an optimal acquisition of the myolectric signal in terms of intensity a noise reduction. Electrodes (integrated snaps or in external arrange) should be located in the middle of the muscle, aligned with the orientation of the fibers. Reference electrode, has to be connected to another section of the body, different to the initial muscle defined.

6.5 Servo-Motor SG-90

Specifically, in the project, servomotors will work as mechanical actuators, driven by the myoelectric signals generated by the muscles of the amputee. The motors power source will be a rechargeable battery whose technical specifications will be described later.

Characteristics of servomotors do not correspond to the characteristics of components used in commercial models of hand prostheses, but they fit to the basic technical requirements that a functional prototype can request.

Technical specific data of the device is presented, to clarify the operation and the geometric constraints in the final 3D model.

Servomotor SG-90 can rotate approximately 180°, 90° in each direction. Can be controlled by language code, through some microcontroller platform (Arduino, Raspberry, or PIC) that can generate the PWM signals.

The control of direction will depend of the variation on time, from 1ms to 2 ms, with a PWM signal frequency of 50Hz and 20ms period. Movement can be described as follows:

- For a 1ms On-Time, the motor will be in 0°
- For a 1.5 ms On-Time, the motor will be in 90°
- For a 2 ms On-Time, the motor will be in 180°

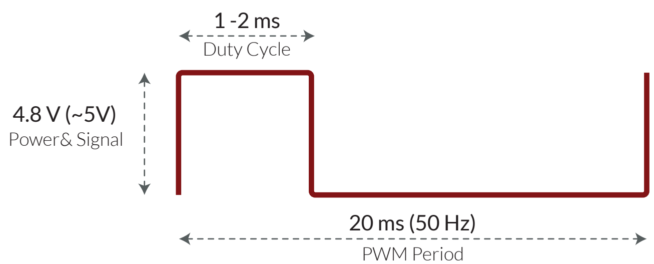


Figure 74 Servomotor working Cycle

Varying the time among this range, allows to gradually control the motor position from 0° to 180°[94].

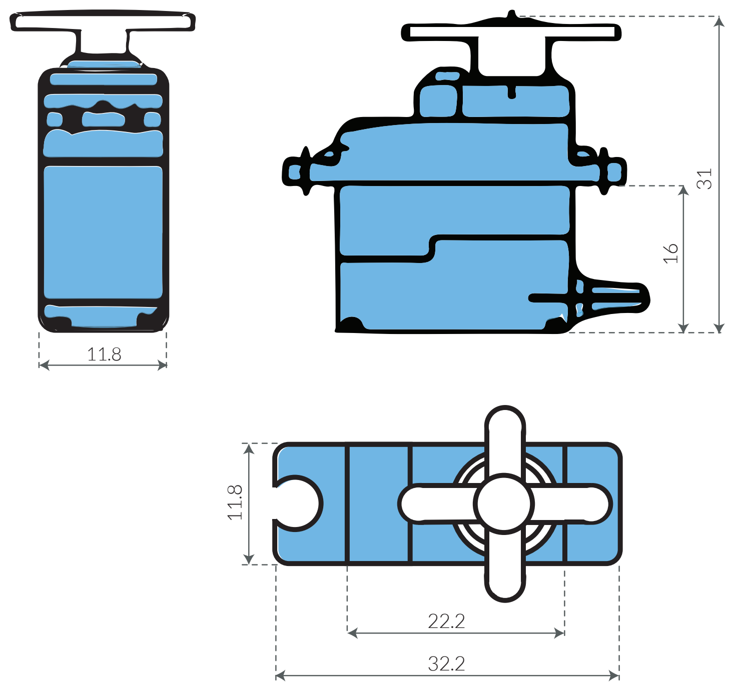


Figure 75 Servomotor SG90 dimensions

SG90 SERVOMOTOR DATASHEET	
Operating Voltage	4.8 V ~5V
Torque	2.5 kg/cm
Operating Speed	0.1 s/60°
Gear Type	Plastic
Rotation	0° - 180°
Weight of motor	14 g

Table 15 Technical Datasheet

6.6 Electronic arrangement

A base electronic arrangement is presented, with the purpose of make sense the reader about the functional components and how this are organized inside the project. Circuit configuration was carry out at laboratory as trial version of a possible implementation. Because the lack in some components that are presented as proposal and the characteristics of the project (design of socket and forearm structure) electronics are just mentioned as and indicative function. However, designed schema, can works as guide of construction on future considerations.

Refining in microcontroller code will be related with the level of development in the design of a possible grasping device. Reason why, is not presented as part of the project.

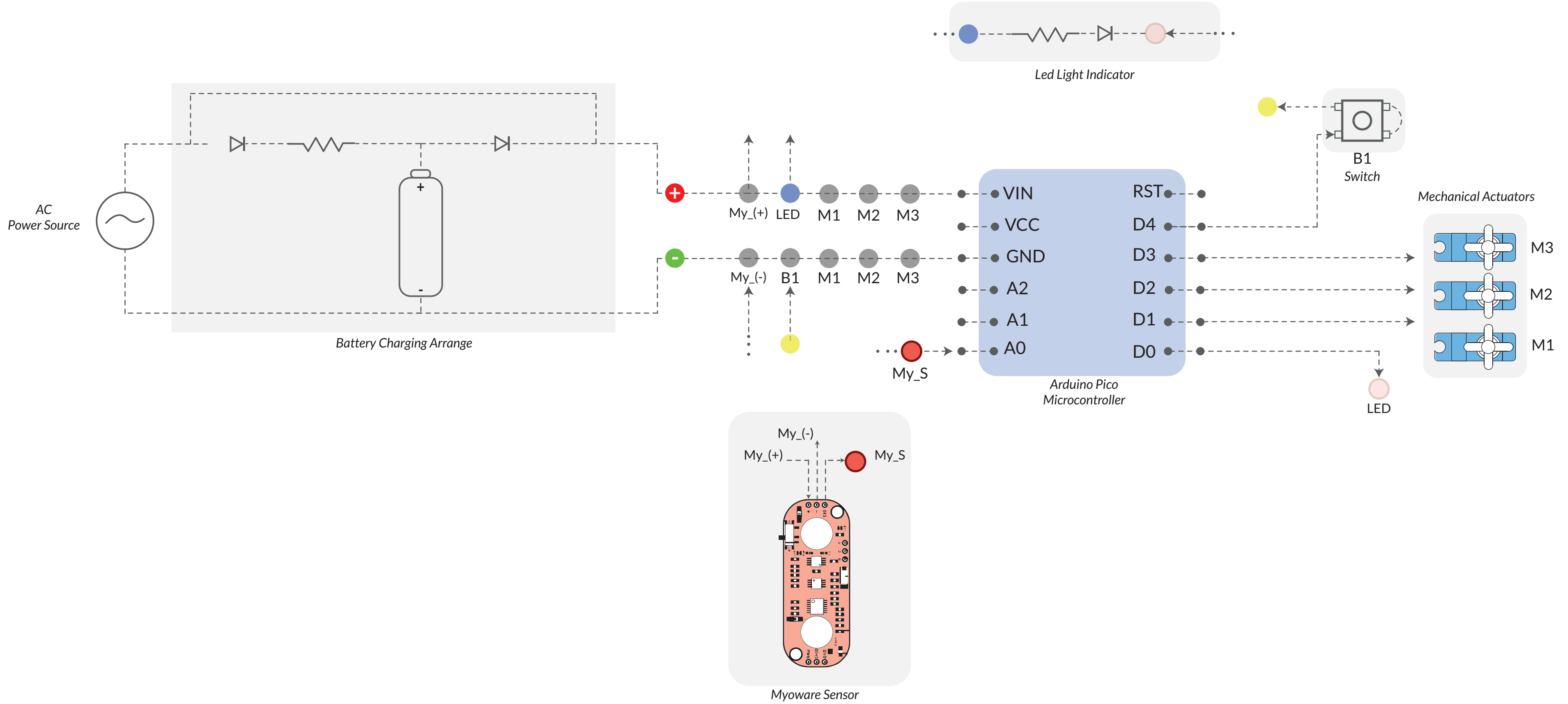


Figure 76 Technical Datasheet

7

POWER SOURCE: BATTERIES

This chapter describe basic concepts related with the theory of selection of batteries. Define too, the several batteries technology developed at the moment, describing briefly its functional principal and operative characteristics. Finally, the idea of flexible batteries is presented as new generation of portable power sources. Outstanding brands related with this technology are shown as reference point.

7.1 GENERALITIES

As far as a basic definition a battery it's a device able to convert chemical energy into electricity [62].

Technological gadgets, as became an excuse for which nowadays, almost everybody can have a close relationship with batteries, either in everyday technological devices (mobile phones, watches and wearables) or healthcare applications as hearing aids, pacemakers or hospital care devices.

Clearly, these electronical devices, are powered by electrical energy - as more extended and efficient method- stored somehow in batteries that according the application can be primary (specific amount of stored energy) or rechargeable.

In the context of wearables devices and the use of smart textiles, functional requirements of batteries are related with flexibility, lightness and easy-refilling.

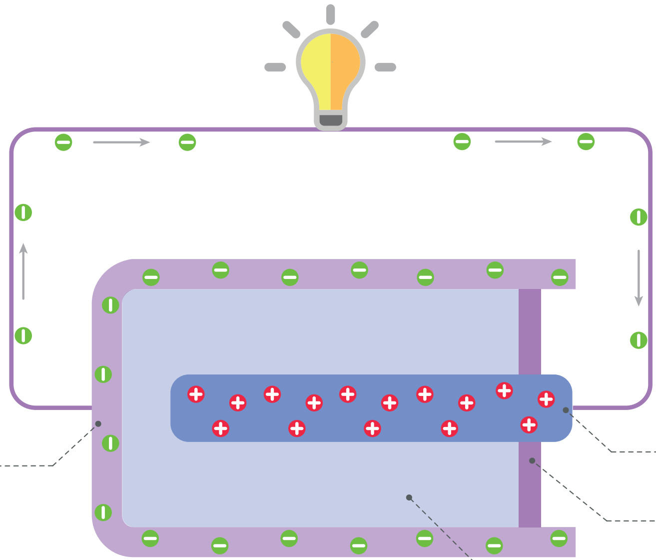


Figure 77 General schema Dry battery cell

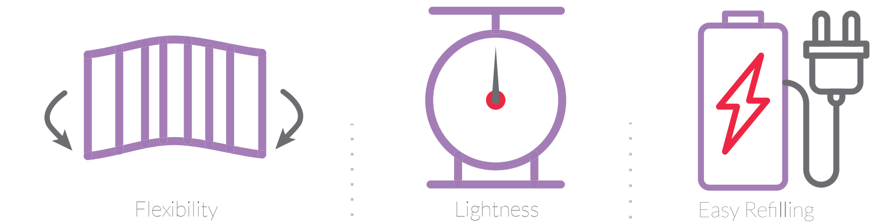


Figure 78 Functional requirements

Batteries can be classified according the power required by the electronical device from which is used and based on the chemistry of their internal reactions. Considering the first criteria, a general classification can be:

-Low end batteries: in the level of microwatts. Used in watches, pacemakers and hearing aids. With a nominal capacity of 10-120 micro-ampere-hour at 1.5V. Easily to embedded into smart textiles

-Mid-Range: For wireless communication. It requires an average power around of 500 mW. Usually powered by AA batteries.

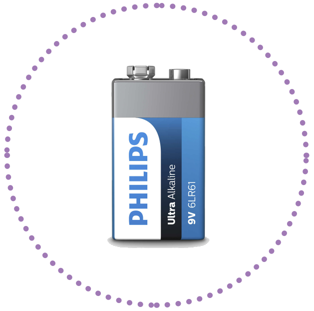
-High End: In the level of 50 W, which is currently provided by a Lithium-ion rechargeable battery. Bulky and weighing

The second criteria of classification can be more precise, pointing technical requirements of a project or technological availability of the market.

Some specifics data about that classification are summarized in the schema following schema .

Lead Acid Battery

- High discharge rate
- Low energy density limits
- Used in: automobiles, hospital equipment, powered wheelchair, emergency lighting



Alkaline Battery

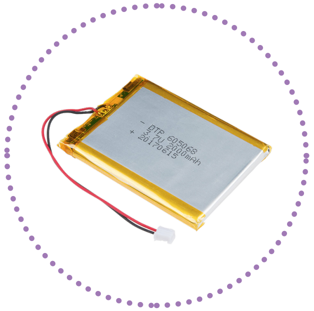
- Higher energy density compared with lead acid batteries
- Shorter charge cycle
- Not optimal for smart textiles

Nickel Cadmiun Battery

- High discharge rate
- Low energy density
- Largest charge cycle
- Long service life with periodical recharging
- Low manufacturing cost
- Contains toxic metals, and can be not safe for healtth

Nickel-Metal Hybride

- Higher energy density
- Low charge cycle if it`s compared with NiCd batteries
- Safer alternative to replace NiCd

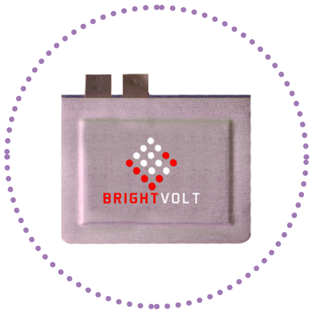


Lithium Ion Battery

- Higher energy density
- Large charge cycle
- Without battery memory effect*

Lithium Ion Polymer

- Similar to Li-Ion batteries in terms of energy density
- Lower cost if its compared with Li-Ion batteries
- Dry polymer electrolyte enable a slim geometry
- Potentially flexible



PME ® Flexible Battery

- Battery composed by a cathode, an anode and a separator with flexible characteristics.
- Materials for the electrodes arranged in flexible substrates through coating or printing methods.
- Manufactured through different techniques (polymer binders, free-standing films or electrode flexible matrix)
- Thin and flexible
- Actually in develop and research

7.2 TECHNICAL TERMINOLOGY

With the objective to choose the right power source that could fit properly with the demands of the project, its necessary to know about some technical terminology. This will make easier the entire comprehension of the design process

- ***Cell Voltage***

Voltage provided by the power source. The nominal voltage given, its often related with the MPV (mid-point voltage), that is the measured of voltage when the battery has discharged 50% of its total energy[95].

Another important reference value is related with the voltage at the end of the battery life or End of Discharge Voltage - EODV. Both, can define the behavior of the battery and are represented through the battery charge/discharge curve.

- ***Charge cycle***

Maximum and minimum charge voltages differ from the reference values MPV and EODV. Depending of these peak and lower values the charge/discharge curve can be flatter or being more inclined.

Flatter discharge curve means less voltage variation, ideal condition to consider as an important design criterion.

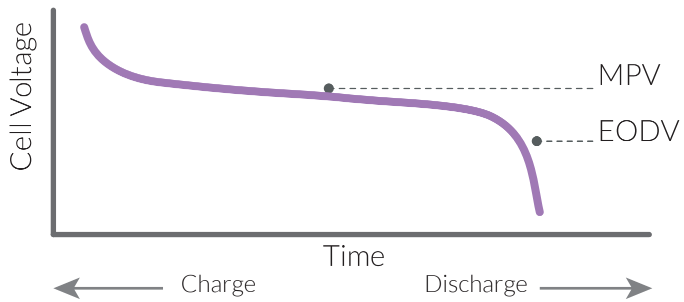


Figure 79 Charge/Discharge Curve

- ***Internal Resistance***

Called too Internal equivalent series resistance (ESR), it's the value that limits the amount of maximum current the battery can deliver.

The current that pass through the ESR, reduce the terminal voltage – defined by the Ohm Law V=I*R.

The amount of heating generated by the battery in working conditions, is calculated using the ESR value and through the expression $P=R*I^2$

- ***Peak Current:***

Can be defined as the maximum amount of current that a battery is possible to deliver. Depends directly of the internal equivalent resistance of the battery

The usual measure, given to characterize a battery is the Ampere/hour, and define the current that a battery delivers for 1 hour before the battery arrives to the end of life.

- ***Energy density***

Can be expressed either in terms of mass or volume.

The energy density is the amount of electrical energy stored in a battery of a given weight or volume, usually measured in watt hour per kilogram (W h/kg) or Watt hour per liter respectively.

The operating period is determined by the power requirement of the electronics and the energy density of batteries employed.

$$E_p = \frac{W * t}{m}$$

***E_p**= Energy density where*
***W**= Power required (Watts)*
***t**= Time*
***m**= Mass (kg)*

If an electronic circuit consumes one watt and the batteries employed weigh 20 g and have an energy density of 150 W h/kg, the operating period will be 3 hours.

7.3 Flexible batteries Products in the market

Into the innovation proposal in terms of technology, the thesis project remark the possibility to use flexible batteries as power source method. Even it's a technology still in develop, the functional requirements of lightness and weight distribution of the prosthesis can fit very well with this newflanged kind of devices. Some of the most representative manufacturers, in terms of operational maturity of their products, are presented below.

- ***Amo Green Tech – Li-Ion Flexible Battery***

Recently released to the market in some Samsung and LG devices, Amo Green batteries' technology can operate normally when they are forcibly folded on 180° or twisted left and right up to 20°[96].

Designed for hardworking conditions, batteries can still operate normally subjected to cuts and nails with nonmetallic elements.
Unlike what happens in another flexible batteries, Amo Green Tech count with a cell easily bendable that eliminates the necessity of space between cells [97].

Overheating, risk ignition and leakage is avoided by using a special binder technique of electrodes and a 3D net-structure coating. The use of PAN (polyacrylonitrile) instead of PE (polyethylene) and PP (polypropylene) increases the temperature of overheating to 300°- normal Li-Ion batteries can reach just 130° to 150°-.

Because the content of adhesives -material that allows flexibility- density of energy is about 30% less than normal lithium batteries. Technology is still in development and prices are twice a normal Li-Ion polymer battery.
Operational data of the batteries was not supplied by the producer.

***Obtained from**: *http://itersnews.com/?p=105684*

*Figure 80 Amo Green Flexible battery**

- ***BrightVolt PME ® Flexible Battery***

PME® flexible batteries from BrighVolt, it's a patented technology that means Polymer Matrix Electrolyte and its basically the composition of Lithium salt, GPI-15 polymer and chemical solvent.
Technological breakthrough of this company lies in the higher energy density of its products thanks to PME®, that bonds directly to the electrodes creating thin layers and eliminating dead weight.
Thin and flexible, BrightVolt technology implements solid state battery with no liquid lithium, characteristic that protect batteries from leakage on heavy duty performance.
In continuous research, BrightVolt is centered in the develop of batteries for medical equipment, powered cards and wearable devices.
Up to now, available commercial technology manages small level of amperage, from 14 mAh to 29 mAh. Higher current capacities can be reached by a particular necessity of the client on direct contact with the company but are not into its commercial catalogues.

Figure 81 BrightVolt 14mAh Battery

- ***JENAX- Flexible Lithium Polymer Battery***

J.Flex batteries can be rolled and bended, opening the multiple possibilities in terms of technological wearable devices. Used from fashion to healthcare or IT gadgets, industries have the privilege to meet design, comfort and efficiency in their products [98].

Into its most functional characteristics are the use of gel polymeric electrolyte, encouraging a rapid movement of lithium ions and allowing a low internal resistance.

Counts with a high energy density – proportional to the small size – and because the way is packed, almost and absence of battery overheating.

Some of their actual characteristics are shown in the following table.

Category	Contents
Type	Li-ion Polymer
Dimension	27x48 mm
Nominal Voltage	3.8 V
Capacity	30 mAh
Operation Temp.	-20°C to 60° C
Cycle	80% @ 1.0 C/1,000 cycle
Standard current	Charge 1,0 C CC/CV to 4.25 V, 0.1C cutoff Discharge 0.2 C to 3.0 V
Max Current	Charge 1,0 C (30mA) Discharge 2.0C to (60mA)

Table 16 Jenax battery Characteristics

- ***Prologium – FLCB (Flexible Lithium Ceramic Battery)***

Its main innovation is the use of the solid-state Lithium ceramic electrolyte instead of traditional liquid-state one. Furthermore, the introduction of FPC (Flexible Printed Circuit) battery substrate, made FLCB batteries adopt characteristics like bendability, flexibility, rollability, noncombustible properties, no leakage and safe discharge phase, even after penetration, punching or cutting [99].

Product	FLCBxxxxxxAAAA			
	027038	046046	051076	107163
During Fabrication	27x38	46x46	51x76	107x163
Nominal Voltage (V)	3.75	3.75	3.75	3.75
Max Voltage (V)	4.35	4.35	4.35	4.35
Nominal Capacity (mAh)	17	45	90	470
Thickness (mm)	0.43	0.43	0.43	0.43

Table 17 Prologium Flexible batteries

Large footprint of FLCB batteries gives high flexibility in terms of size and capacity. Standard catalogue products can go from 27x38 mm to 107x163 mm, and a thickness of just 0.43 mm, supplying from 17 mAh to 470 mAh.

Tolerance to high/low pressure let charge-discharge phases under extreme vacuum environments without leakage. Finally, the possibility to roll up the batteries, thanks to the high flexibility open the doors to unimagined applications where space configuration is essential in the product conception.


8

CASE STUDY

This chapter describes all the user research work, carry out during the project development, necessary to synthetize a final product design brief.
Besides a deep bibliographical research, a direct patient interaction in its daily journey, opened the opportunity to explore unknown user experience scenarios most of the times, out of academic literature scope.

8.1 Generalities

For the develop of the project, a clear design brief is needed to guide all the product-design developing process [62]. In applications where is integrated not just a functional approach but involves a central human role, end-user needs must be identified primarily.
Because in the case of prosthesis, each patient has a characteristic health condition, lifestyle, and requirements to supply, it was fundamental -for the actual work- to align the reach of the project to just one case study.
Starting from that, a set of single user requirements and perspectives, allows to make a more detailed study and bring as a result a customized prototype.

8.2 The case study

To obtain a real perspective about how limiting it can be to live with a trans-radial amputation condition and which are the design opportunities that are open to solve the question initially raised at Chapter 1, the cases study research was done in Colombia, with the idea of looking for people without access to prosthetic devices and in general with less safe working environments[23] or extreme condition lifestyles.
A second parameter important because the nature of the project, was to find patients with an open and interested mindset in technological devices and willing to receive eventual training in the use of a prosthesis, vital point of a successful prosthetic design process [100].

To face the direct interaction with the selected patient and extract useful information for the project requirements, empathy map – formulated by XPLANE as design toolkit- became a useful resource as reference framework to target well-conceived data collection. This tool helps to develop deep, shared understanding and empathy for customer issues[101], allowing to catch integrally what people does, says, thinks and feels.

The goal point out under 3 aspects: 1) get insight and learn about the patient life, 2) observe and see what person communicate with its actions and 3) have the chance to connect empathetically with the analysis individual [102].

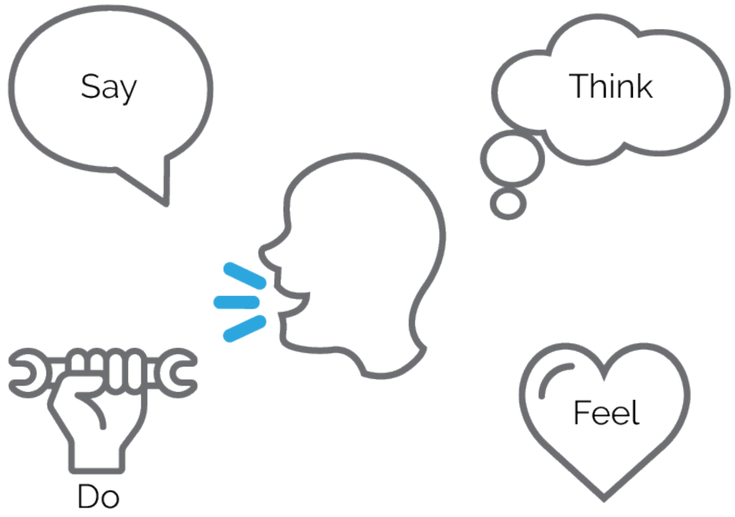


Figure 82 Empathy Map – By XPLANE

Following these mentioned methods, the selected patient profile is presented as follows.

8.2.1 PROFILE

Name: Henry Fuentes
City: San Gil, Santader - Colombia
Age: 34 years old
Amputation Cause: Automovilistic accident
Ocuppation: Carpenter

Henry lost his right arm at 27 years old in an unfortunate accident while he was driving a motorcycle in a Venezuela highway. After being during 15 days at the hospital the consequences of its new amputated condition were not a barrier to continue doing what he considers his passion: the carpentry, profession that he practices since he was 17 years old.
In a fast and autonomous rehabilitation process, 8 months after the accident, Henry starts to work again with the wood, even his boss did not pay enough arguing that because the handicap condition, quality and efficiency of the final work would not be the same.
Instead of being a reason to push down his desire to get ahead, this sort of discrimination became a motivation to transform the general perception of society about the role of disable people and how good they can do the things, and a way to prove it was creating his own carpentry workshop.
Nowadays and with the support of his friends and family, is dedicated to the handcrafted made of chairs, tables, and wardrobes in a rural area of his town. One of his dream is to give more quality to the products he does and have the possibility to put them on sale at a more competitive price.

