FACULDADE DE ENGENHARIA DA UNIVERSIDADE DO PORTO

Development of a device dedicated to skin suture assistance

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DISSERTATION

MASTER'S DEGREE IN BIOENGINEERING

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Resumo

Na parede abdominal são reconhecidas nove camadas distintas, as quais, ordenadas de fora para dentro, são: pele, tecido subcutâneos, fáscia superficial, músculos oblíquos externos, músculo obliquo interno, músculo transversus abdominis, fáscia transversal, tecido adiposos pré-peritoneal e peritoneu. A pele faz parte do sistema tegumentar e é considerada como o maior órgão do corpo humano. Da mais superficial à mais profunda, a pele é composta por três camadas, nomeadamente a epiderme, a derme e a hipoderme. Para qualquer cirurgião, fechar a parede abdominal é uma prática básica, porém, demorada. Uma técnica inadequada leva a uma sutura mal-executada da qual podem advir sérias complicações pós-operatórias ao paciente, tais como infeções e hérnias incisionais que, por sua vez, podem dar origem a regimes de antibióticos, readmissão hospitalar ou até mesmo a uma segunda cirurgia. Embora a escolha da técnica mais adequada de fecho abdominal demonstre ser essencial, também os materiais escolhidos para a realização da sutura representam ser igualmente essenciais e, contudo, são frequentemente negligenciados. O objetivo desta análise é, numa fase inicial, investigar tanto as características anatómicas como fisiológicas da pele, descrever as suas propriedades mecânicas e explorar as principais técnicas de sutura e materiais atualmente utilizados. Segue-se a introdução do processo de desenvolvimento do produto, bem como a descrição das patentes atualmente existentes que podem competir com o nosso produto. Finalmente, são descritas as técnicas de fabrico aditivo que estão disponíveis para a criação do protótipo.

O tema desta dissertação de mestrado é o desenvolvimento preliminar de um dispositivo com um sistema alternativo de apoio à sutura da pele e da fáscia, que esteja em conformidade com os regulamentos europeus para dispositivos médicos. Este trabalho começou pela definição do conceito de acordo com as necessidades do cliente e, por conseguinte, a sua validação pelo Dr. Pedro Lobo. De seguida, idealizou-se o projeto mecânico dos vários sub-sistemas que constituem o equipamento e desenhou-se os esboços em 2D. Para finalizar, recorreu-se a modelação 3D para obter os sistemas individuais conseguidos na etapa anterior.

Em conclusão, o objetivo rege-se pela necessidade de obtenção de um sistema mecânico funcional cujo desenvolvimento satisfaça, da melhor forma possível, as necessidades e requisitos identificados e que promova efetivamente o fecho do elemento suturante previamente desenvolvido.

Palavras-chave: Pele, suturas, dispositivo de apoio a sutura, desenvolvimento de produtos médicos.

Abstract

Nine distinct layers are recognized in the abdominal wall, namely, from outermost to innermost layer skin, subcutaneous tissue, superficial fascia, external oblique muscles, internal oblique muscle, transversus abdominis muscle, transversal fascia, pre-peritoneal adipose tissue, and peritoneum. The skin is part of the integumentary system and is considered the largest organ of the human body. It is composed of three layers, from surface to depth: epidermis, dermis, and hypodermis. For any surgeon, closing the abdominal wall is a basic but time-consuming practice. However, an inadequate technique leads to a poorly performed suture, causing the patient serious postoperative complications, such as infections and incisional hernias, which in turn can give rise to antibiotic regimens, hospital readmission, or even a second surgery. While the choice of the most appropriate technique for abdominal closure proves to be essential, the materials chosen to perform the suture are equally essential, and yet are often neglected. The aim of this review is, therefore, to investigate both the anatomical and physiological characteristics of the skin, describe its mechanical properties, and explore the main suturing techniques and materials currently in use. We introduce the product development process, as well as the currently existing patents that may compete with our product. Finally, the additive manufacturing techniques that are available to create the prototype are described.

The subject of this master's dissertation is the preliminary development of a device with an alternative system to support suturing of the skin and fascia, which complies with European regulations for medical devices. This work began with the definition of the concept according to the surgeon's needs and its validation by Dr. Pedro Lobo. Then, the mechanical design of the various systems that make up the equipment was idealized and the 2D sketches were drawn. Finally, 3D modeling was used to obtain the individual systems sketched in the previous step.

In conclusion, our goal is to obtain a functional mechanical system so that it is possible to develop a prototype of the product that satisfies, in the best possible way, the surgeon's needs and that promotes the closure of the previously developed suturing element.

Keywords: Skin, sutures, suture support device, medical device development.

Acknowledgement

With the conclusion of this project, I would like to express my sincere gratitude to all those who contributed not only to the achievement of this work but also helped to shape this academic journey, and make it memorable.

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To all my friends who accompanied me during this journey and who directly or indirectly gave their contribution for me to reach this goal. For all the moments of study, affliction, companionship and conquest shared since the beginning of this journey, as well as many other stories and such adventures that I will carry with me for life.

Finally, to my mother and father, for being my pillars, for all the values transmitted and for all the support in everything they have provided me throughout all these years, for encouraging me to always follow my dreams with all their unconditional love.

Marta Pinto Torres

"Success is not final; failure is not fatal: It is the courage to continue that counts."