Figure 83 First interview session

Figure 84 Workshop routine analysis session

8.2.2 Interview

In total three meetings were held. First two as an initial recognition and interview sessions, and the last one, to observe and analyze the work routine of Henry at his workshop. A summary of the requested information requested in the first two sessions is presented with the respectively patient response.

1. ***How long time ago you had your accident?***

“I suffered my amputation event 7 years ago, after crash with a car when I was riding a motorcycle. I was 27 years old and at that time I was working as carpenter in Venezuela.

2. Have you ever used any prosthetic device?

“No, but after all the medical assistance and recovery process, I started a short physiotherapeutic rehabilitation process that included sessions of mirror therapy (to deal with occasional phantom pain), some therapies to regain muscle mass and exercises to learn to do everything with my left hand. That therapies allowed me to adapt my condition with an almost “normal” routine. Initially it was offered the possibility to have a prosthesis, but because bureaucratic issues, at the end I was not included in the acquisition process.”

3. According to your lifestyle do you consider convenient to use a prosthetic device?

“For sure, even than I consider I can deal with most of the activities by myself, to use a prosthesis will open the possibility to me another simple activity for which I have limitations, as for example play videogames with my son at the phone and tie the shoe laces without using my mouth”

4. In which specific aspects you think, a prosthetic device would improve your life quality?

“Specially I consider, the most important aspect is the aesthetical perception the other people can have about me. Sometimes searching for jobs or just trying to date with some girl, I have felt how they initially judge me by my handicap condition. On the other hand, an important aspect I consider the use of a prosthesis would bring to my life, is the fact that some precision task carrying out at my job as positioned a metal nails, or positioned wood pieces at the workshop machines, could be easier if I can use a prosthetic device”

5. Would you be opened to take an eventual training process to learn how to use properly a prosthesis?

“Sure! In fact, after the amputation surgery, I started to search ways to improve my condition, and I heard about these customized 3D printed devices. Now that I’m in Colombia, my dream is search for the institution that manufacture it and if I have the chance, follow all the training process that I know is required”

6. Can you describe briefly how is your daily routine?

“I wake up at 6 am, take a shower and brush my teeth as a normal person does. For my meals, I got used to using my left hand, so eating is not a problem. For dressing sometimes, I required assistance but is not an often issue, especially when I must button my shirts. Nearly 7.30 AM, I started my activities at the workshop. Every day I work approximately from 6 to 8 hours making chairs, tables or the product that any client has requested before. Into my specific activities are cutting the raw wood, use the saw machine, the milling machine, the sanding machine, hammering and use all the normal devices needed for this job (manual drillers, disc grinders, etc.). For things like move heavy of big size elements, I ask the help of someone.”

7. In which specific activity you think a prosthesis can improve your performance?

“In my job for sure, and basically to define distances, move and positioned small things. To lift weight I think is not possible because I manage heavy loads (near the 80 kg approximately) . Regard me, I think a prosthesis would give more body balance – aesthetically and bodily speaking- and people would pass from judge me by my condition to be centered on the device, so that psychologically can be good for me. In things like tie my shoes laces I think can be a totally new experience”

8. Could you describe qualitatively, how is the level of sweeting on the stump area during hardworking times?

“In normal conditions, I do not feel too much sweating because I have never covered my stump, but, when I do hard working activities and the weather is warm, I can feel in the stump the same levels of sweating that in my healthy limb.”

9. From 1 to 5, and being 1 less important and 5 considerably important, how you evaluate the following prosthetic features:

Feature	1	2	3	4	5
Color’s Interchangeability			X		
Texture sensation		X			
Shape appeal					X
Reduce weight characteristics				X	
Maintenance facilities				X	
User interaction				X	
Comfort					X
Mechanical resistance					X

Table 18 Questionarie requested

To analyze the Henry’s daily working routine, was necessary to visit its workshop, located in a rural area of San Gil, Santander. Photos and video recording of the activities that he often carries out were taken to realize practical issues and problems that were not mentioned and that were beyond the scope of the information provided in the interview sessions. This observation phase allows to obtain feedback from the direct customer identifying its needs for the chosen activity [62]. Some of the most representative activities are shown at the pictures

Figure 85 Lifting wood sticks

Figure 86 Mechanically wood sawing

Figure 87 Mechanical wood sanding

Figure 88 Wood parts milling

Figure 89 Assembly of wooden parts with metallic nails

Figure 90 Mechanical wood sanding

Figure 91 Electrical equipment setting

8.3 Brief Synthesis process

The process to define a consistent brief, would require the information analysis taken from two scenarios 1) the user source – case study- and 2) all the literature references related with the project topic and expressed at the state of art. A value proposition canvas is used to define clearly the points in which the design analysis will put special attention. The graphic contains "gains" and "pains" among the two previous mentioned scenarios.

From the valuated points, is made a classification in terms of intensity in level of performance. Even each aspect it was define as important for the project, those that are highlighted in red, will have a superior degree of priority at the brief formulation and are considered vital needs for project's target audience. For the remaining topics the stablished color scale, define its grade of relevance.

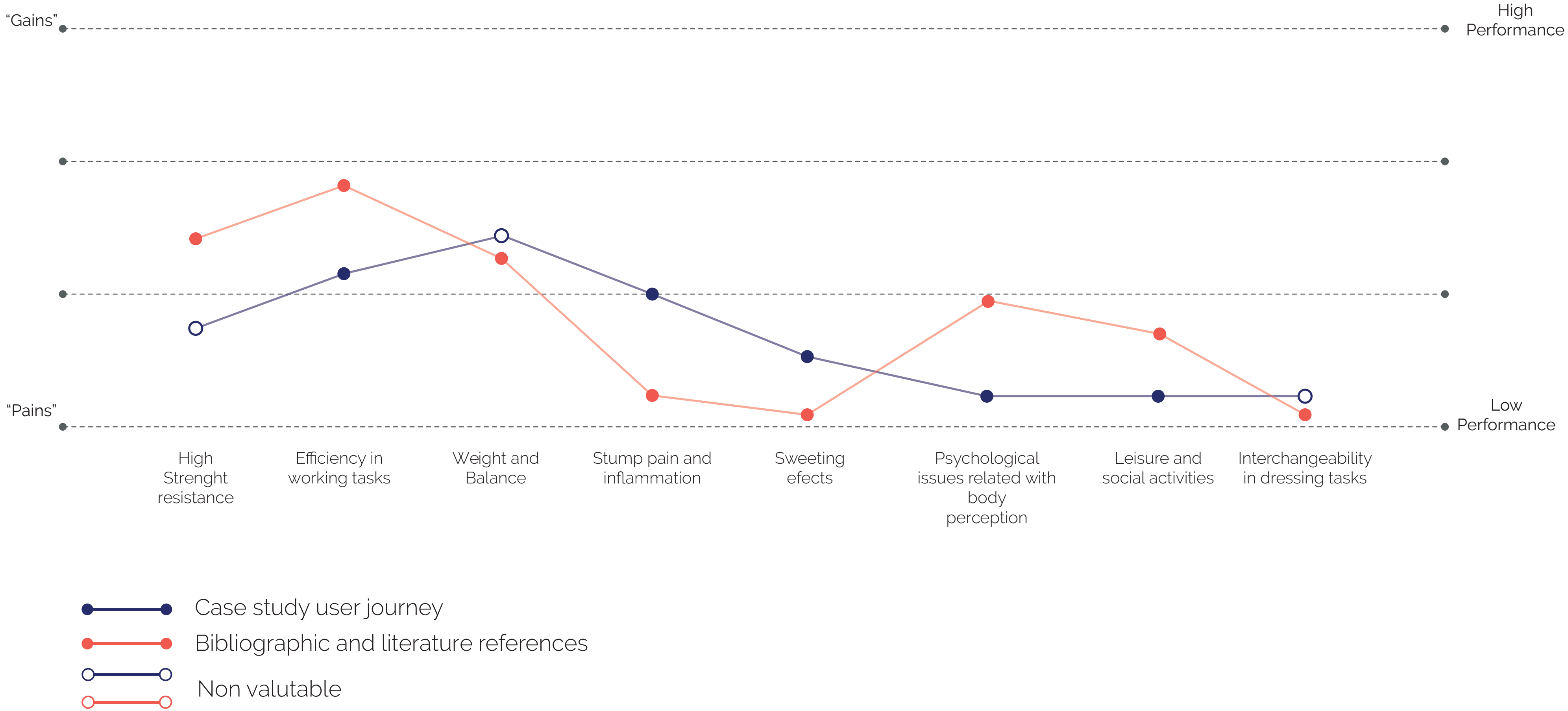


Figure 92 Value proposition canvas user journey

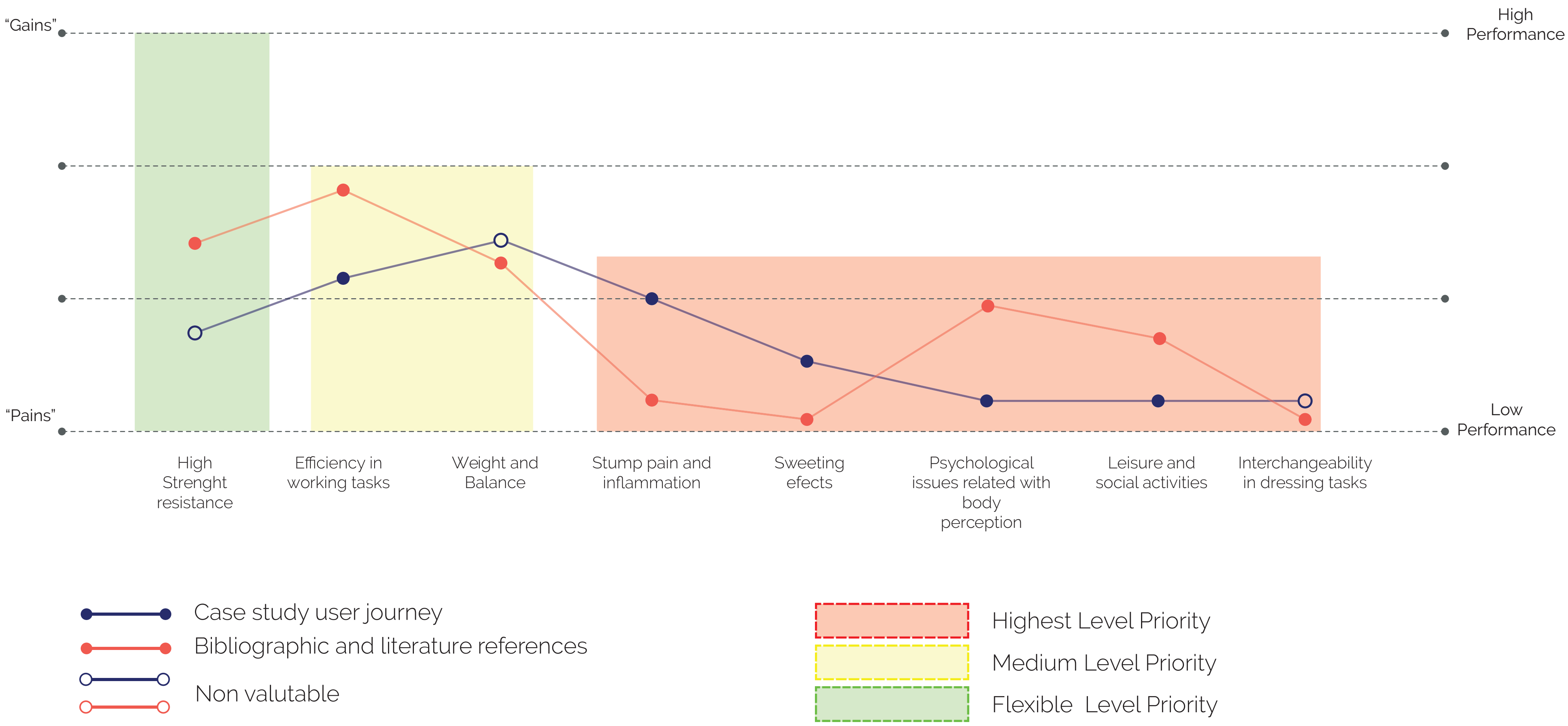


Figure 93 Priority Definition

8.4 Brief

Having into account the question raised at first chapter and the customer analyzed information, the project design brief is defined as follows:

8.4.1 The problem

According to bibliographic research and field data user collection, most of the actual upper limb prosthetic interfaces do not fulfill aesthetical aspects relating with dressing routines or personal tastes that can create an emotional link or sense of proudness between the user and prosthesis. In most of the referenced cases, only functional features are considered by manufacturers, following a purely medical approach[62].
This lack in aesthetical ownership create a psychological barrier between the patient and the device, promoting in most of the cases, a user rejection, justified in how the amputee thinks is perceived by society because its condition.
In terms of functional features, firstly is found that in common prosthetic devices, interface element stump/prostheses, can promote an increase in the level of skin sweating and stump inflammation under normal user conditions. In general, current used socket structures encapsulate a high percentage of skin in patient stump and do not allow a normal perspiration activity.
A second functional flaw is related with user perception of weight. According to literature and user case study, a sensation of lightness and reduction in weight is conceived as determinant factor on device validation performance.
Finally, it was found, most of actual prosthetic gadgets do not support high workloads conditions. Even this issue is determined because patient lifestyle and activities that individually carries out, mechanically performance should be a characteristic easily scalable, according to patient needs.

8.4.2 Brief

Design of an interface socket/upper limb forearm, that allows to attached commercial hand prosthetic devices, complying the following characteristics:

- Interchangeable external aesthetical appeal that allows to improve psychological user perception of the prosthesis.
- Dimensional biomimetically balance.
- Reduction on stump sweating levels using materials that improve the range of skin temperature released.
- Reduction on stump inflammation on using conditions, maintaining functional prosthesis arm clamping.
- Reduction on general weight characteristics, through the use of efficient geometries, and lighter materials.
- Increase in the range of strength prosthetic capacity.
- Easy maintenance through a less complex internal components arrange and electrical connections.
- Simple user interaction.

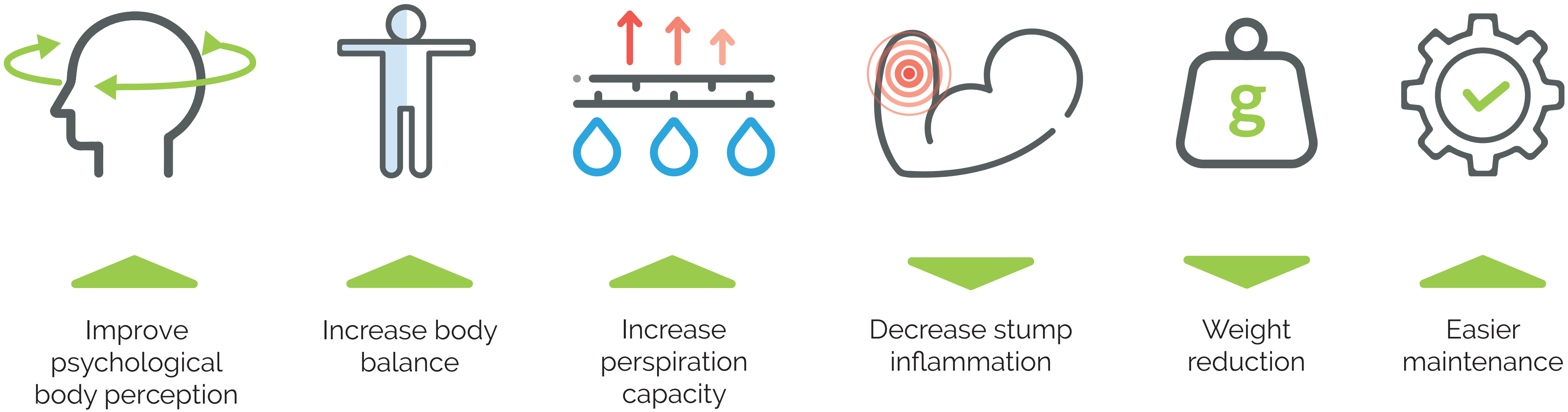


Figure 94 Fundamental brief

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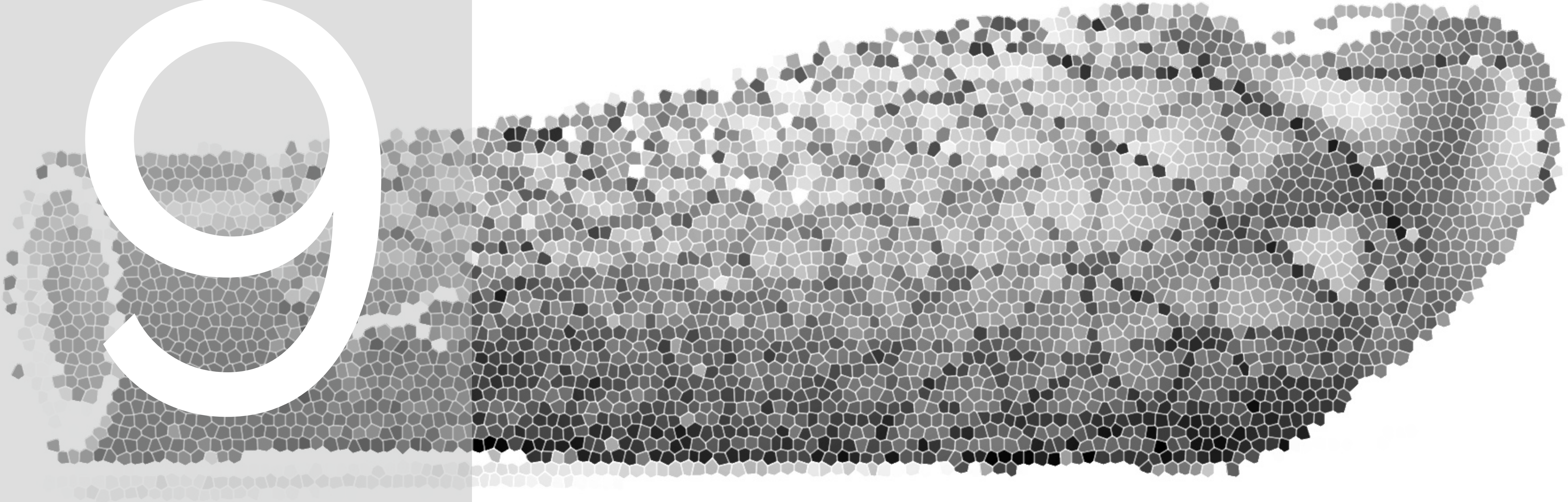


DESIGN CONCEPT DEVELOPMENT

This chapter describes the design method carried out during the project design phase. Engineering functional requirements and creative valuated approaches are described for each of the representative elements that composed the project.

9.1 GENERALITIES

Considering the state of art research at chapter 2, upper limb prosthetic interfaces are classified in two types: exoskeletal and endoskeletal. An approach defined in the project, is to find a solution that can integrate both functional characteristics in 1 product.

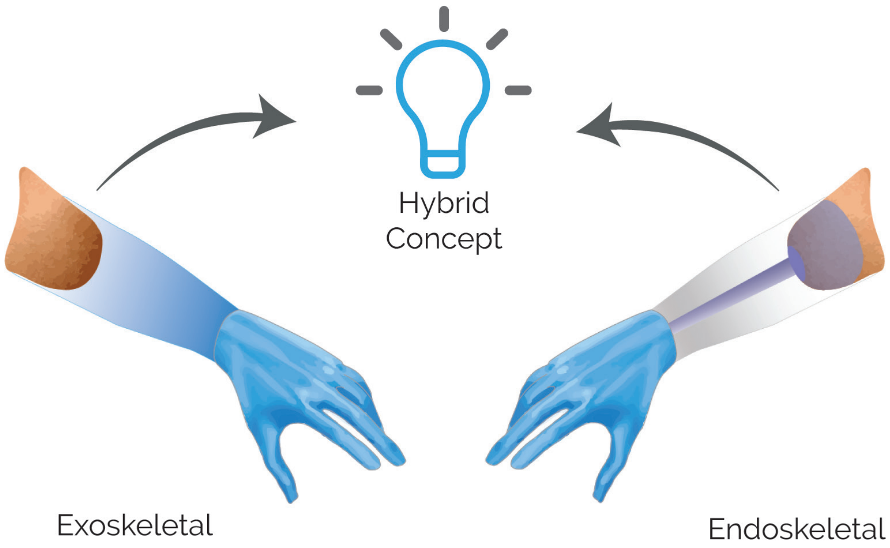


Figure 95 Design Idea

Based on this, an initial device architecture is defined under the idea of a layering system [62], that normally comprises 4 elements:

- *-Moisture management "base layer" or second skin*
- *-Mid insulation layer*
- *-Protective outer layer*
- *-Elements of personal protection*

Translated into the project characteristics, the layering system would correspond to the following components:

- *-Liner*
- *-Interface socket*
- *-Internal structure*
- *-External cover*

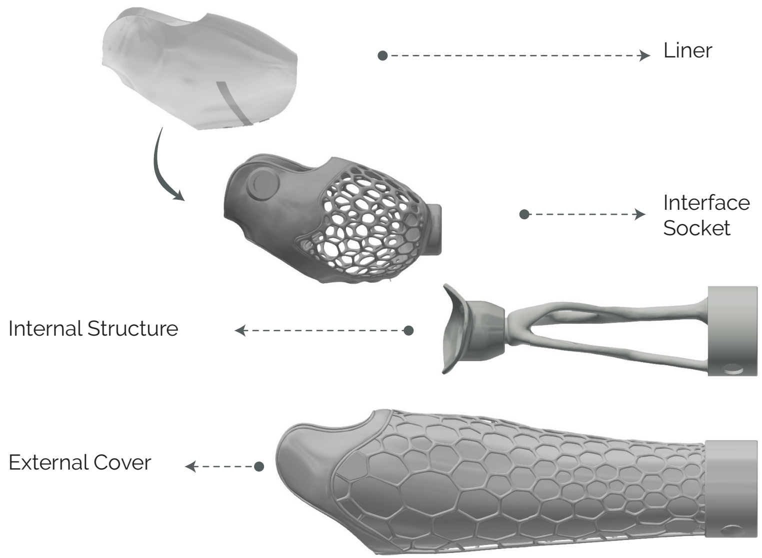


Figure 96 Layering system schema

Design process description is developed in the order mentioned above and driven by a "Demands of the body" design methodology [62] because the wearable device approach given to the project. Aspects considered, are presented on the map and describe later, based on the collected information taken from the case study research.

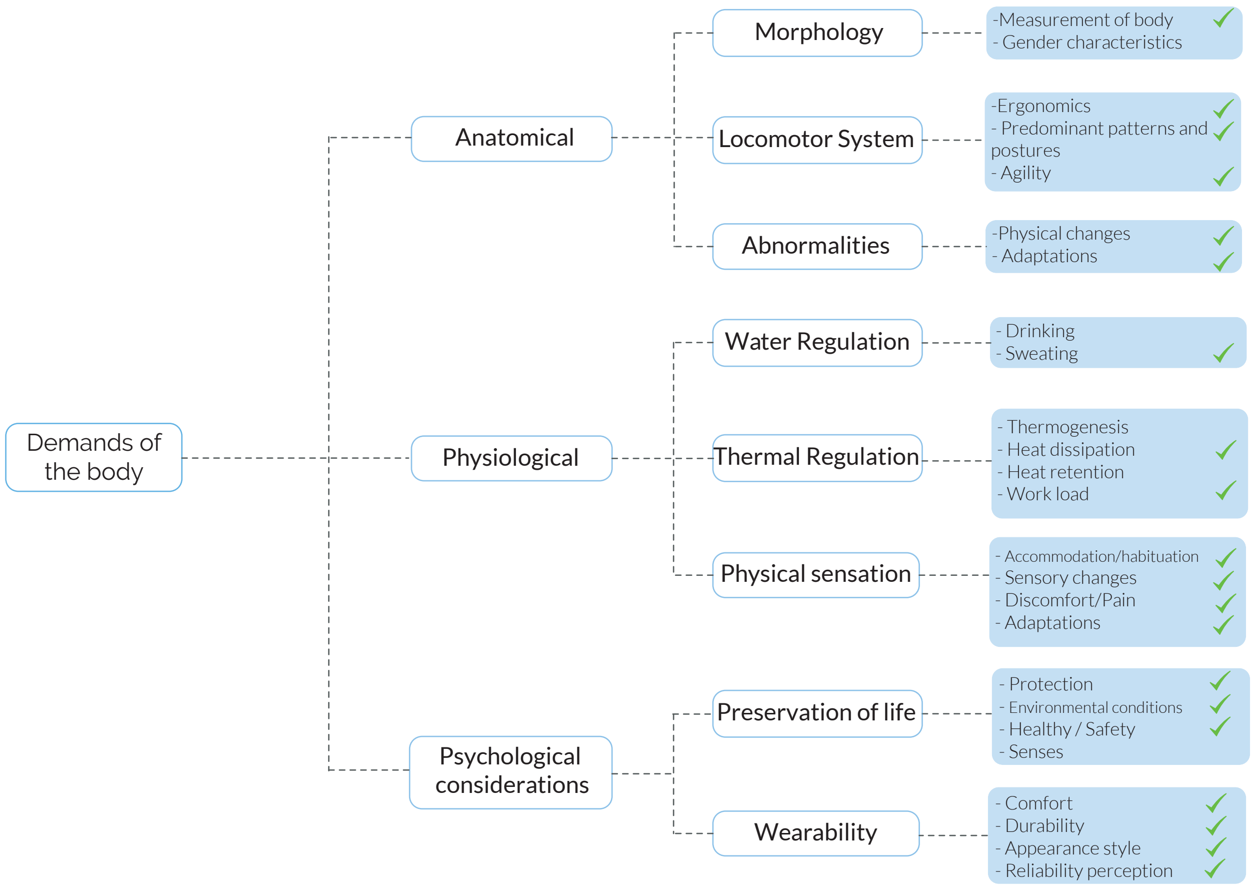


Figure 97 Demands of the body design approach

The following is the collected information from patient case study, and the aspects considered with the application of the previous map structure

- ***Morphology:*** Measurement of the healthy arm and measures of the stump
- ***Locomotor system:*** Postures of the patient in its workplace and its ability to deal with its activities
- ***Abnormalities:*** Physical changes related with stump inflammation and pains, according the patient's activities is carrying out.
- ***Thermal regulation:*** Increase of range of sweating on stump area because heavy duty activities and weather changes
- ***Physical sensation:*** Pain and discomfort due contact with strong elements (wood sticks, metallic parts)
- ***Preservation of life:*** Limb protection from machinery equipment.
- ***Wearability:*** Patient desire of use a prosthetic device aesthetically and functionally comfortable.

9.2 LINER & SOCKET

The socket and liner are defined as the direct contact interphases among the user and the prosthetic device. As it was mentioned previously at the theoretical bases, a high percentage of patient prosthetic user succeed laid down on how well customer integrates the device to its body in terms of comfort and adjustment.

Currently traditional interphase manufacturing process center its production workflow on an iterative plaster casting molds of the patient stump to obtain a refined socket geometry that could properly match with muscle adjustment and the integration ad hoc of the myoelectrical signal sensors. As reference point, is presented the schema at (Figure X) that corresponds with the modelling process carrying out by INAIL Centro Protesi regard the production of upper limb prosthetic sockets. Actual production workflow do not consider the use of interphase liners.

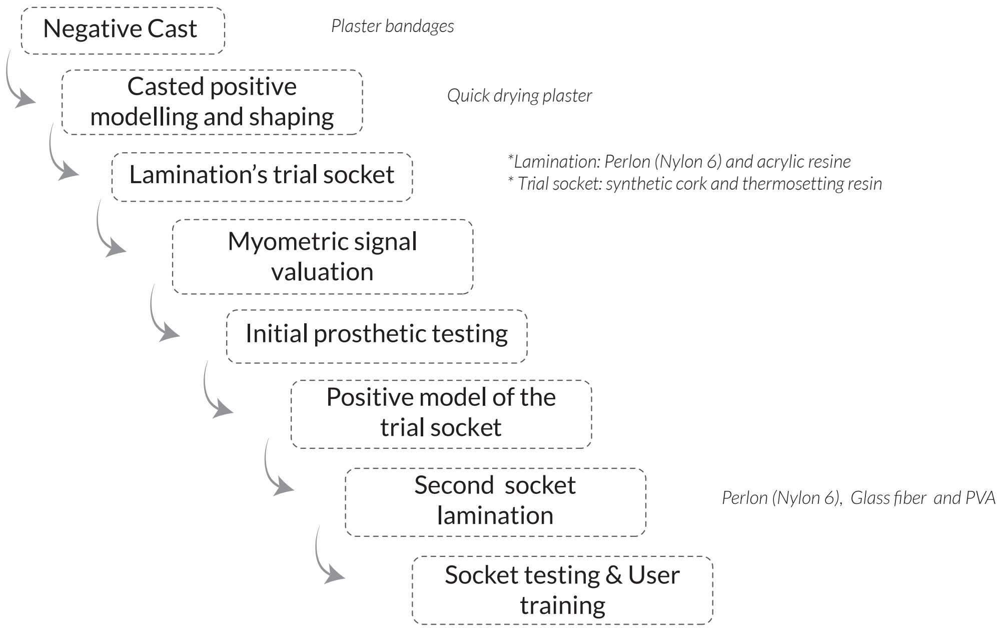


Figure 98 Traditional socket interphase production process - Provided by INAIL Centro Protesi

Figure 99 Casted socket mold

The project thesis approach proposes to take advantage of reverse modelling CAD techniques and additive manufacturing technologies, to reduce prototyping times and related material expenses of traditional process.

9.2.1 PROJECT DESIGN METHOD

Photogrammetry was selected as reverse modelling technique for liner and socket conception, according with the technological available resources. As mentioned on chapter 3, this method makes use of a photo camera and an 3D surface reconstruction software (Agisoft Metashape Photoscan) as collecting and processing data tools.

No invasive user methods where used for this phase. In addition, were taken stump and healthy limb dimensions, as reference values for the 3D generate surface postprocessing, following the guidelines given for E-nable Group [103]. The shown schema explains clearer the used method.

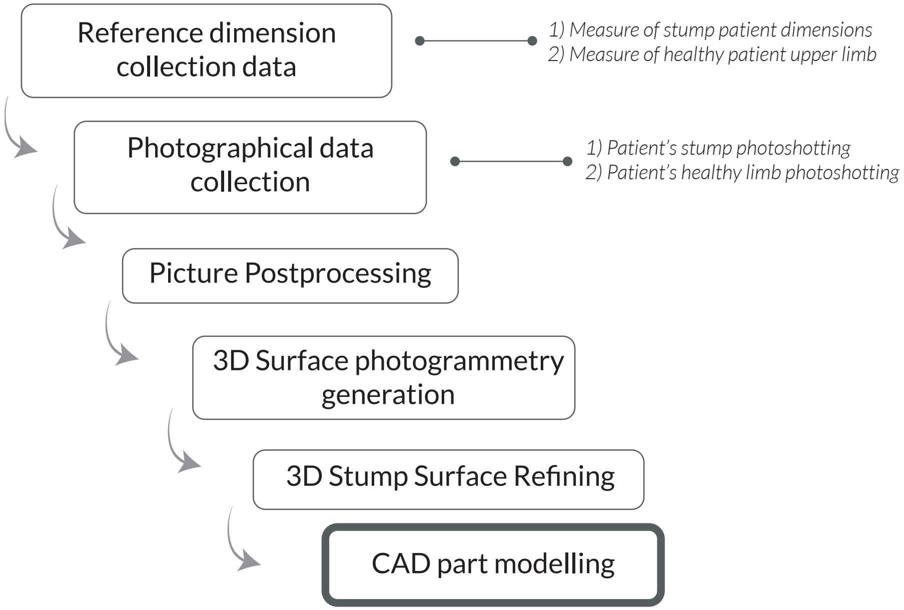
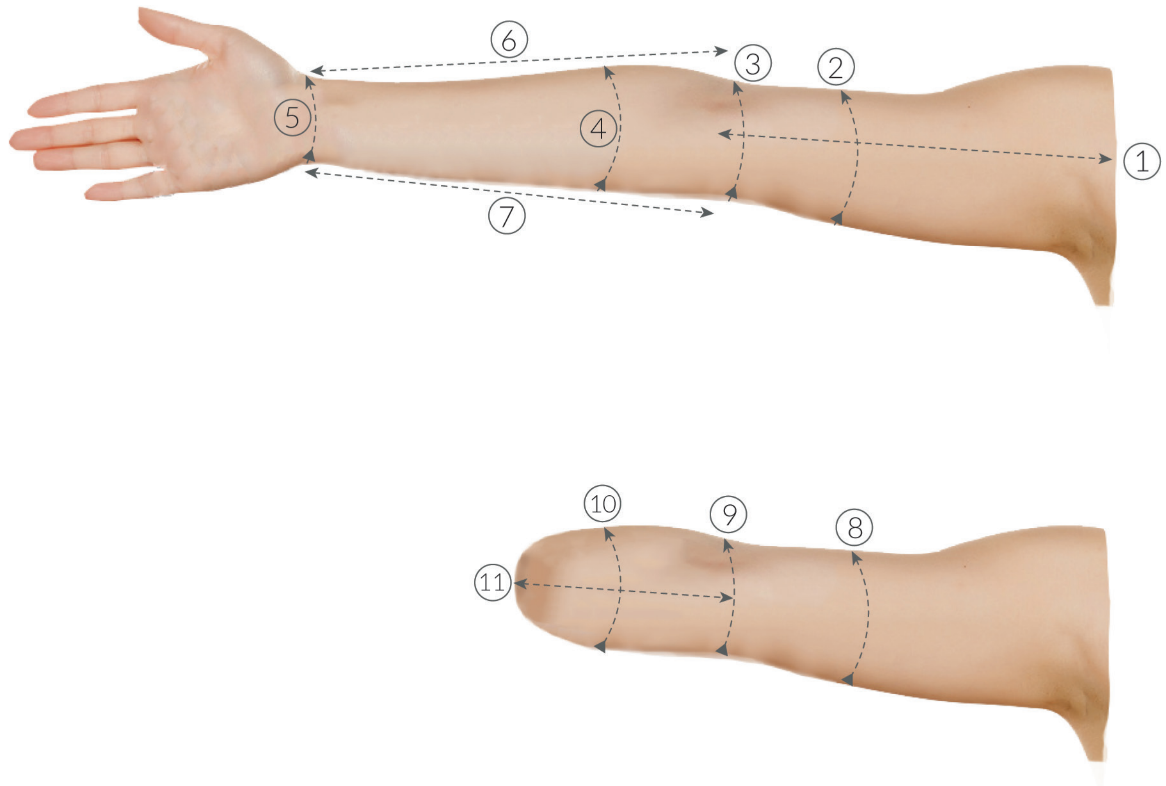


Figure 100 Stump reverse modelling technique

Figure 101 Measurement patient's stump

Figure 102 Measurement patient's healthy arm



1) Shoulder - Elbow Lenght	34 cm
2) Arm contour	30 cm
3) Elbow contour	26 cm
4) Forearm contour	27 cm
5) Wrisp contour	16 cm
6) External arm length	29 cm
7) Internal arm lenght	25.5 cm

8) Arm contour	21 cm
9) Elbow contour	26 cm
10) Remain limb contour	25.5 cm
11) Remain limb lenght *-from elbow-*	10 cm

Figure 103 Case study limbs measures

Figure 104 Stump Photo shooting

After photo shooting session, the pictures were post-processed and used as input data on Photoscan, to generate the stump and healthy arm surface. Both meshes are the initial point for socket and cover prosthesis design. Taken measures allows to verify generated surface dimensional coherence.

Figure 105 Arm Photo shooting

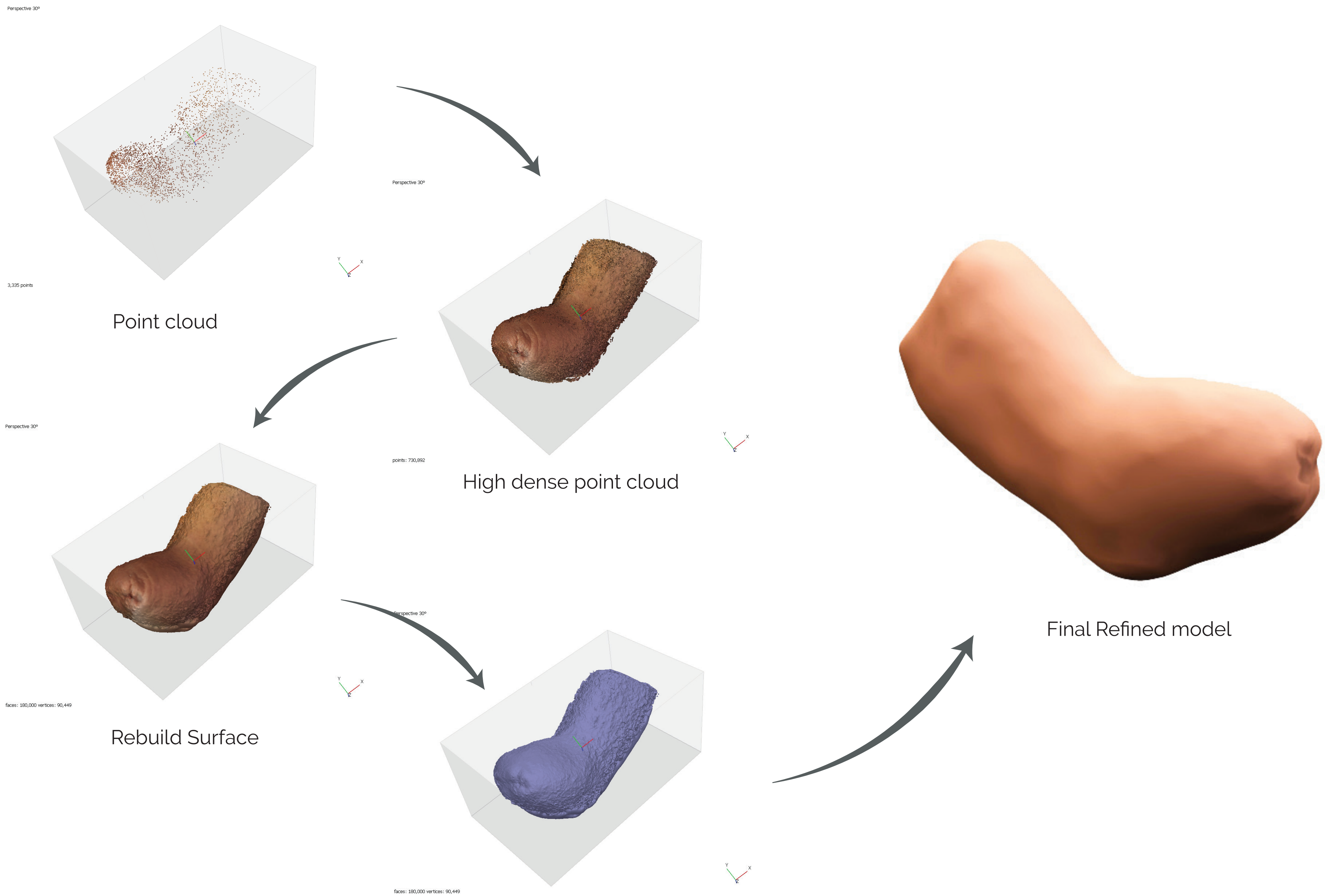


Figure 106 Stump reverse modelling process

9.2.2 Socket design concept

Based on the state of art research, relevant functional aspects were collected from the different socket designs. These outstanding aspects are taken in consideration to conceive the proposal concept and are mentioned as follows

- ***From Muenster Socket:***
  -Compression at the cubital fold
  -Compression at supracondylar rim (humerus epicondyles)
- ***From ¾ Socket***
  -Removal of proximal posterior portion of the socket
- ***From TRAC***
  - Contouring arm anatomy
  - Contouring oleocranon
  - Flexible inner shell
  - A/P & M/L compression

Considered areas are then modified in the stump virtual replica and this allow to define the initial CAD modelling geometrical constraints. 3D modelling socket modelling will be based on the contour of the stump geometry, considering the shown compression areas.

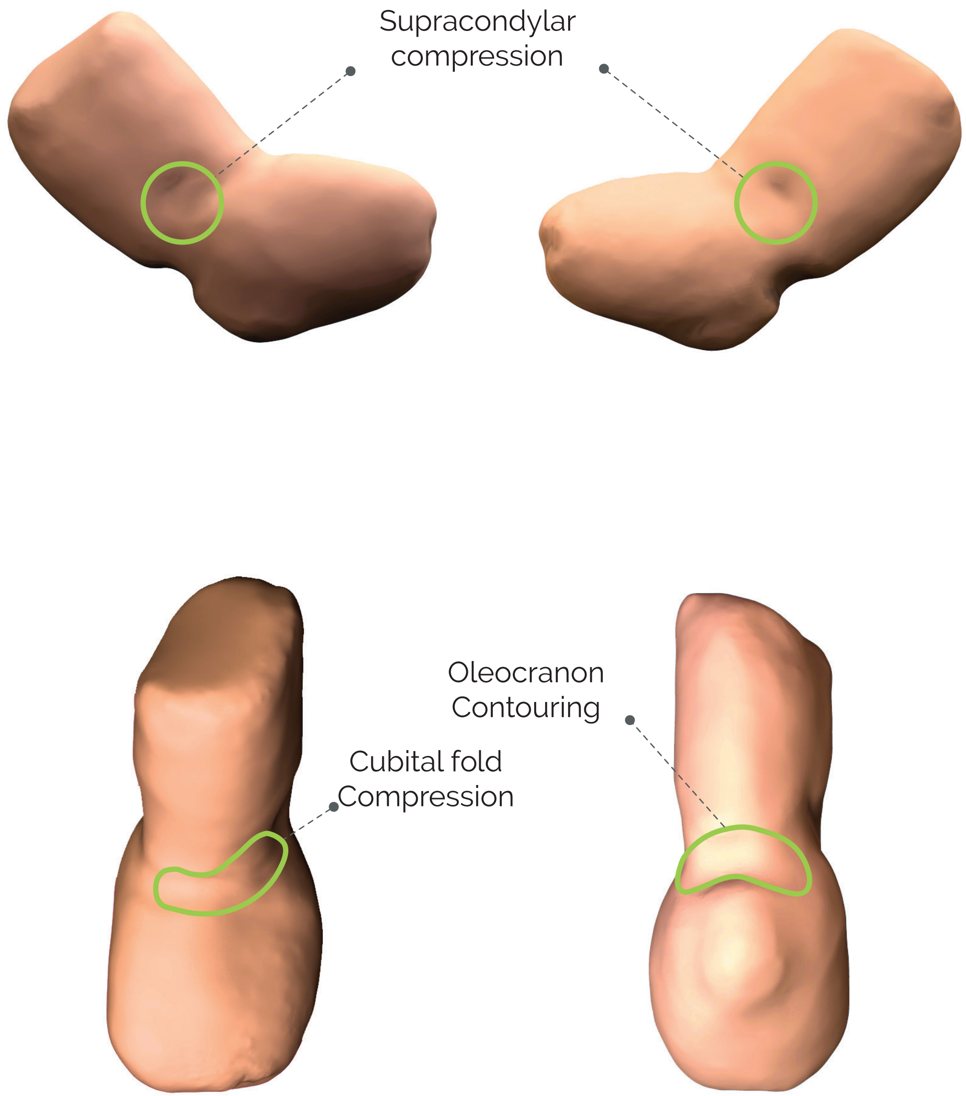


Figure 107 Modified Stump

Muenster Socket

3/4 Socket

T.R.A.C Socket

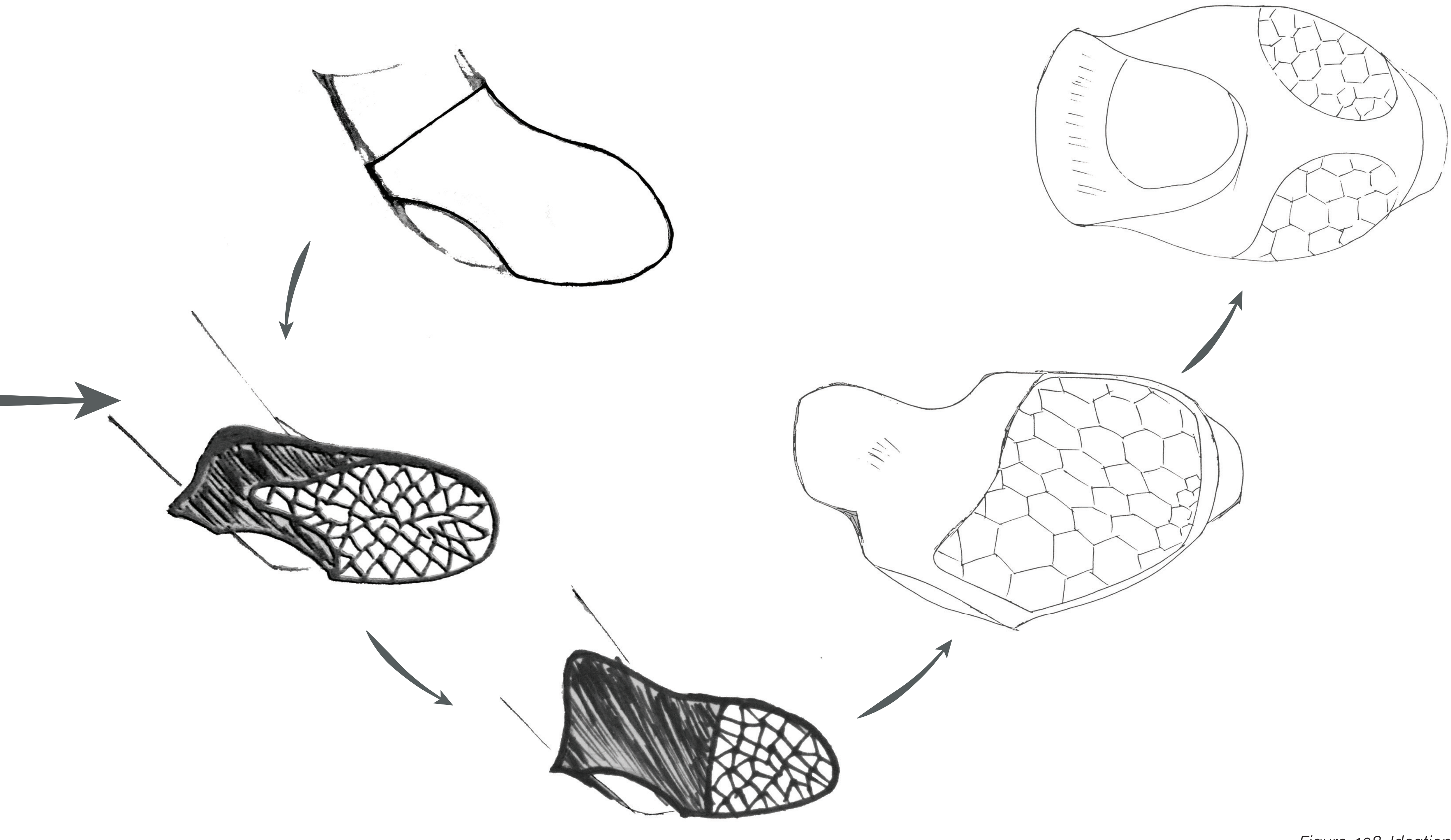


Figure 108 Ideation phase

9.2.2.1 Socket 3D modelling

The proposal design is based on the idea of decrease the level of stump inflammation encouraging good performance on adjusting capabilities. Hence, the socket capability to allow and easy perspiration and promote ventilation of the stump area.
Keeping in mind compression areas previously shown, the conceived socket design is composed by two parts:

- ***Solid contouring element***

Designed to be processed using 3D printing techniques, the contouring structure is made to fulfil the functional and dimensional user requirements. The defined compression areas guarantee the proper medial/ lateral adjustment on supra epicondylar rim, and anterior/ posterior subjection at the olecranon and cubital fold areas. Uncover elbow area increase the user range of movement and comfort. Lateral holes encourage the expansion at distal stump area, due to the long time periods of use.

Inner printed snaps will allow and easier attachment of inner liner, and a simpler user routine of socket maintenance (inner liner clean or replacement). Holes located at the bottom section allows the insertion of metallic electrodes that direct the myoelectrical signals from the liner to external electronical control.

The cavities located in the lateral part of the clamping area, are intended to be use like insertion place for magnetic snaps, that will be used to attach the external cover to the prosthetic component.

Following the manufacturing parameters used by INAIL, this part is designed to be manufactured using Nylon 6.

Figure 109 Modelled Socket

- ***Generative flexible net***

Designed to be manufactured on 3D printed flexible resin, this part works as an expandable net that brings support to the stump, allowing to respond the stump shaping changes related to the inflammation. The geometrical generative arrangement guarantees an adequate performance in terms of expansion and contraction of the material, in addition to promoting an adequate flow of air ventilation. Furthermore, and a non-less important, gives an aesthetical touch to the socket interface.

The flexible net is designed to be mounted on the structural component, gluing the coincident edges with Sil-PoxyTM silicone rubber adhesive that provides a strong, flexible bonding between silicone parts with elongation requirements[104].

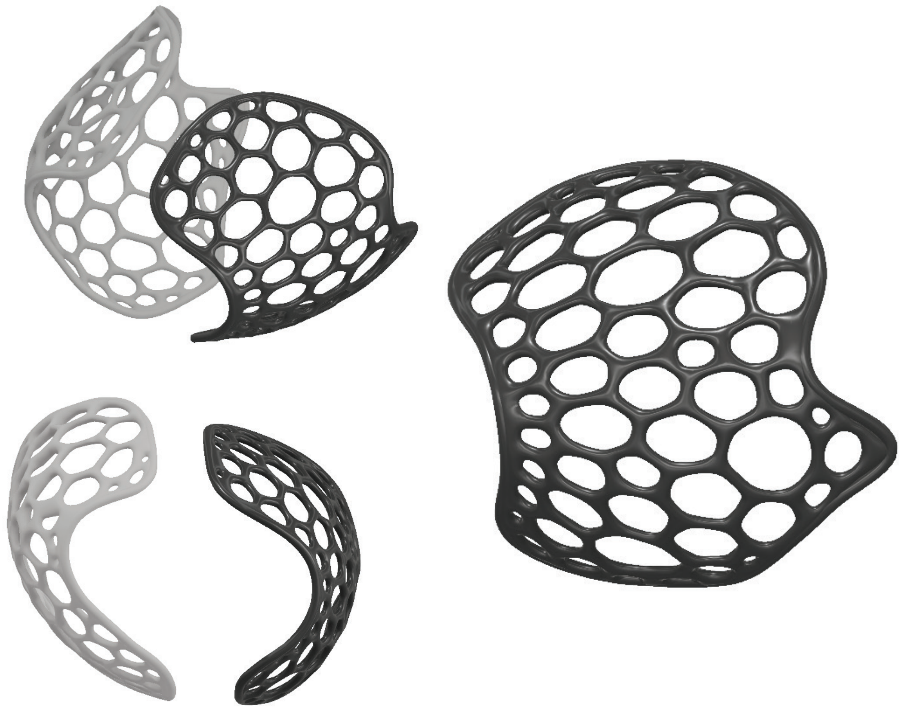
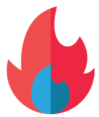


Figure 110 Model Flexible Net

9.2.3 LINER

Liner design approach is driven based on the integration of conductive fabrics, that would replace the use of metallic myoelectric sensors, and the use of smart textiles that promote more comfortable conditions in terms of heating release and perspiration rate control.
Following the case study requirements, heat generated, and perspiration rates were analyzed evaluating the intensity in the activity the user normally carries out.



	Heat Generated (Watts)	Perspiration Rate (cm^3/h)
Sleeping (cool & dry)	60-80	15-30
Walking 5 km/h (comfort zone)	280 -350	200 -500
Hard physical work (hot & humid)	580 -1045	400 -1000
Max. Sweat rate	810 -1160	1600

Table 19 Heat produce at different activities

According to the user analysis context, the daily user routine can be considered as a hard-physical work. Values on the table [62] work as reference point in the defined characteristics of the chosen material.

The liner system is composed by a multilayer arrangement with a based piece made in a passive* smart fabric. The select one for the project realization was the reference Sensitive BFT5 Bonded, with a composition of 72% PA and a 28% of EA, often used in sportswear production. Polyamide gives fiber a high resistance to traction and abrasion beside a high degree of elasticity. Elastane provides a perfect shape fitting, water repellency, excellent resistant to molding, and a good bacterial control.

A warp knitted honeycomb structure present on Sensitive BFT5 fabric, grants a high level of flexibility and a close fitting to the body shape, conceding at the same time quick drying sweating behavior, pulling away the moisture efficiently and avoiding uncomfortable sensations on the contact area[105].

The final fabric layer shape will be the result of the inner projection surface of solid modelled socket.

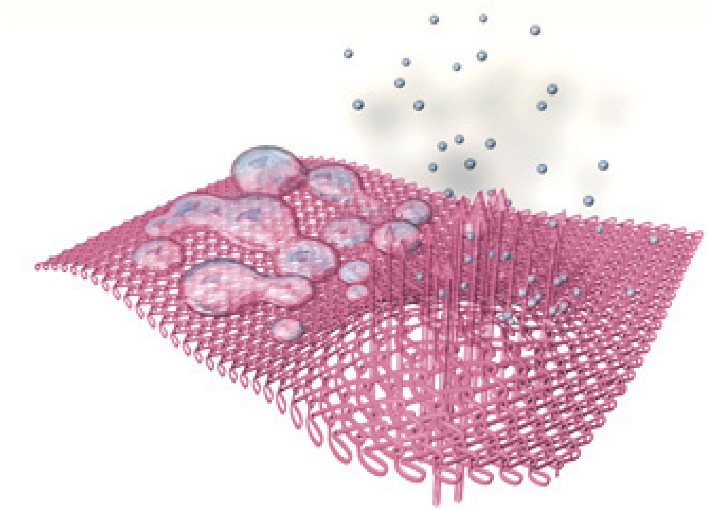


Figure 111 Honey Comb fabric structure - By Sensitive

Regard the conductive textile**, this is selected based on signal conductive capacity and stretchable characteristics, key attribute on garments used for medical and sportive applications[62]. With a composition of 95% Silver Nylon and 5% of Spandex, the reference 5640862 from the Circuitex catalogue, was the selected material after its experimental evaluation performance at laboratory.

Passive Smart: Can sense the environmental stimuli. Include insulating and moisture wicking structures
****Active smart:*** Can sense and react to the condition or stimuli. Include attributes such as anti-microbial protection

Aseptic skin conditions are considered too and the way to face this issue is through the use of a snap button arrange system that allows to remove the liner for washing and socket cleaning maintenance. Two sets of snap pressure buttons are distinguishable. The first set made in Polyacetal plastic is focused on the liner attachment to the socket body. A second arrange use metallic snap buttons that will work as connector point for the myoelectrical sensor signals.

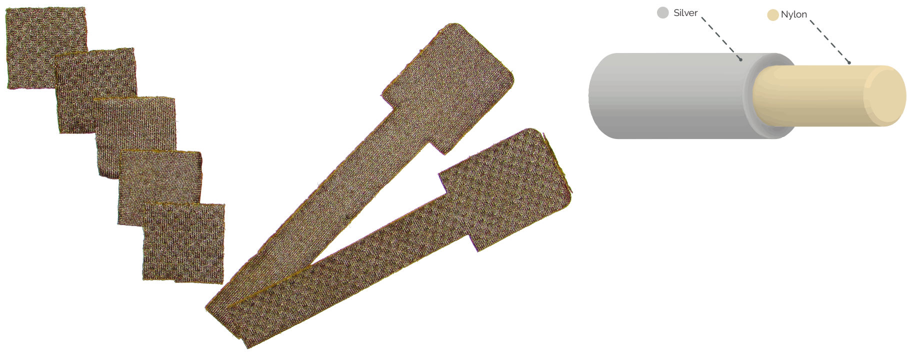


Figure 112 Circuitex 5640862 Conductive fabric

Final electrodes dimensions are presented as follows

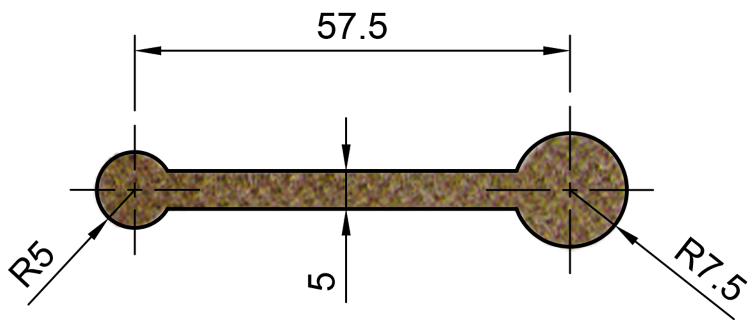


Figure 113 Electrodes final dimensions

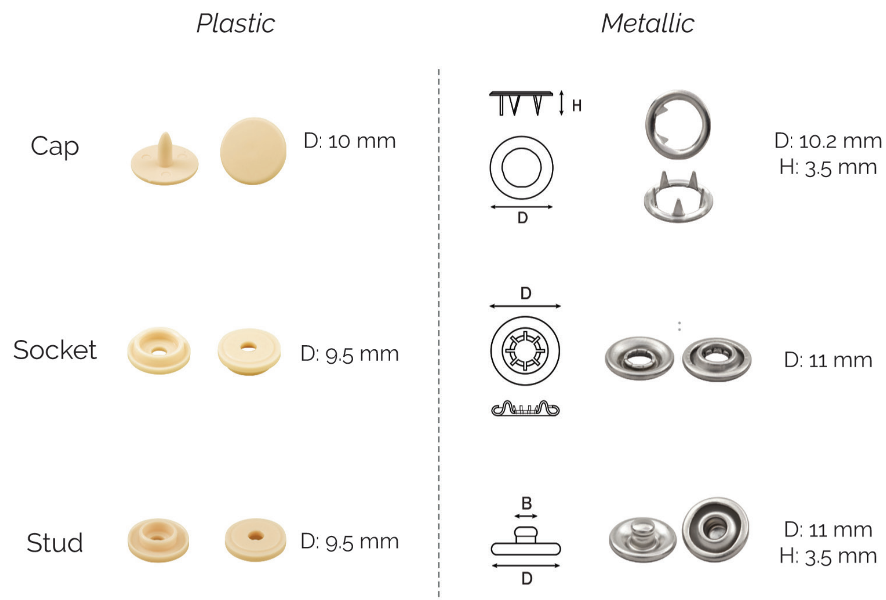
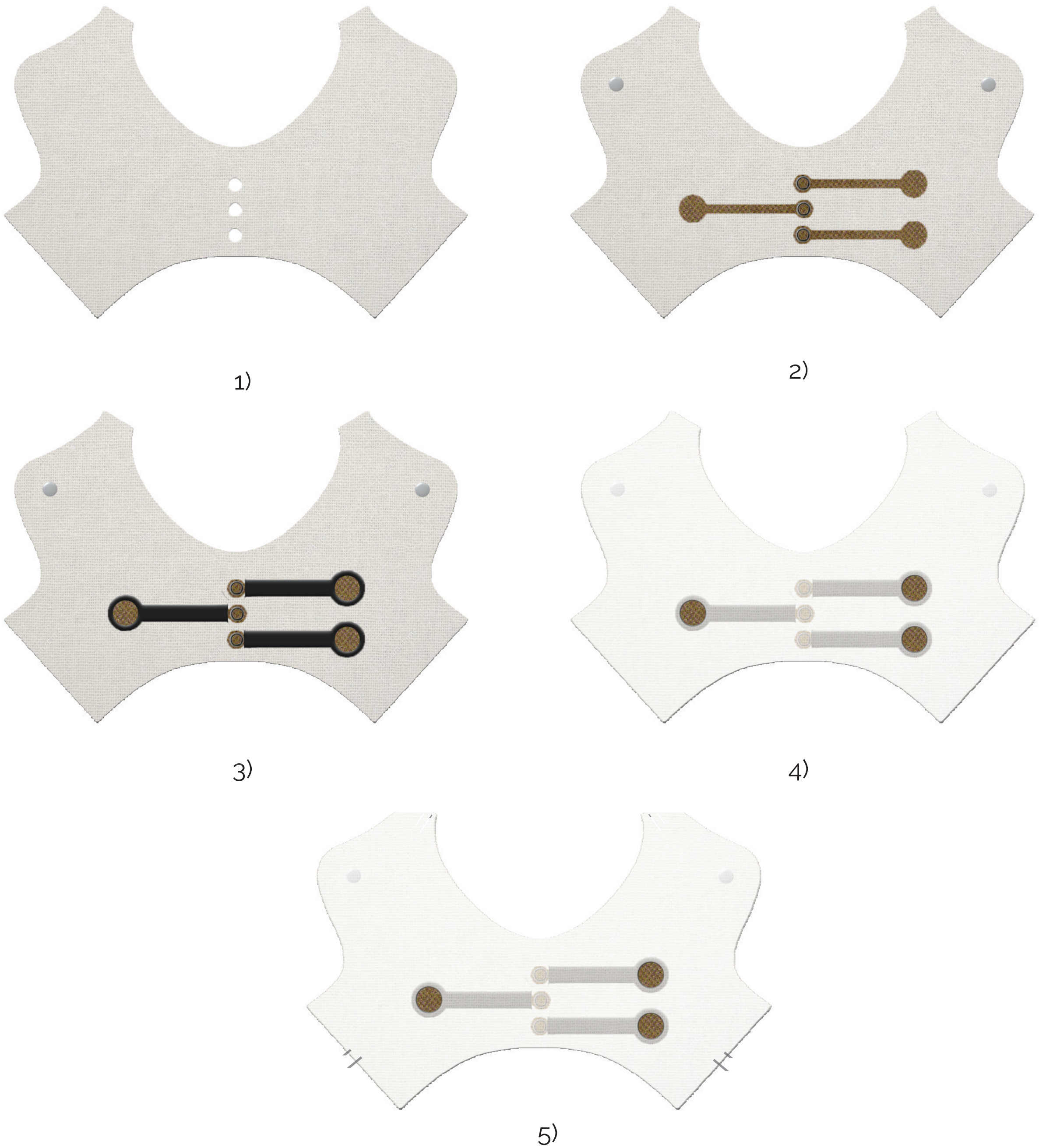


Figure 114 Plastic and Metallic snap buttons – Commercial catalogue By Daudè

The complete liner assembly sequence is presented as follows



Liner assembly sequence

1) Base laser cutting fabric surface

2) Conductive fabric electrodes placement and plastic snaps fitting

3) Electrodes gluing isolation

4) Termowelding fabric layers

5) Border Sewing

Figure 115 Liner Assembly Sequence

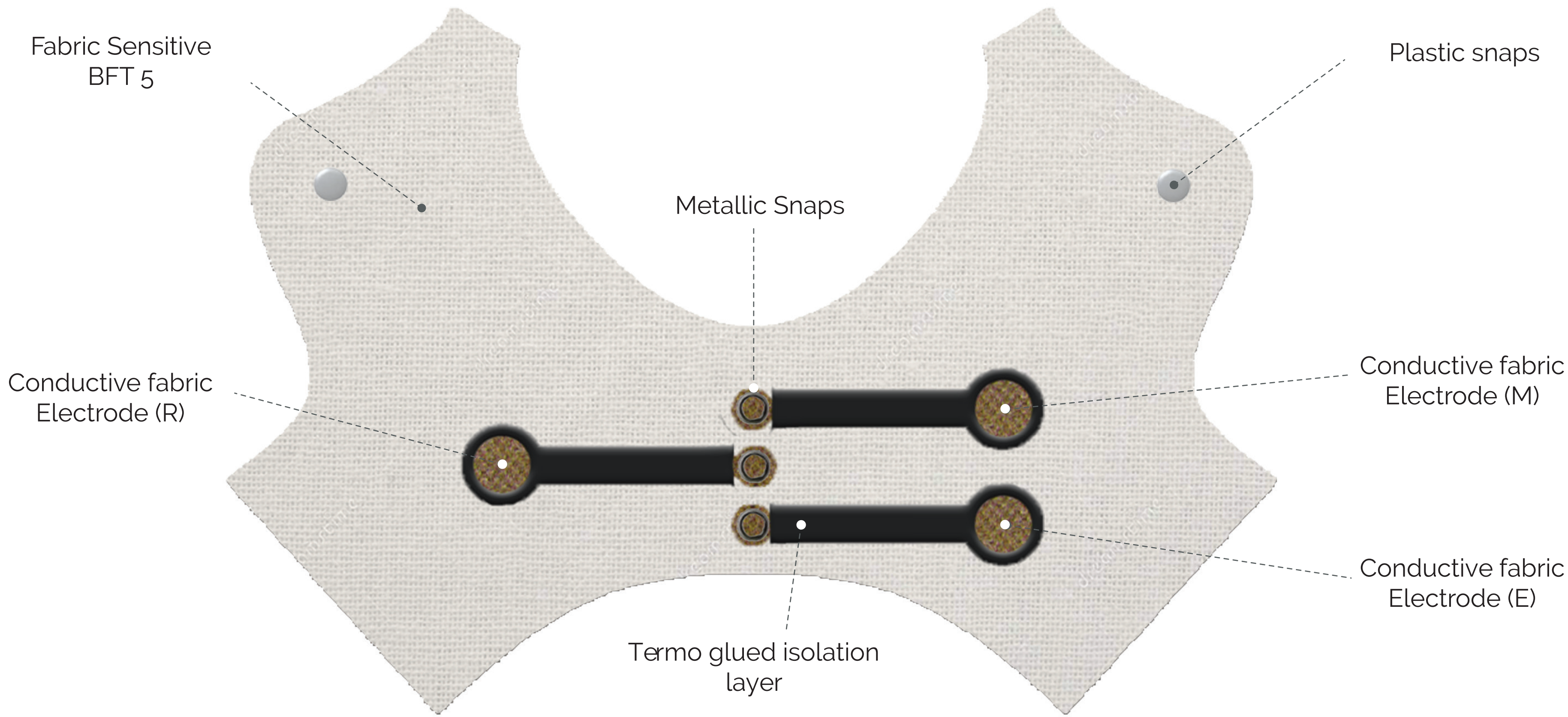


Figure 116 Liner Components

The liner, donned by the user would looks like in the picture

Figure 117 Wear Liner

9.3 INTERNAL STRUCTURE

Internal structure design approach is based in the bone biomimicry related with the ulna and radius of the patient. Its role will be to endure the loads and mechanical effort due the patient routines.
The definition of biomimicry for this case, concerns the mimesis on mechanical resistance to breakage and the geometrical shape parameters.
As scope of the thesis project, the 3D CAD modelling of the internal structure is figured it out through the application of generative CAD modelling techniques, using the generative plugin of Fusion 360. The use of this method requires to understand the initial conditions of the mechanical system and the characteristics related with the behavior of the referred bones in experimental context.

9.3.1 SCIENTIFICAL OVERVIEW

To analyze the bones mechanical behavior, is necessary to remind some fundamental definitions:

-Mechanical stress: Ratio between an applied force and the cross section area where the force is applied [106]

-Mechanical strain: Ratio between the final dimension and the original dimension, after a load is applied

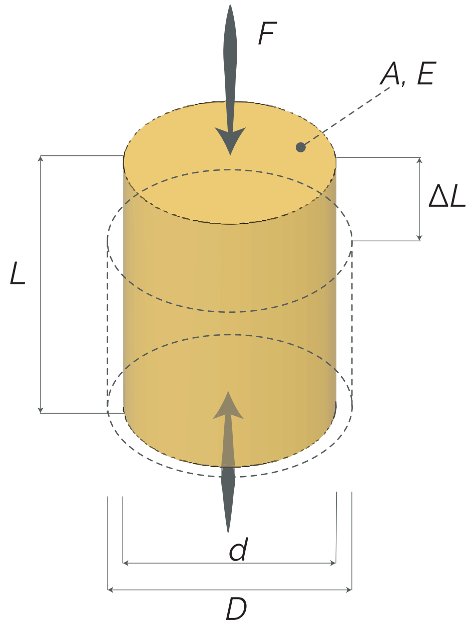
-Young Modulus: Mechanical property that measures the stiffness of a material. Can be defined too as the ratio between a tensile stress applied and the tensile strain

-Strength: Ability of a material to manage stress without failure

-Poisson ratio: Ratio between lateral strain and longitudinal strain of a deformed body

-Failure load: Maximum applied load, that fracture the material

The graphic summarizes the previous explained concepts



Stress $$\sigma_L = \frac{F}{A} \left({}^{N}\!/_{m^2} \right)$$

Strain $$\varepsilon_L = \frac{\Delta l}{l} \, (-)$$

$$\varepsilon_T = \frac{\Delta d}{d} \, (-)$$

Young Modulus $$E = \frac{\sigma_L}{\varepsilon_L} \left({}^{N}\!/_{m^2} \right)$$

Poisson Ratio $$\upsilon = \frac{\varepsilon_T}{\varepsilon_L} \left({}^{N}\!/_{m^2} \right)$$

Figure 118 Mechanical fundamental equations

Even is well known, bone structure corresponds to an anisotropic structural arrange, for this simulation model, is considered as a material with linear elastic properties [106]. This assumption allows to try with several materials (including aluminum, titanium, polymers etc.) aiming to arrive to similar bone mechanic characteristics.

According to experimental research, the approximate load value, able to be managed by the radius before breaking, is nearly 2200 N [106][107]. The scenario in which most upper limb bones fracture happens, correspond to the fall of a person forward onto outstretched arms [108] at 75° between the floor and the limb [109]. However, another experimental test defined that in a forward fall, the range of load reaches from 1100 N to 4100 N, values that in some cases the arm is able to manage without breaking.

Following this analysis, studies point that exist a percentage distribution of load based in the person fall case. For a neutral wrist position and a 75°

forearm pronation, the percentage of load distributed respectively is 37% for the ulna and 63% for the radius [110]. The ulna failure load, depending the analyzed cross section is nearly 3138 N and 980N in its bigger and small section respectively [111].

Figure 119 Fall Scenarios- By Melton

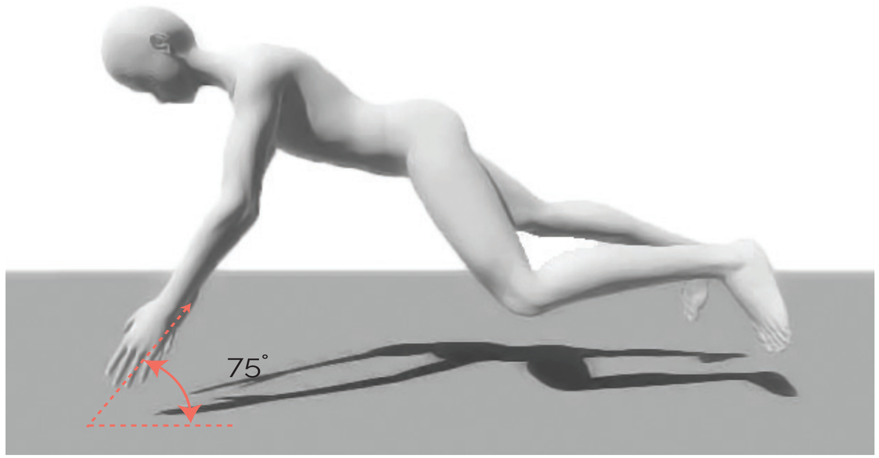


Figure 120 Selected falling scenario

9.3.2 Border simulation conditions

The input parameters that were considered to configure the generative simulation are related to the geometry, the forces applied and the selection of materials that can probably meet the functional requirements.

- ***Geometrical parameters***: To the definition of the geometrical initial shape, ulna and radius surfaces were reduced to simpler solids, keeping dimensional characteristic from its cross sections. Dimensions of bones models, where interpolated following academic research table as reference, allowing to scale the digital bone model with the patient arm dimensions. The internal structure length to design, will correspond to the length of the healthy limb, minus the length of the remaining stump.

  Below is presented the reference bone geometry along with the simplified CAD model emulating the radius pronation of 75°. The base modelled on the simplified model, correspond to the dimension of standard prosthetic hand couplings.

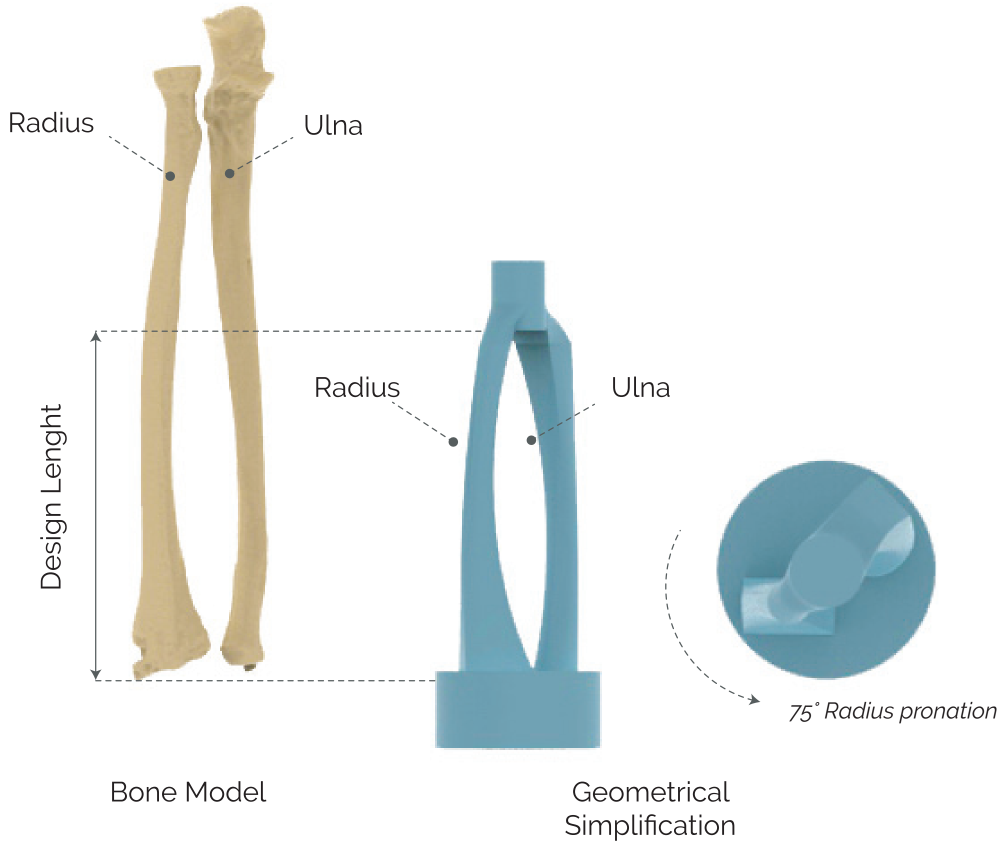


Figure 121 Geometrical simplification

- ***Applied forces:*** According the bibliographic research, load conditions that imitate the worst bone scenario, are related with a fall in which the arm is inclined 75° regard the floor. The load used is the maximum value found experimentally, equal to 4100 N. Fixation constraints are setup on the upper part of the simplified model, with restrictions in UX, Uy and Uz equal to 0.

Figure 122 Load model

- ***Selected materials and process:*** To run the simulation were defined 10 materials between polymers, composites and metals. The model is reduced to 10 materials because the iteration restrictions of the generative software.

  The list is composed by: ABS, PC, PC/ABS, PET, Nylon 6/6, CFRP, GFRP, Al 6061, SS 316L and Ti 6Al-4V.

  The selected manufacturing process to be used, was defined in the software as additive manufacturing.

9.3.3 SIMULATION & GENERATIVE MODELS

The goal of the generative simulation is to produce design modelling proposals that can accomplish the mechanical requirements of the case study beside a reduction in mass according to the scope referred at the brief. Based on that, the computational model would try to deliver the topologies that best suit those constraints. A safety factor equal to 2 was defined as last modelling parameter.

After the iteration, near 27 different topologies were generated by the software. The mechanical characteristics are summarized on the graphics.

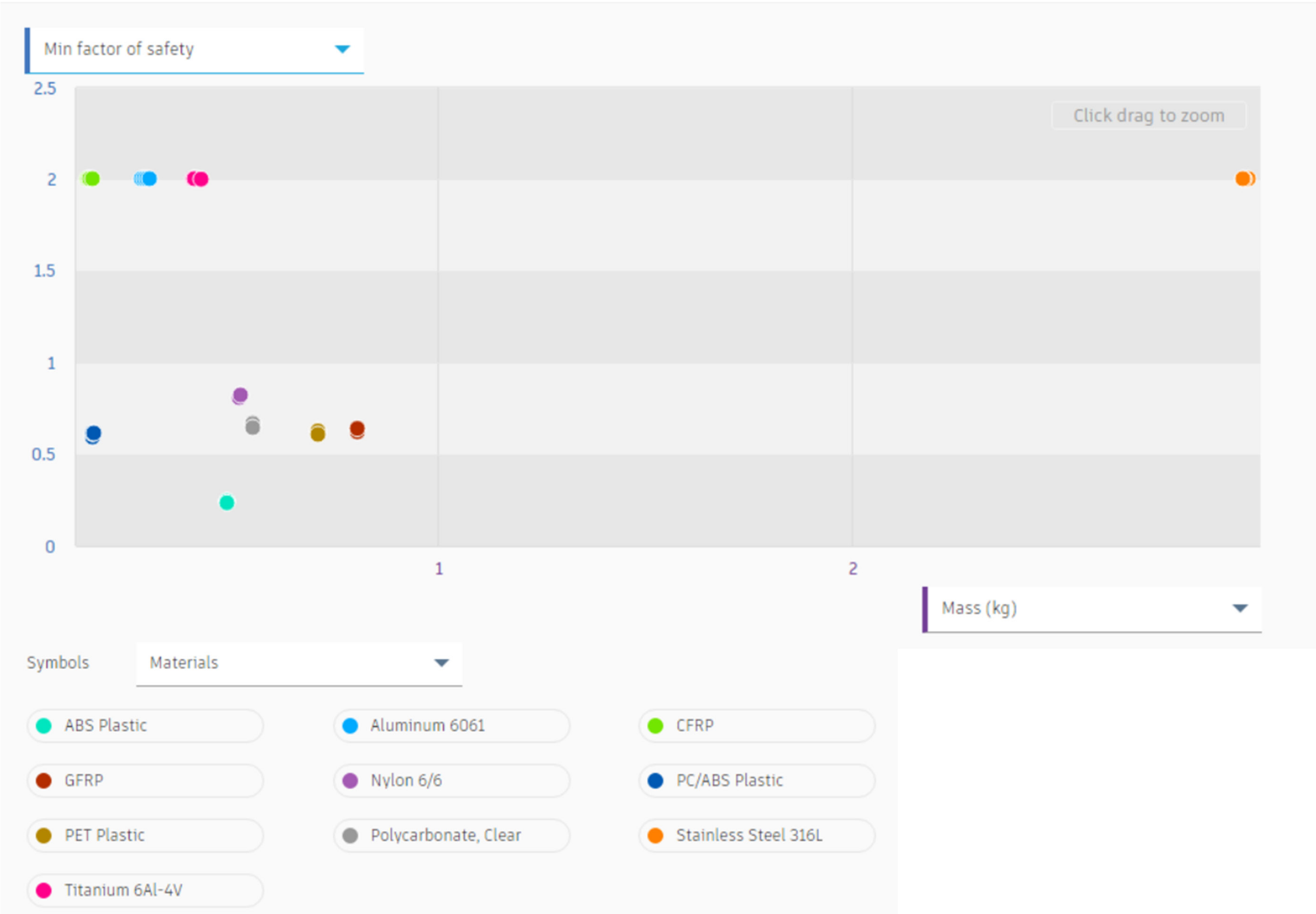


Figure 123 Min factor of safety vs. Mass

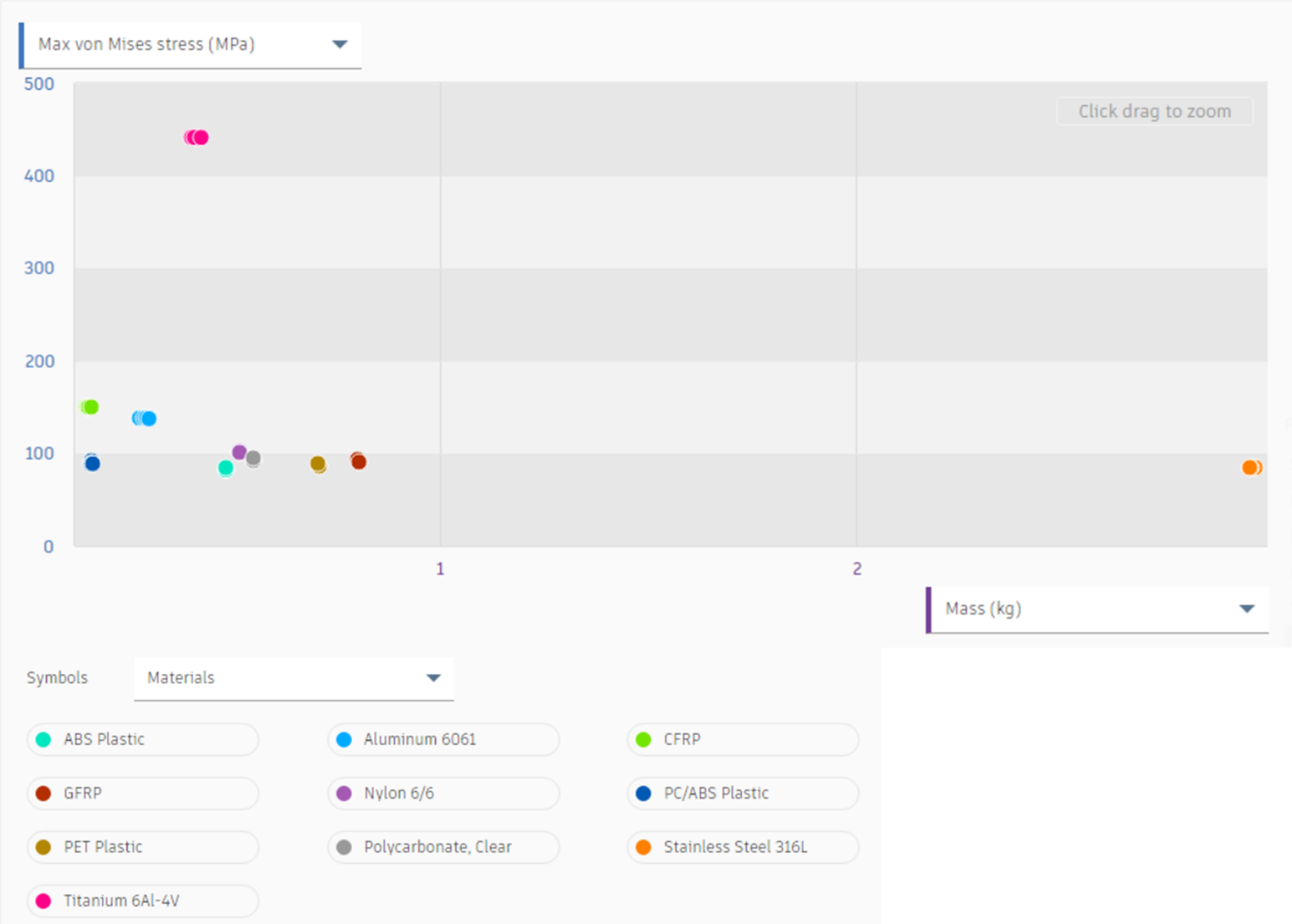


Figure 124 Initial results - Max Von Mises stress vs. Mass

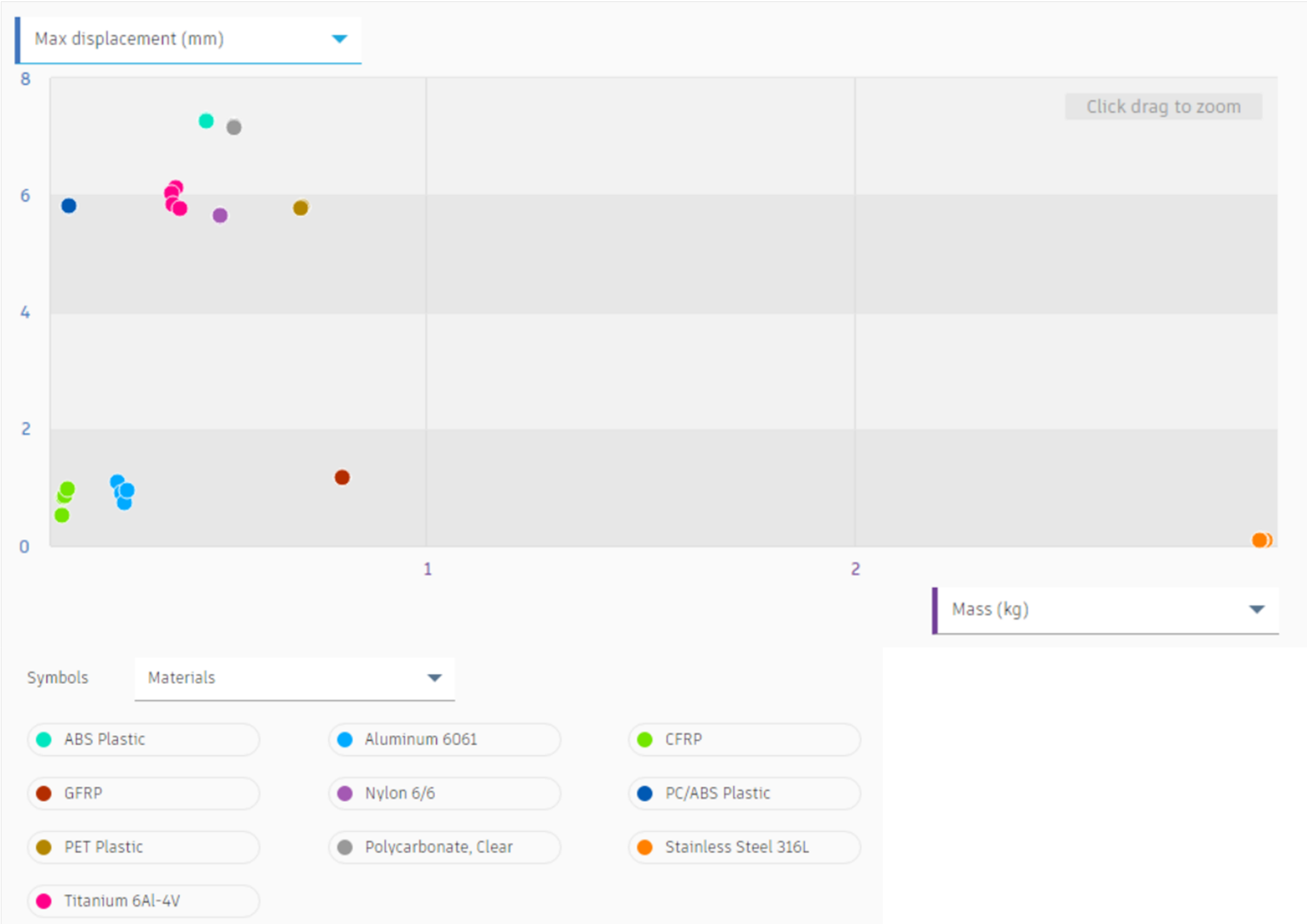


Figure 125 Initial results - Max displacement vs. Mass

Models were filtered in base on a minimum safety factor, reduction in mass, and minimum displacement. After the filtering setting, functional models are reduced to 8 topologies under the follow characteristics

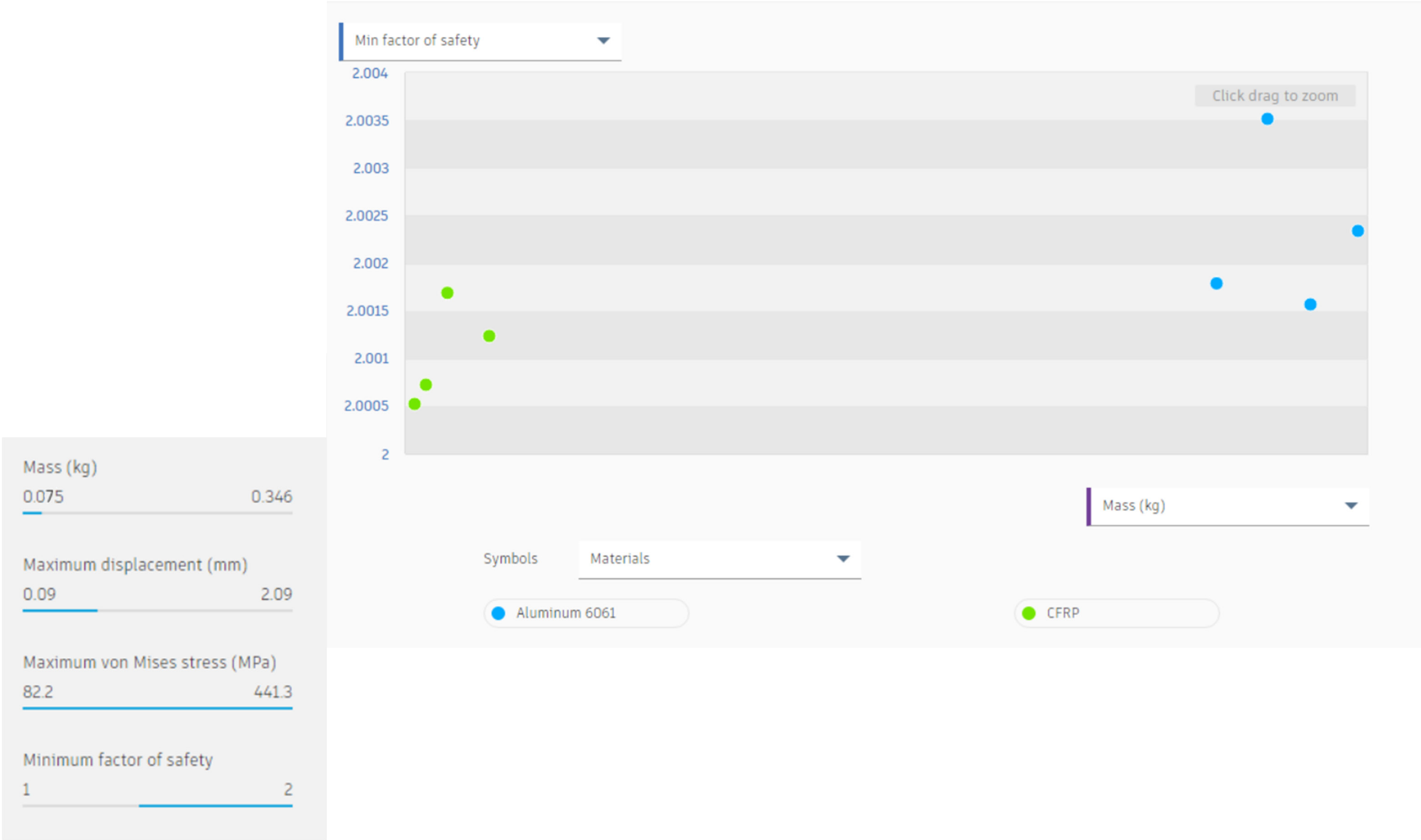


Figure 126 Filtered models

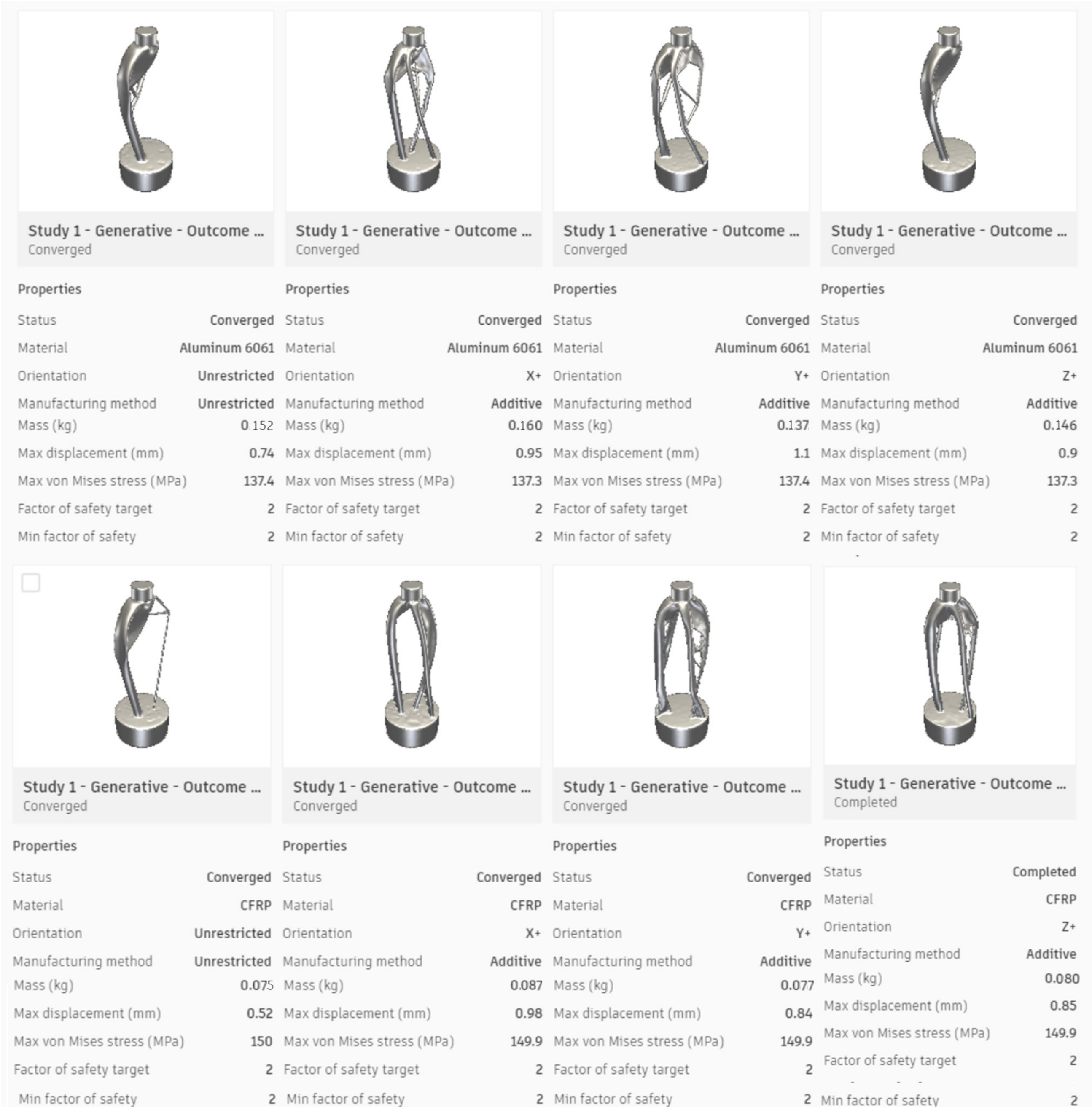


Figure 127 Generative functional models

9.3.4 Model selection

As is possible to see in the *Figure 118*, remaining topologies present, similar functional characteristics with a defined grade of distinction in terms of mass. Final filtering setting drives to a set of models made in CFRP (Carbon Fiber Reinforced Polymer) composite material with the apparent highest functional performance, and Aluminum that provides, comparatively, same functional load capability with a slightly higher percentage on mass concentration. Any functional result was obtained with polymeric materials.

Even the simulation was setting pointing out the search for a model with the minimum mass rates and the higher mechanical properties and that all the presented models theoretically can be used because are into the performance range, designer selection criteria took in consideration factors as an adequate geometrical balance (related with the weight distribution and center of mass location), the level of slenderness perceived (factor that influence directly the manufacturing possibilities) and the stress concentration in the upper joining section .

Based on that criteria, the selected model corresponds with the geometry presented in the graphic *128*. Behaviour to stress loads is presented on *Figure 129*.

Figure 128 Model Selection

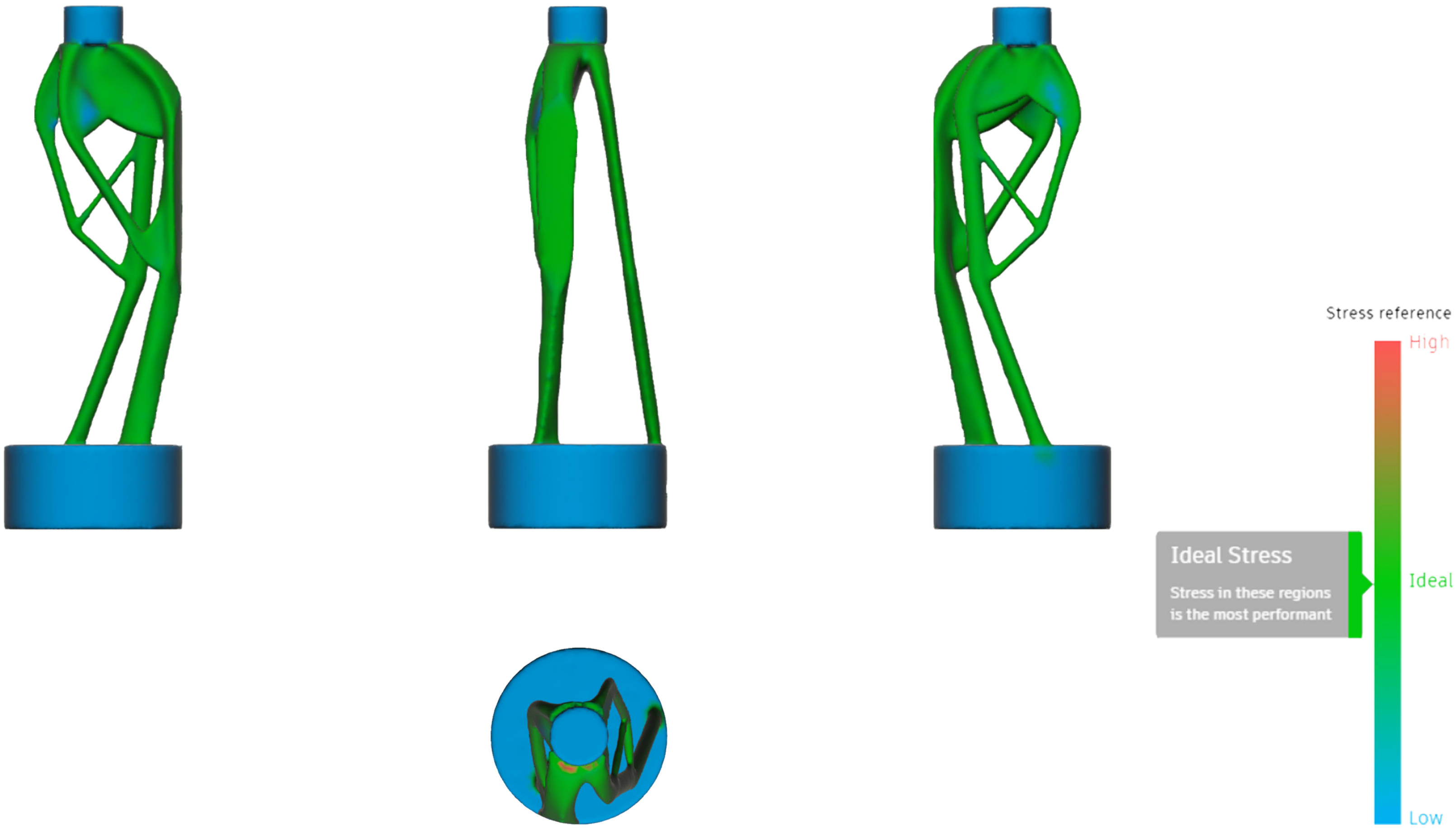


Figure 129 Mechanical Stress performance Generative model

A refinement of the generative geometry becomes necessary to make the piece fully manufacturable and useful. This geometrical refinement implies a slight increase in the mass, especially in the areas where more stress is concentrated, and the geometrical modifications own of the integration of the external parts into the full assembly.

A final comparative analysis in terms of mass percentage reduction is presented, among the base model, the generative topology and the final part that would be used as forearm internal structure. The reduction in mass between the base model and the software generative topology is about a 30%. After modelling refining the difference between base model and the final part round about 18%.

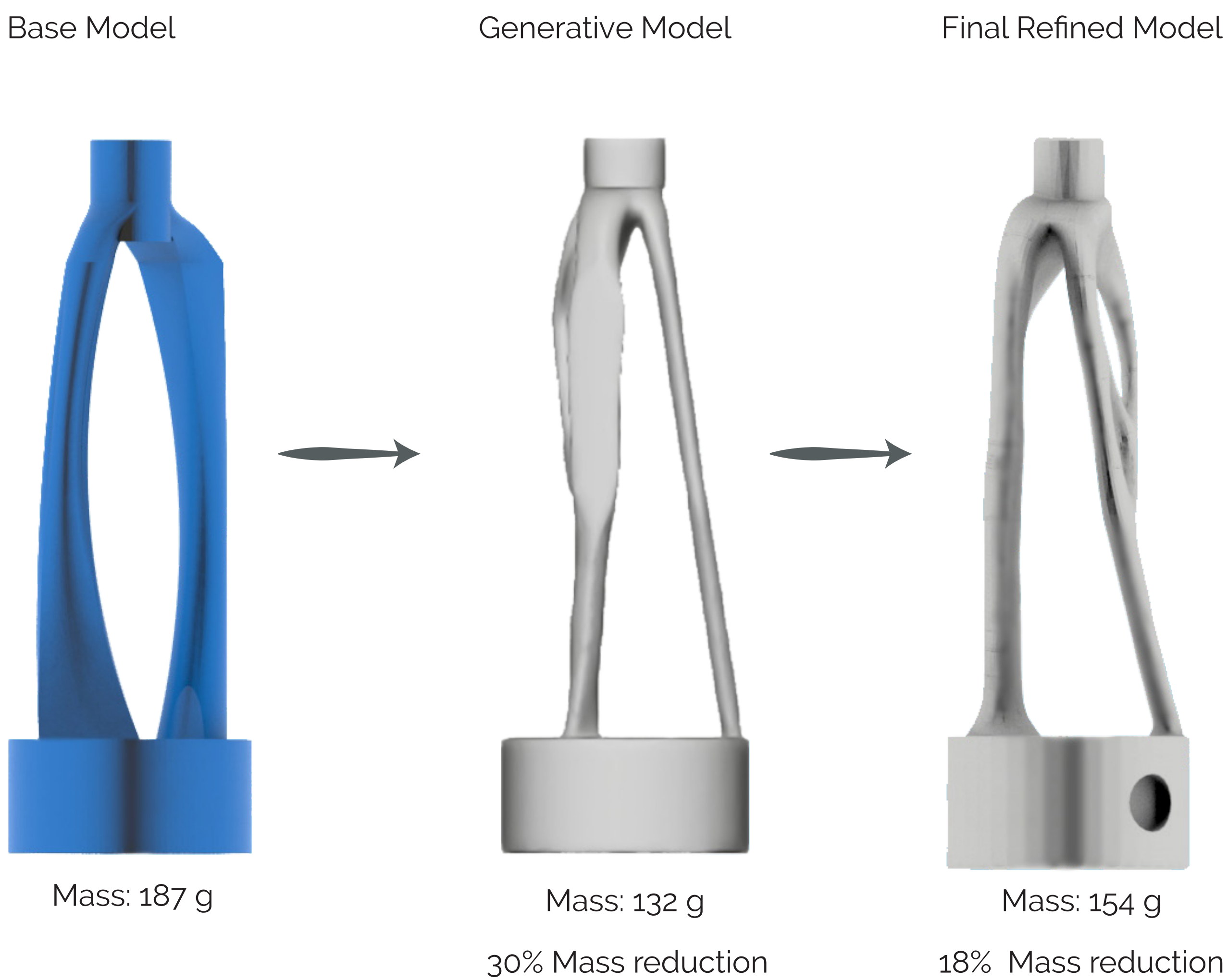
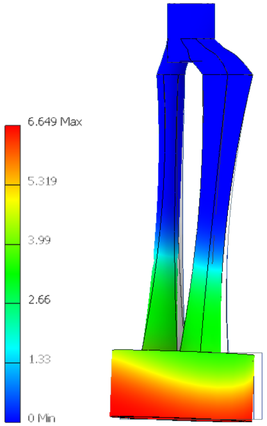


Figure 130 Mass percentage reduction

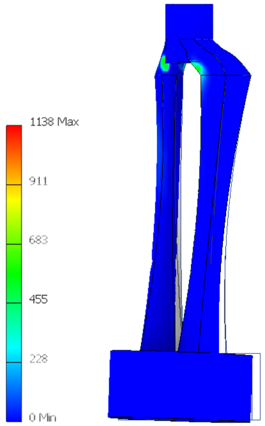
In terms of mechanical resistance, the results of a FEM analysis point out to an outstanding improvement in the strain conditions achieved with the refined geometry under the same load conditions, in comparison with the base model. Furthermore, the reduction of the concentrated stress in the joint section, and an improvement in the general safety factor of the part. In this sense, final FEM analysis, indicate compliance with the performance conditions initially set.

Base Model

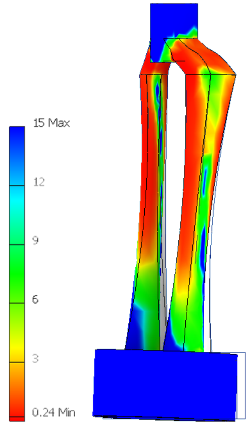
Figure 131 Figure 44 Comparative mechanical properties



Max Displacement: 6.649 mm

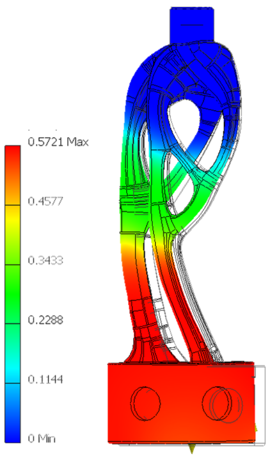


Max Von Mises Stress: 1138 MPa

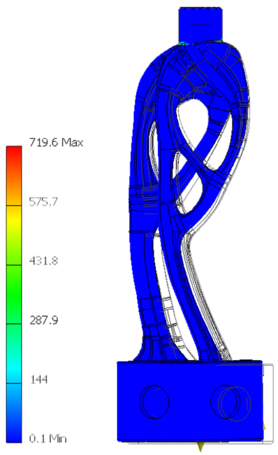


Min Safety factor: 0.24

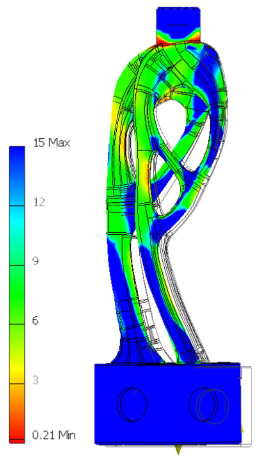
Refined Model



Max Displacement: 0.5721 mm



Max Von Mises Stress: 719.6 MPa



Min Safety factor: 0.21

9.4 External Cover

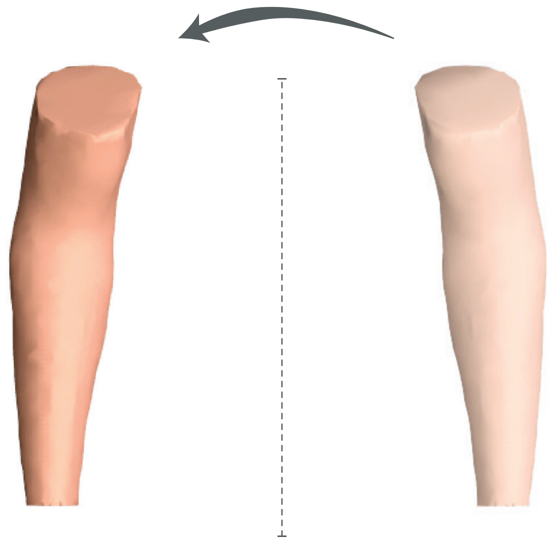
The external cover works as a vehicle for self-expression, reason why, must look stylish and attractive in terms of the aesthetic that concerns to the wearer[62]. Functional reliability must be expressed and guarantee based on the quality of the used materials in addition to the manufacturing process employed.

The conception of the external cover geometry follows a similar methodology than used in socket modelling.

Through the use of reverse modelling techniques, the surface of the arm's case study was generated and modified according the measures taken from the patient.

The refined surface was modelled, and mirror reflected, to serve as geometrical reference to design the external cover in the missing arm. Considering the socket geometry some modifications were needed to define properly the mechanism of fixation and assembly.

Scanned - Left Healthy Limb



Limb Mirroring

Figure 132 Mass percentage reduction

9.4.1 Ideation

Beside the aesthetical approach, functional requirements linked to the external cover were taken into account, encouraging to meet the best balance between form and function.
Lightness', flow air circulation, impermeability and the capacity to be interchangeable, were references values that direct the realization of the cover.
Some initial sketches and models can give an initial idea of the developed concept

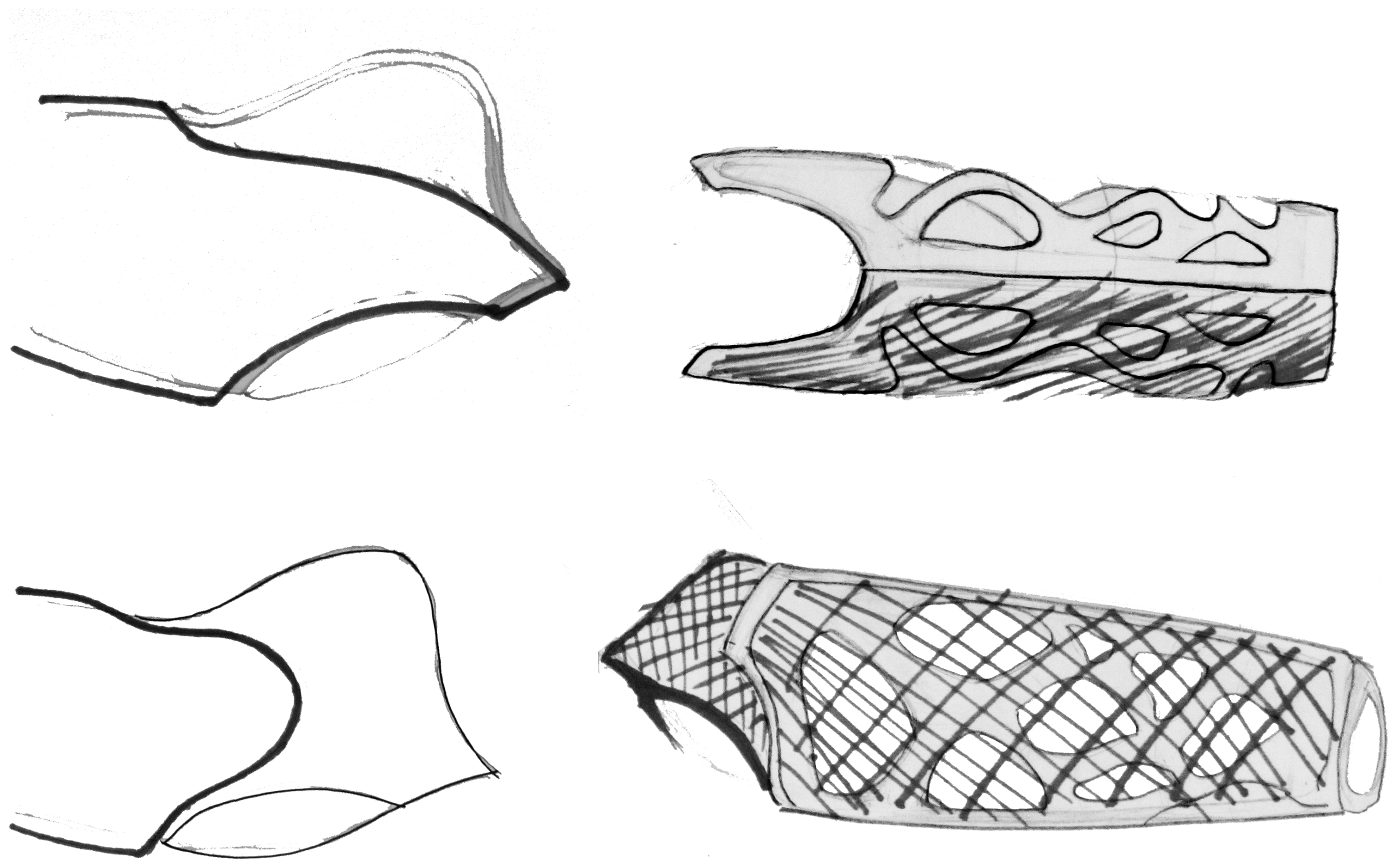


Figure 133 Ideation Sketches

Two geometrical concepts inspirated in hyperboloid structures and hexagonal molecular DNA arrangement, were finally defined as aesthetical concept for the outer shell. In addition to be aesthetically striking, this geometries have the capacity to resist high levels of loads [112], promoting a representative degree of material savings, which makes them lighter at the same time.

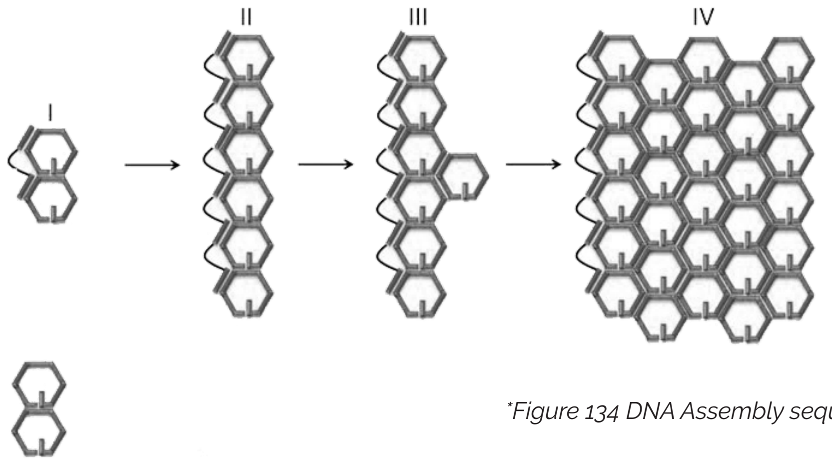


Figure 134 DNA Assembly sequence

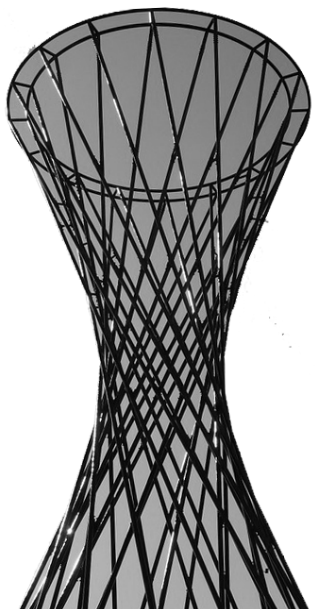


Figure 135 Hyperboloid structure

9.4.2 Design Description

The external cover is a hybrid arrangement composed by a base layer of 3d textile -Muller- covered in a waterproof colored fabric layer -Sensitive- that remains inside a 3d printed generative net made in ABS. Both elements are assembled together using magnetic pressure snaps, giving the possibility to be attached or unattached according the chromatic user preferences.
A base layer made in 3d textile makes easier the flow of air and give structural support to the external plastic net, without lose flexible characteristics.
The sequence of fabrics assembly is shown on the schema 124.

The generative net, apart from give an aesthetical value, works as a shell from which will be supported the contact loads experienced by the user in its daily routine. Net holes encourage the freshness and lightness, without affect the structural resistance.
Connected through the use of pressure magnet snaps, the external cover is attached to the socket in its lateral area and assembled with the internal forearm structure at the distal part, where the connection with the hand prosthetic device has place.
External shell is divided at the bottom part, to allow an easy change of the inner cover, according the user requirements.

***Taken from:** https://www.nature.com/articles/ncomms1535*

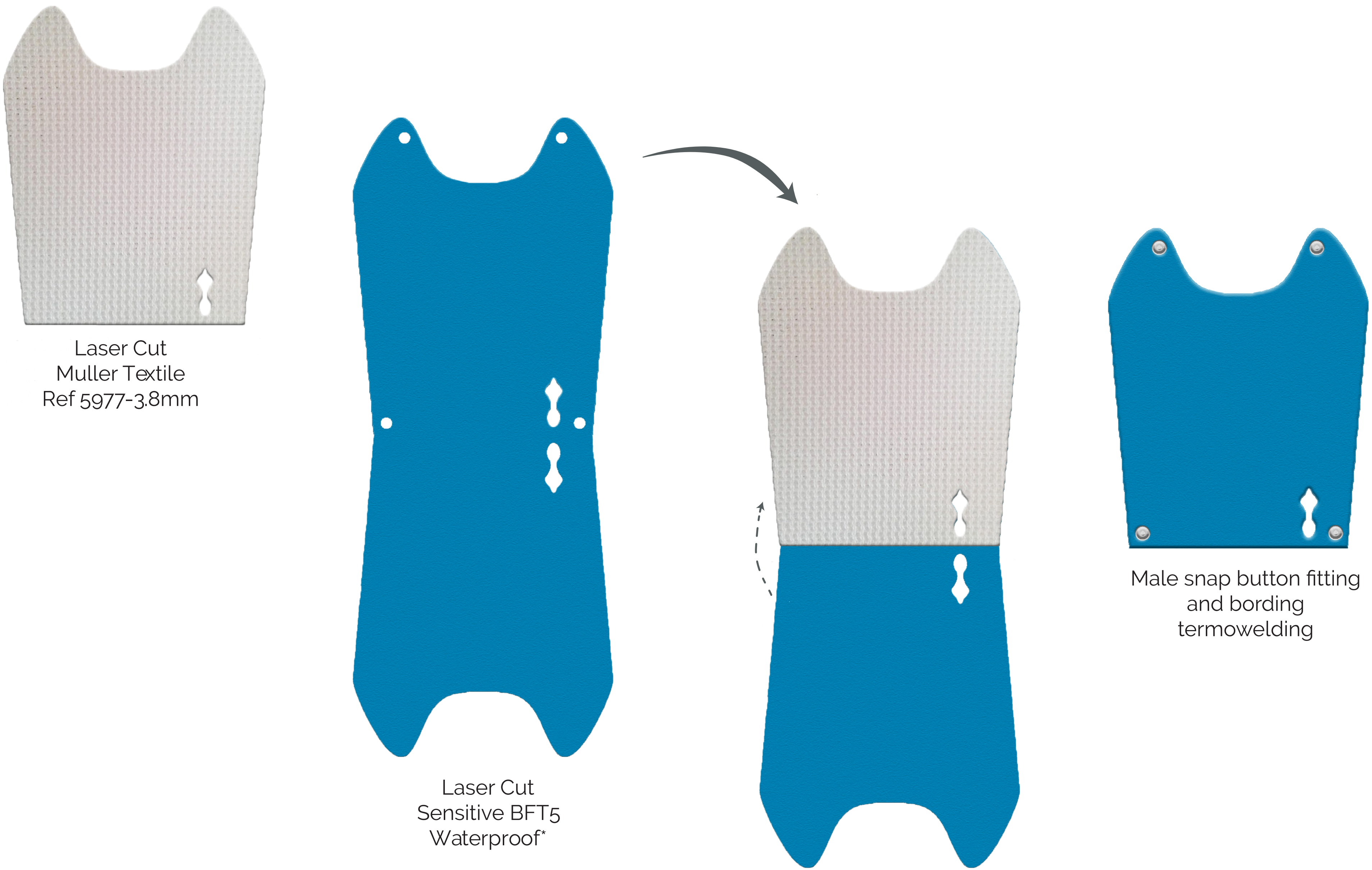


Figure 136 Assembly fabric cover sequence

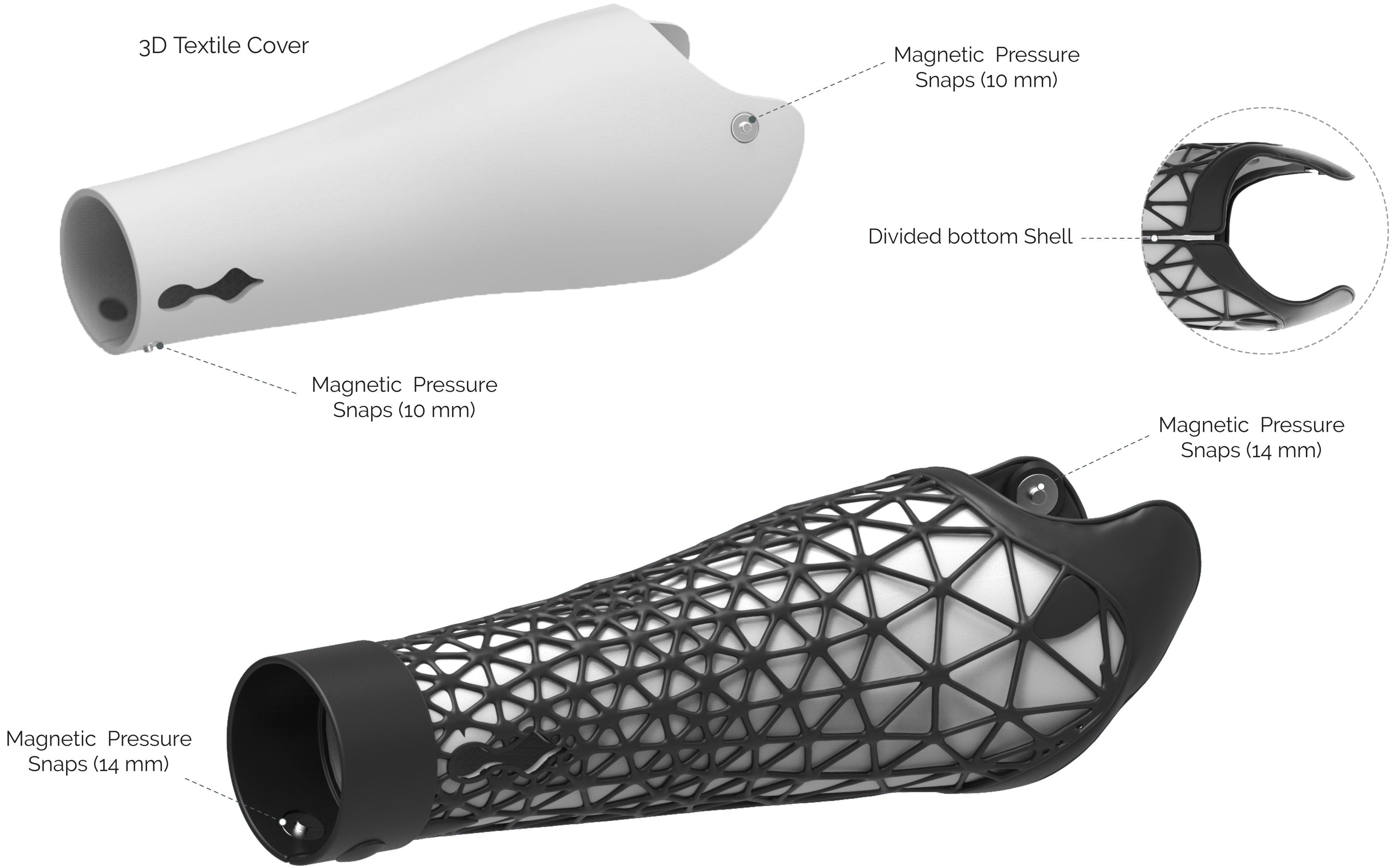


Figure 125 External Cover shell

9.5 Other Elements

9.5.1 Interphase Connector

Working as interphase element, this part was designed to allow an easier connection/disconnection between the inner structure and the socket. Manufactured in 3d printed Nylon 6, on one side is in direct contact with the external projected region of the socket, and in its other side, will contain the mechanical union of the entire system, through a bolted union that links the three parts.

Mechanical resistant was tested projecting that in case of overload, this will be the piece that will break first.

Figure 126 Interphase connector

9.5.2 Electrical Plug

Designed as the system user interface, will indicate the level of power charge in the batteries, when the system is plugged to the electrical network.

Furthermore, will indicate to the user when the batteries are reaching their minimum charge levels.

Its electrical configuration, was briefly explain at chapter 6, but the production technologies and complete engineering process, are out of the scope of the project

The schema shows the interaction functionality of the plug. When the patient use the device, the led lights are turned off to save power. At arrive to the minimal charge, the outer led will start to flash, to indicating that batteries

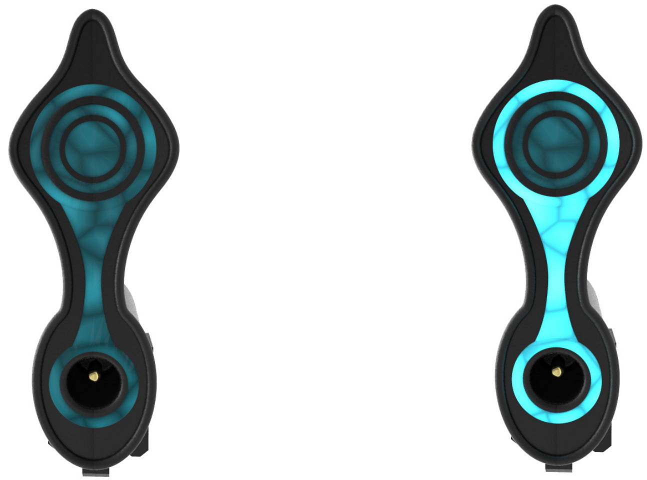


Figure 127 User routine Led Light interface

Charge Indicator

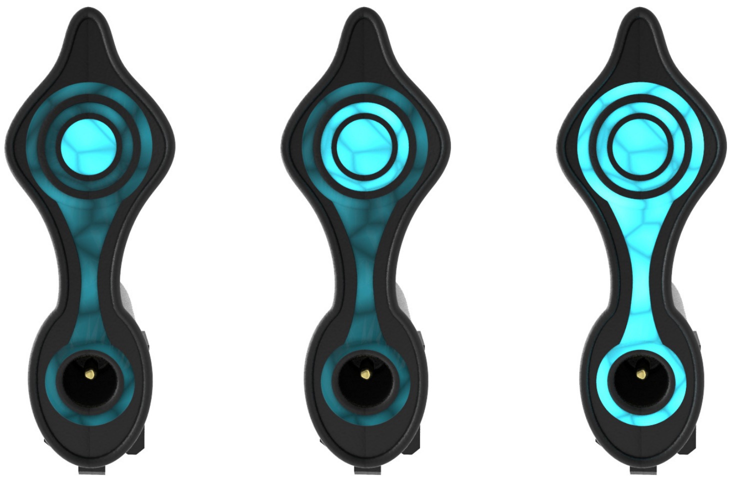


Figure 128 Charging Led Light interface

are arriving to its minumun level of charge and must be plugged.

When the device is plugged, light will start iluminate from center to outer, indicating the battteries are full when the light set is complete.

9.5.3 Flexible Batteries

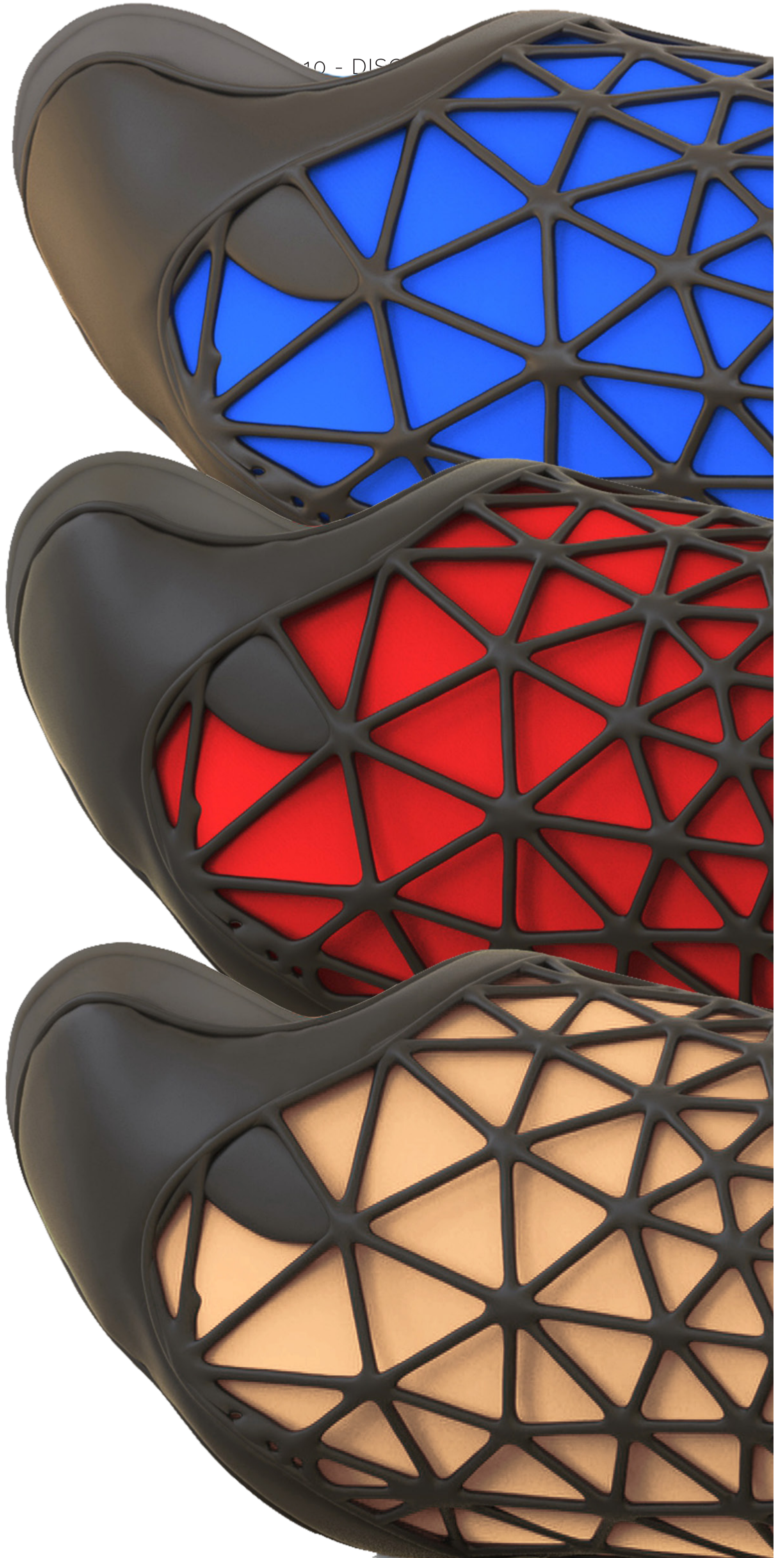
The flexible batteries produced by Prologium, were the option that best meets the requirements of flexibility and high charge concentration. The possibility to request customized batteries opens the door to the design of different possibilities, according to the characteristics of the used prosthetic hand.

The load power estimates were made from the information of the electronic components used in the laboratory, information that is supplied to chapter 6.

The results of the estimation, allowed to deduce the necessity of a minimum of 6 flexible batteries with dimensions 65 mm x 167 mm that can supply a total of 1.7 Ah, to a maximum of 4.7 V

Figure 129 Flexible cell battery

10



DISCUSSION & RESULTS

This chapter presents the results of the project, citing clarifications and design recommendations for future work related to this topic

10.1 RESULTS

Even a real performance of the product could be evaluated just with a functional prototype and with the patient as evaluator in terms of acceptability, comfort and functionality, an analysis of the prosthetic interphase concept effectivity can be done assuming the proposed scenario in the value proposition canvas diagram, in which is possible to compare, the level of theorical improvement that was reached in the design project again the previous user initial state. The valuation given to the parameters, are part of the designer criteria, and is backed up with the opinion given by the patient regard the resulting prototype and with the project supervisor' professional criteria. About each aspect is presented an individual feedback analysis.

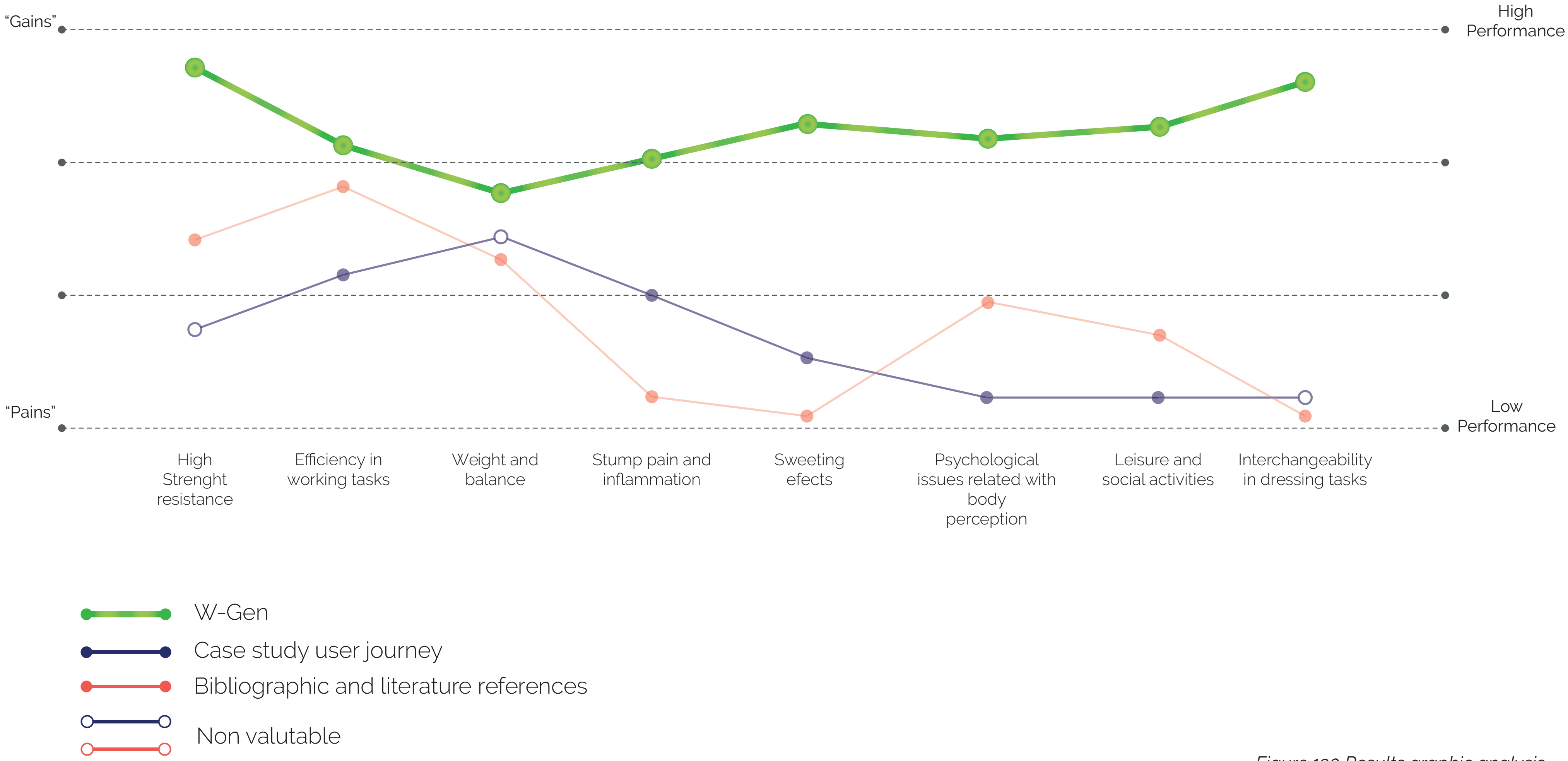
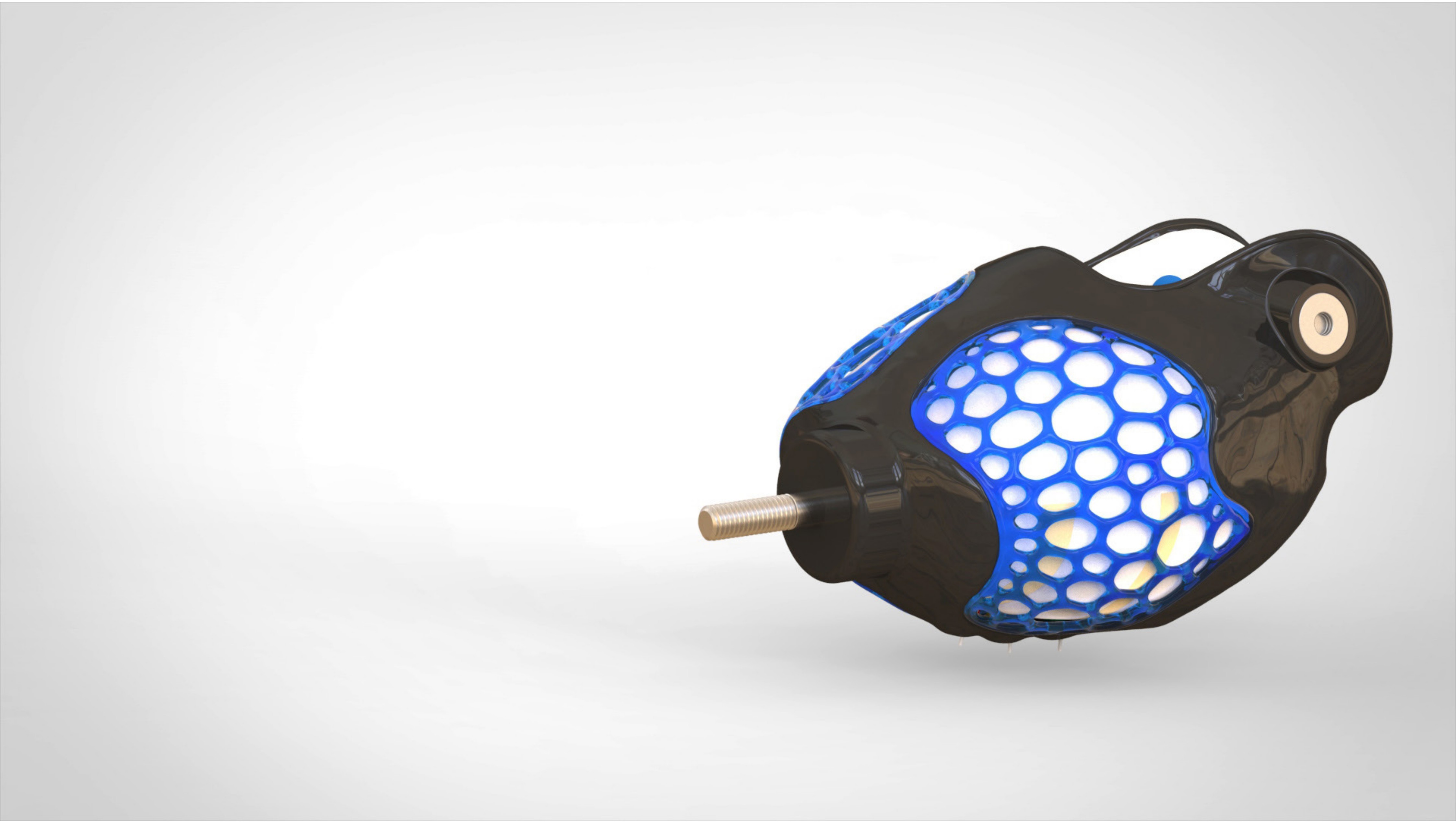
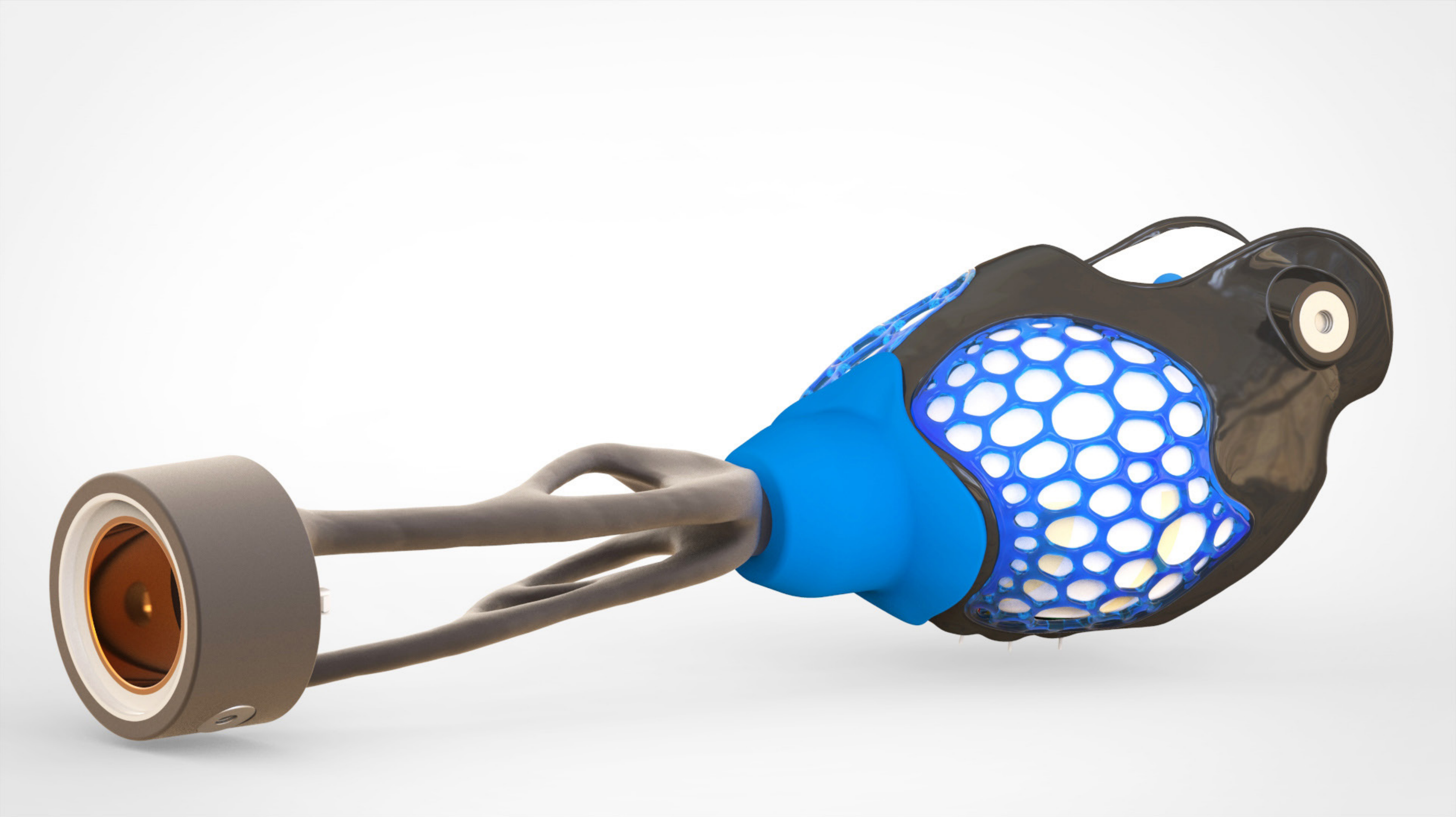
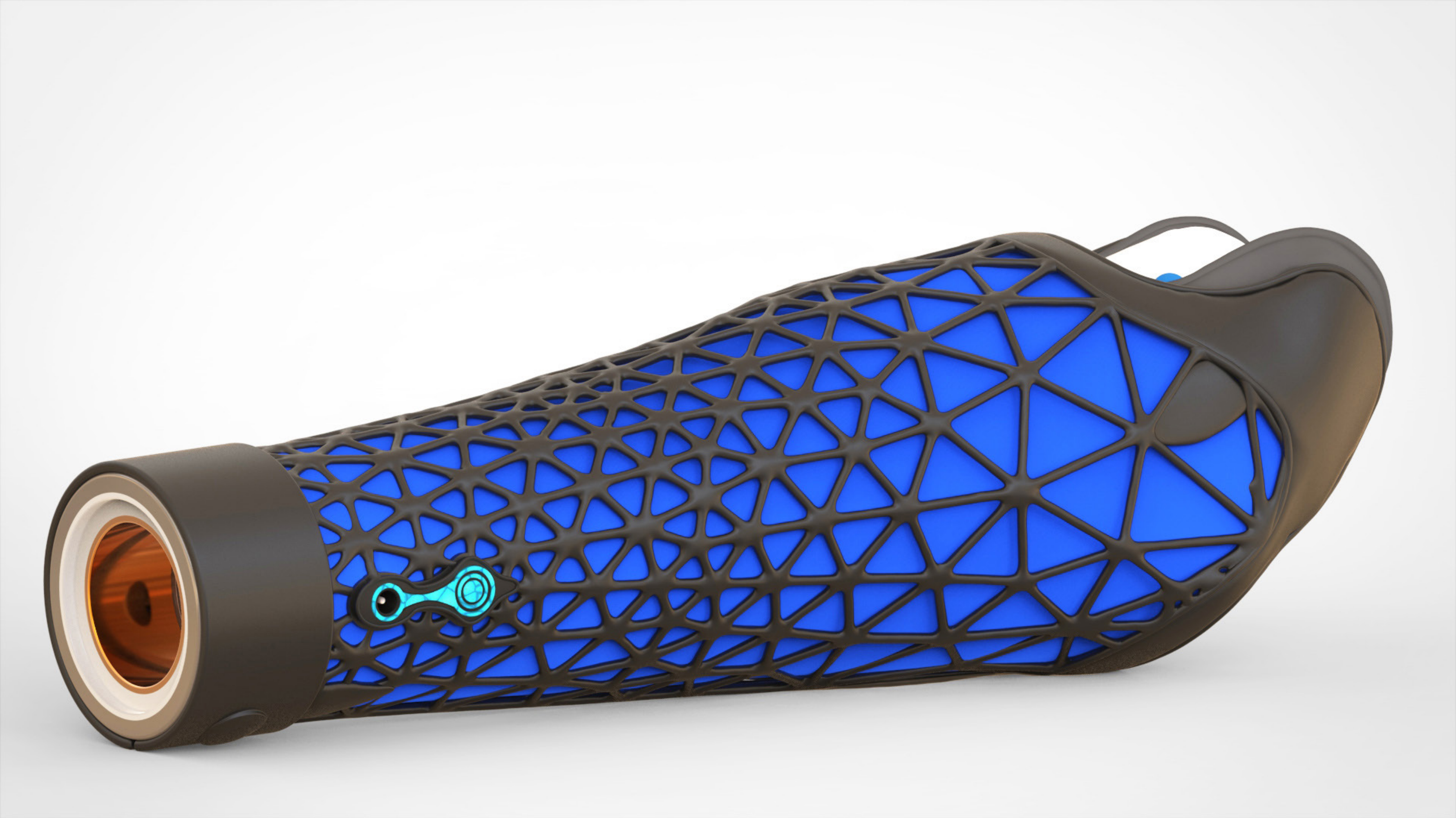
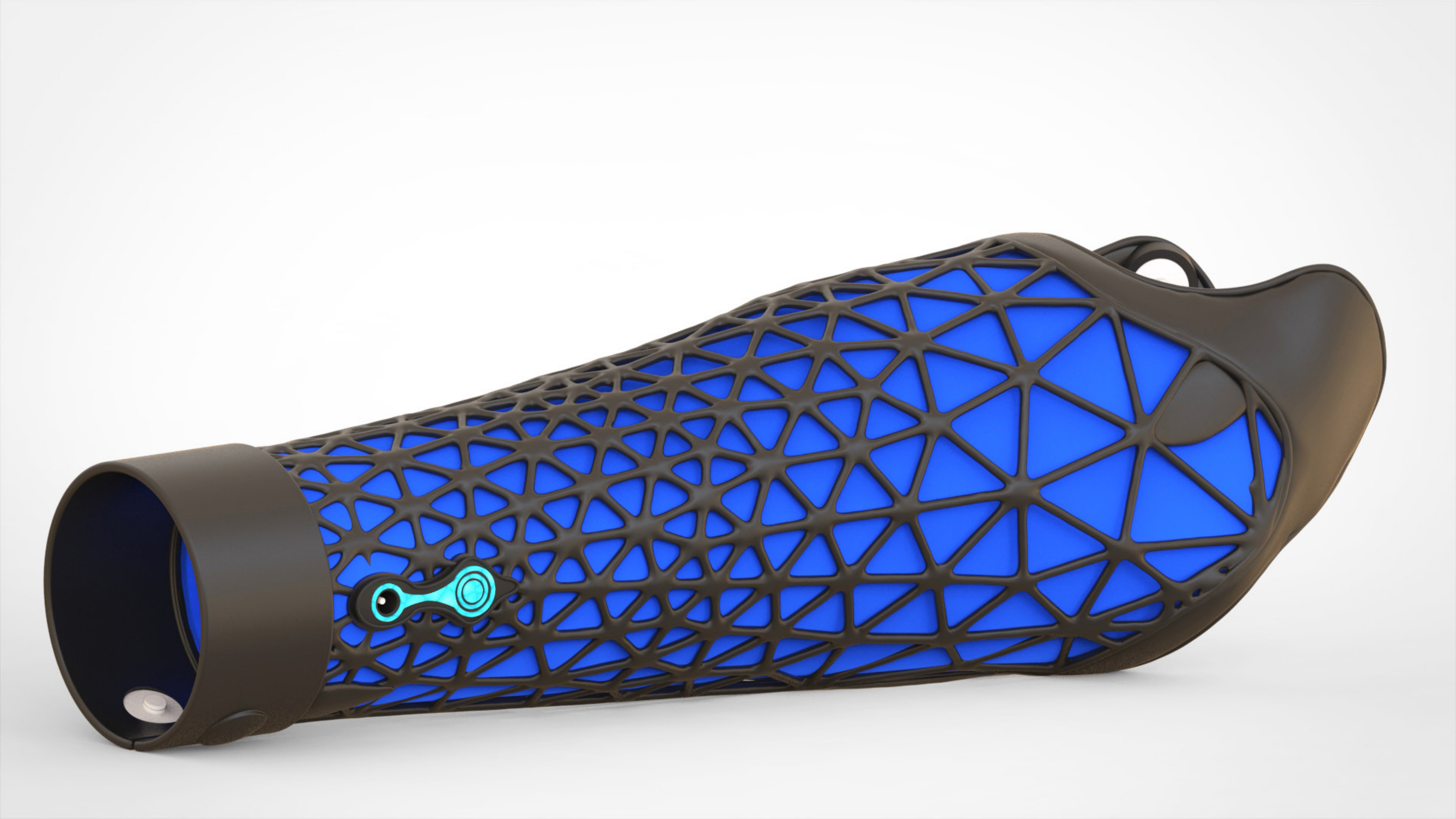


Figure 130 Results graphic analysis









- ***High Strength Resistance:*** The final model will be able to manage a maximum load of 4100 N, similar conditions to those managed by the bone group ulna/radius. This strength capacity, according with the generated design specifications in terms of material and topology, are related with the selection of powder aluminum as material for the internal structure and produced with additive manufacturing techniques. Actual upper limb prosthetic interphases cannot manage this level of bio mimetic mechanical strength, reason because why, it is considered that the objective initially proposed regarding the increase of the mechanical characteristics was achieved.

- ***Efficiency in working task:*** Based in the increase of the mechanical properties, it's possible to inferred, an improvement in the activity's performance, especially for heavy duty requirements. The possibility to be able to deal with higher loads, keeping functional features is the reason because the valuation is slightly higher than actual prosthetic upper limb devices.

  Its needed to clarify that a real valuation of the improvements, must be given by the user under the daily working conditions, and with the use of the hand prosthetic device, attached to the prosthetic forearm.

- ***Weight and balance:*** Weight characteristics of the designed upper limb forearm, are around 520 grams, with the inner structure made in Aluminum. Having into account the integration of the prosthetic hand device (Hannes, with 480 grams, produced by INAIL), the entire system weight is about 1 kg.

  Academic references [113], recommends for upper limb prosthetic devices (adults case) a weight under 1.5 kg. According to this, the obtained result in the project, conforms the stablished parameter.

  Considering that this weight is achieved for heavy duty applications (extreme case of design) it's possible to say that the use of different materials to produce the inner structure, can be a way to reduce more the final weight of the integrated prosthesis. The adjustment in the inner structural load capacity to lower levels will still fit with the functional user requirements and probably will reduce the manufacturing cost. A table shows the possible materials to use, and the levels of load able to manage.

DESIGN POSSIBILITIES

	Material	Max Design Load	Forearm Weight	Prosthesis Weight
Heavy Duty	AlSi10Mg	4100 N	520 g	1000 g
Medium Duty	PC	2500 N	451 g	931 g
Light Duty	ABS	500 N	441 g	924 g

Table 19 Design Forearm possibiliti es

In terms of weight balance, the goal of the project was to keep the center of mass, aligned the most with the central axis of the remain portion of the stump, to avoid discomfort user sensation and encouraged the feel of the structural bio mimesis.

In the longitudinal direction the center of mass is placed in the connection area of the prosthetic hand and the forearm at 250 mm from the elbow joint, something expected -because the weight of the prosthetic hand- even the reduction and improvement in the weight distribution of the forearm structure.

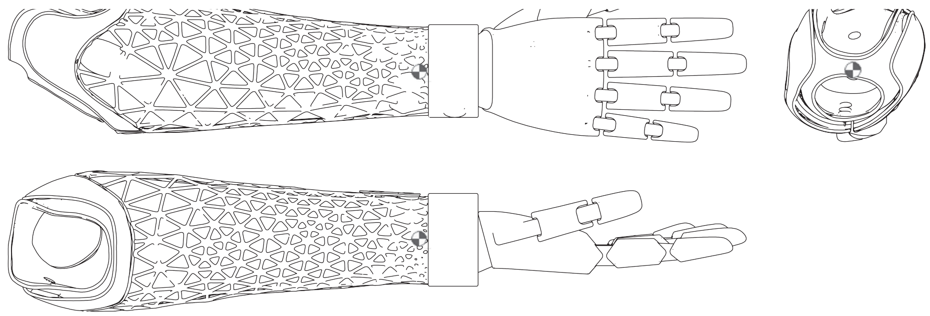


Figure 131 Center of mass location

Based in the advantage to have a lighter system, the level of force managed by the elbow flexors (biceps and brachialis muscles) using the prosthetic arrangement is about 50 N, a value that according the references is considered like that found in people without amputation.

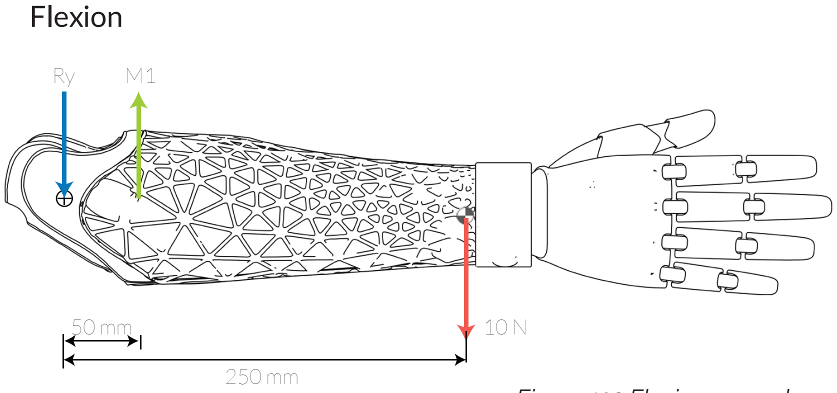


Figure 132 Flexion muscular schema

For extension case, the triceps acts as elbow extensor and managed a load of near 83.3 N, with a reaction load in the elbow that is about 93.3 N. Normal values according consulted references regard performing daily living activities said that forces generated at elbow can be up three times body weight [17]. Found values, are inside that functional constraint.

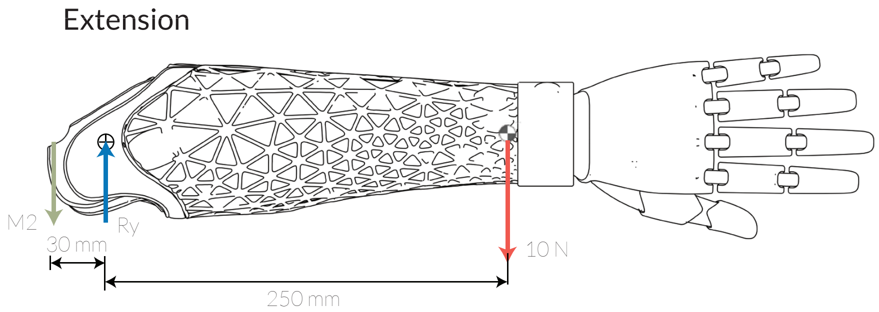


Figure 133 Extension muscular schema

- ***Stump Pain and Inflammation:*** Insertion of the flexible net in the area of increased susceptibility to stump inflammation, it is expected to counteract the effects of pain generated after prolonged periods of use of the prosthesis, guarantying still the fitting adjustment to the stump. Because is the first time a prosthetic socket is conceived under this structure, it becomes necessary to do usability test, to confirm the adequate performance of the interphase. The previously mentioned can be considered as future step of the project.

- Sweating effects: Base on the technical information supply by the fabric producer, its possible to warranty a decrease in the harmful effects that can produce an excessive level of perspiration in the stump area. Furthermore, antibacterial effects created because the conductive electrodes into the liner, promote better usability conditions.
  The socket structure conceived a better air flow, geometric characteristic than not much of the current sockets at the market offers. As before, only real test will ratify what theoretically is presented as functional.

- ***Psychological issues related with body perception:*** Even it's a parameter that can not being valuated quantitatively, to define the improvements related this issue, the project was shared and explained to the patient requesting for a qualitative feedback about aesthetical aspects of the project. In general, the perception was positive and according to him, the aesthetics more attractive than he was expecting of the project. Psychological effects on the patient because the use of a prosthetic devices can be evaluated with more precision just after a period of prosthesis usability.

- ***Interchangeability in dressing task:*** Because the possibility to choose the cover color according the user taste or situation, this project achieves the transformation of the prosthesis use into a dynamic element and part of the user's daily routine of dressing.

- ***Other results:*** The imperceptible integration of conductive textiles as electromyographic sensors into the inner liner to replace the use of metallic pieces, make part of the wearable approach given to the project, in the aim to reduce as much as possible the electrical wired connections and enhance a most transparent manufacturing process for the socket.

10.2 Future Considerations

- Even the project development process follows a totally customized methodology, it considered that the geometrical proposal presented can be parametrized to works as a digital and most efficient method to produce prosthetic devices. Scaling the conditions of load to which the prototype was designed and modifying the bone length according the amputation condition of the patient are part of the future considerations of the project
- It's necessary to understand than the use of reverse modelling techniques as body scanning method, have into account just the geometrical definition of the stump surface. To design a prosthetic socket that can accomplish fully functional conditions using just CAD and design digital tools, would require an analysis about the muscle pressure behavior, and an identification of the muscle volume conditions. The mentioned above, to guarantee an adequate fitting of the 3D printed socket in the stump. Part of research about this topic is carried out at MIT.

- This project is a first approach to the integration of the technology of flexible batteries to prosthetic devices, in order to reduce the weight that the patient must deal. It is expected that with the technological advance, these batteries will achieve higher nominal load capacities, which will allow the use of hand prosthetic models, without limitations on operating autonomy. Currently, Li-ion batteries continue to be the option that best fits the functional requirements of devices of these characteristics.

- Although several possibilities are currently being explored in the use of composite materials for the preparation of prosthetic devices, this technology is expected to advance in the direction of the use of additive manufacturing methods. The additive manufacturing nowadays, allows the conception of forms topologically more complex, opening the way to the more widespread use of generative modeling methods.

- Aesthetical appeal of the external cover integrated the concept of generative geometries (hyperboloid and cellular) as proposal of wearability. In the same way in how it was used this formulation of patterns, variations and exploration of different geometries are open to be applied, according the taste of the user.
- Even though traditional upper limb prosthetic production methods (based on lamination, plaster casting molds etc.) continue to be made the most extended and feasible ways to manufacture due to cost conditions and well stablished know-how , it is expected that step by step new digital design technologies will be able to integrate more actively into the productive chain of prosthetic devices, allowing in this way, the improvements in times production and saving of resources.

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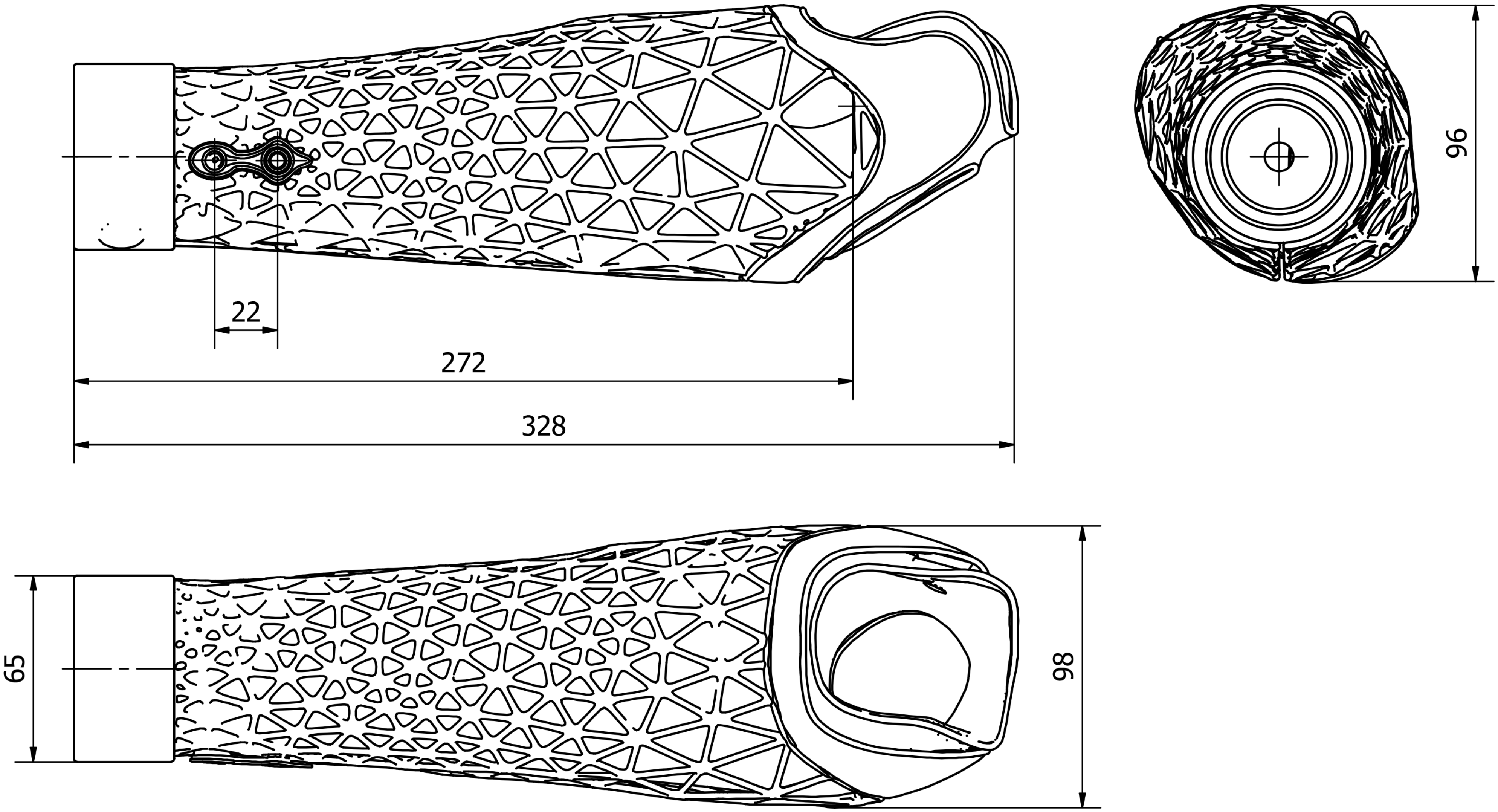
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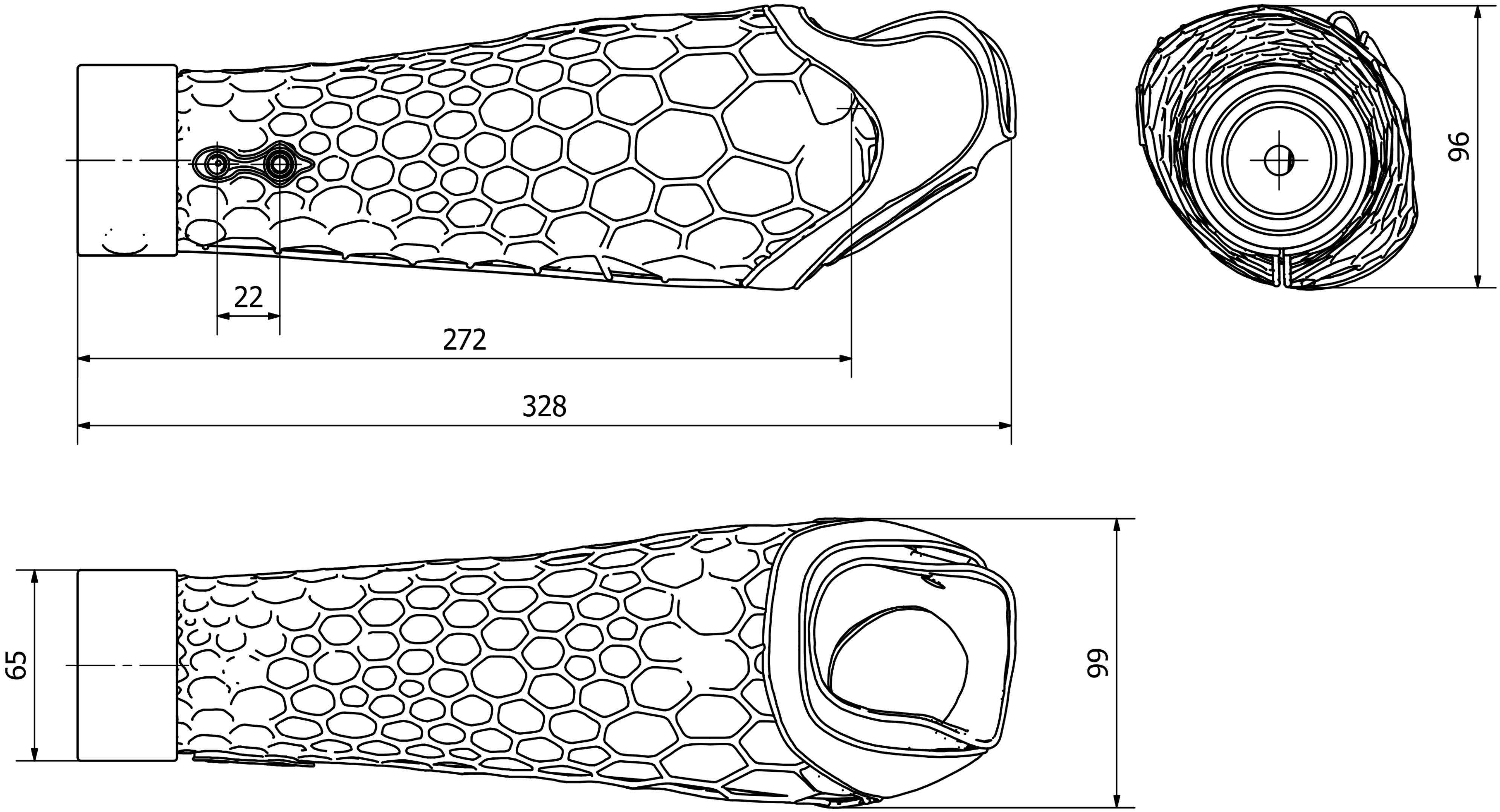
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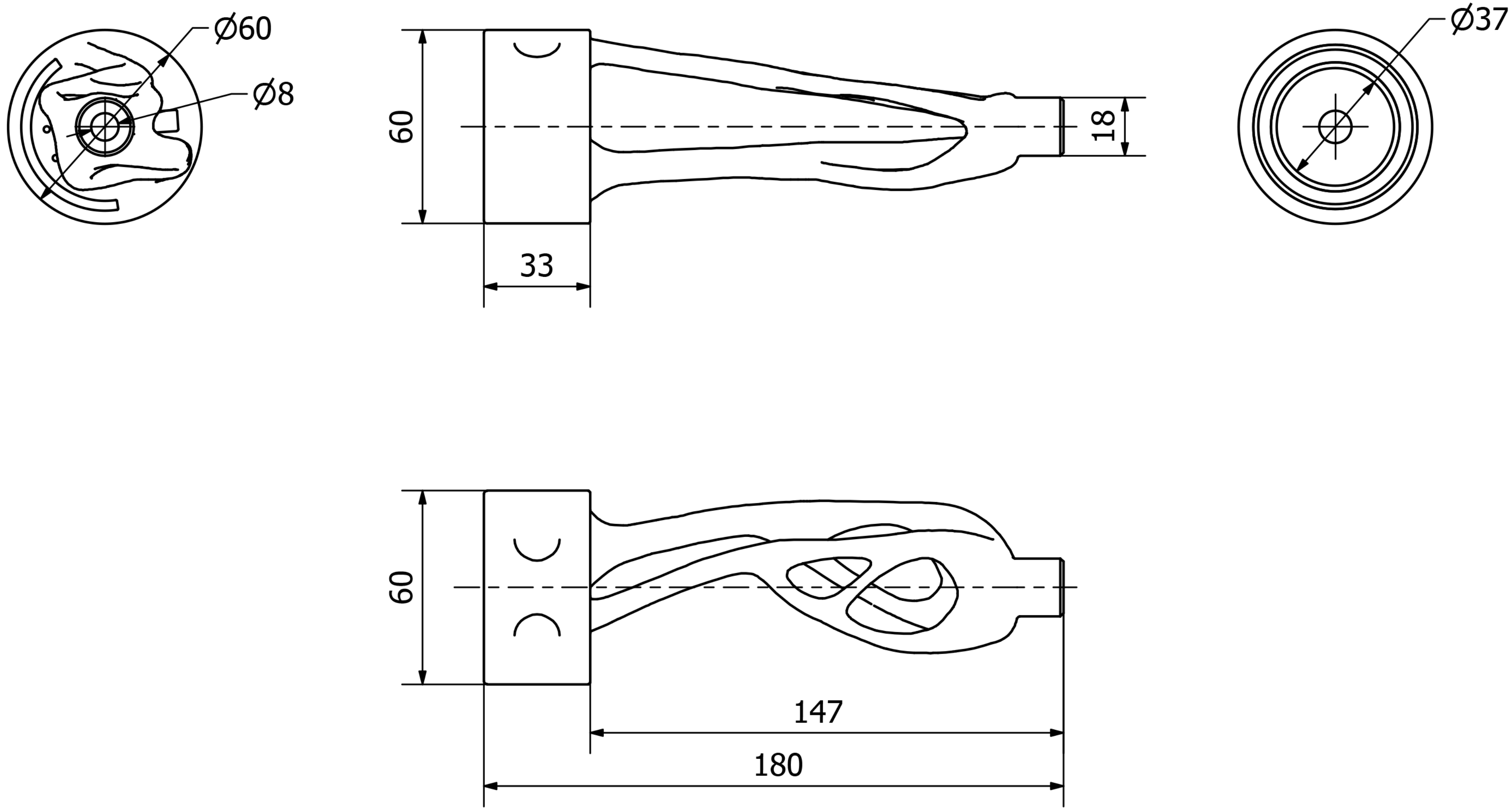
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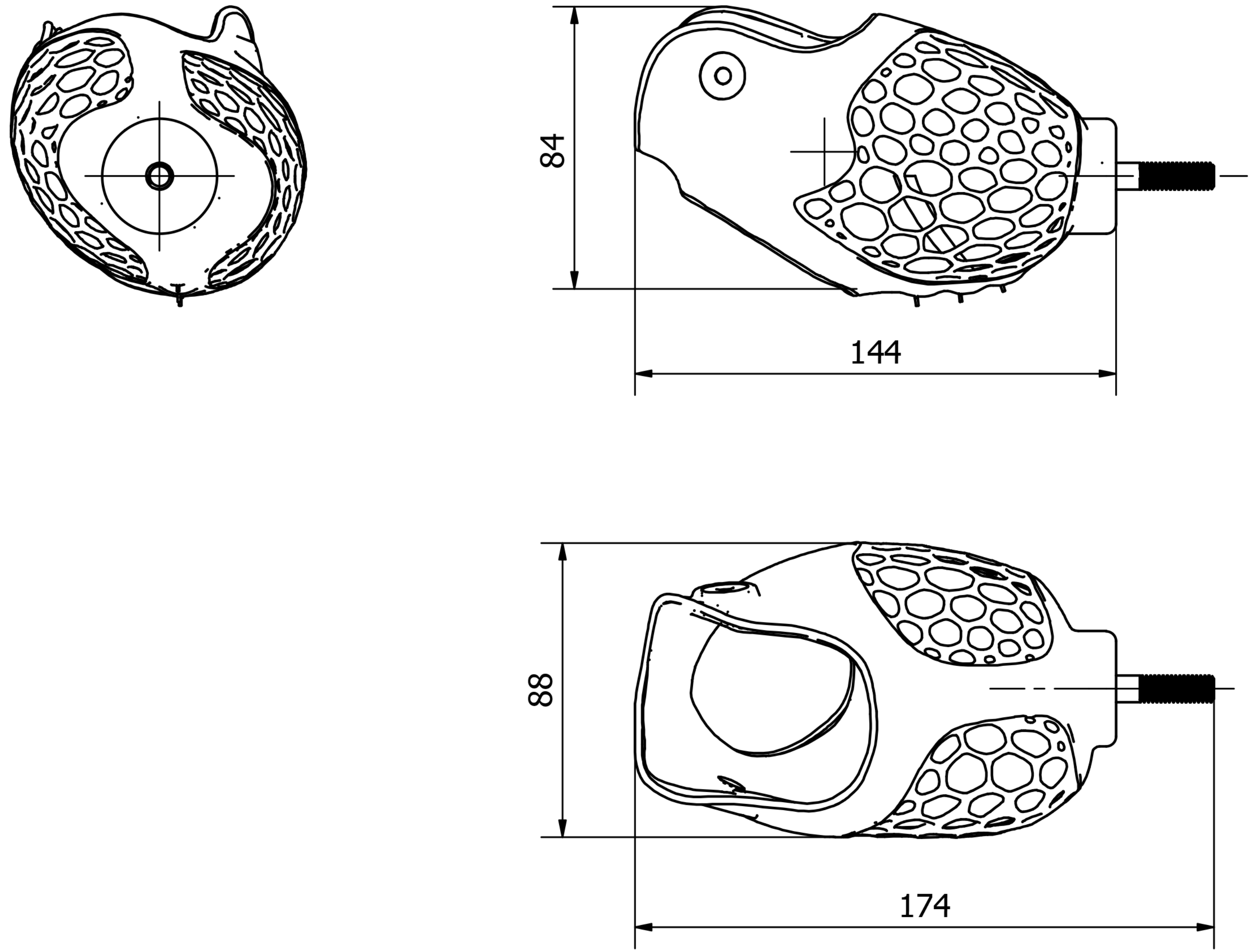
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