Winston S. Churchill

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Abbreviations and Symbols

List of Abbreviations

PLA	Polylactic Acid
PGA	Polyglycolic Acid
PLGA	Copolymer PGA and PLA
FDA	Food and Drug Administration
TLmax	maximum stress
MD	Medical Device
EU	Europion Union
US	United States
CDRH	Center for Devices and Radiological Health
PMA	Pre-market approval
ISO	International Organization for Standardization
AM	Additive Manufacturing
SLA	Stereolithography
DLP	Digital Light Processing
FDM	Fused Deposition Modeling
SLS	Selective Laser Sintering
SLM	Selective Laser Melting
CT	Computed Tomography
MRI	Magnetic Resonance Imaging

List of Symbols

σ	Stress
ε	Strain
E	Young's modulus
v	Poisson's ratio

Chapter 1

Introduction

1.1 Motivation

According to the World Health Organization (WHO), there were an estimated 266.2 to 359.5 million surgical procedures in 2012 and the volume of surgeries will continue to grow [1]. Surgical procedures are defined, according to the Organization for Economic Cooperation and Development (OECD), as medical interventions involving an instrument incision performed in an operating room and generally involving anesthesia and/or respiratory assistance [2].

Closing the abdominal wall is a basic practice for the resident physician. However, an inadequate or poorly performed technique leads to an imperfectly done suture that can bring the patient postoperative complications such as infections and incisional hernias, which can lead to antibiotic regimens, hospital readmission, or even a second surgery. Despite the importance of proper abdominal closure, the materials chosen are equally essential but are often neglected [3].

The skin is considered the largest organ of the human body, occupying on average some $1.8m^2$, represents 16% of the total body mass and providing a barrier between the body and the external environment. It protects against mechanical, chemical, osmotic, thermal, UV, and microbial invasion [4].

The skin is part of the integumentary system and is formed of three layers, from the innermost to the surface, the epidermis, dermis, and hypodermis [4].

The motivation for the development of this device to support the suturing of the fascia and skin arose from the need highlighted by the experience of Dr. Pedro Lobo, a general surgeon. The innermost layers, such as the fascia, are sutured manually due to the difficulty in finding a device capable of holding the edges of the tissue while suturing the soft tissue structures. There is the need to develop a suturing device that, when allied with the suturing element, and with a new design, can suture both the skin and the innermost layers, more efficiently and practically.

1.2 Objectives

The main objective of this dissertation is to develop the mechanical system for the suture support device for skin and fascial tissue. With this in mind, the first goal is to study and understand the anatomy, physiology, and histology of the skin, as well as its mechanical properties, in order to define the requirements that must be met in the development of the device.

Following this, it is important to analyze the current suturing techniques, equipment, and different materials, as well as to review the materials used in recent years and those that are promising, so that the decision on the composition of the skin suture support device can be conducted more assertively.

To obtain a device capable of entering the market, it is necessary to design the medical product development process, become familiar with the standards, the class of the device, and the certifications according to the regulations of the European Parliament and the Food and Drug Administration (FDA). In addition, it is important to be aware of established patents in the market to analyze potential competitors.

Then, the production processes by additive manufacturing must be studied to choose the most adequate production process for the prototype device under construction.

Finally, following this theoretical study, the main purpose is the generation, analysis, and selection of style concepts best suited to the identified requirements; the definition of the product, based on the style concept (design) and development of the mechanical solution for the skin and fascia suturing system with the closure of the suturing element, elucidating all the polyglycolic acid (PGA) components to be sketched in Illustrator and Sketchbook software and then applying 3D modeling in SolidWorks software to obtain the individually created systems.

1.3 Dissertation structure

Structured coherently, this dissertation contains, asides from this initial chapter entitled Introduction, four additional chapters.

In Chapter 2, the reader will find a review of the fundamental topics to obtain the knowledge necessary to understand this dissertation. Firstly, the anatomy and physiology of the skin are described. Next, theoretical concepts in the area of biomechanics, such as Young's modulus, Poisson's ratio, and viscoelasticity, are presented to make more understandable the mechanical properties of the tissue under study. Also in this chapter, knowledge about the suturing techniques practiced in a hospital environment is introduced. Different suturing techniques are described, as well as the characterization and classification of the materials. A review of materials for both stapled and surgical suturing is given, analyzing those currently in use and those under development. Also in this chapter, the overall product development process and the development of a medical device are presented. The standards and certifications imposed by the FDA and the European

Parliament regulation are described. Finally, various prototype production processes through additive manufacturing are described, as well as the materials that are used and their applications in biomedical engineering.

In Chapter 3, the preliminary study of the market is presented, identifying existing suture equipment and patents in the market. The study of how much the provisional patent application would cost is laid out as well. Afterward, the concept development is presented, with the initial identification of the requirements requested by the surgeon, Dr. Pedro Lobo. The design concepts were explained, detailing how each one of the systems would potentially work. This is followed by the identification of the concept that best met the needs of the doctor. The entire mechanical conception is presented, as well as the different solutions considered for each system designed to reach the final construction of the suture support device. For each solution, there is an explanation of the necessary components, the mode of operation, and the 2D drawing. Finally, the design of the system was built in 3D.

In Chapter 4, all of the considered systems were discussed and compared to obtain the best solutions.

In Chapter 5 concludes this dissertation, presenting the main conclusions to be retained from this project and perspectives for future work to be developed.

In Annex A shows the transcription of the interview with Dr. Pedro Lobo, which supported the choice of the final concept.

Chapter 2

State of Art

This chapter provides a review of the fundamental topics to obtain the necessary knowledge for the development of this dissertation.

Firstly, the anatomy, histology, and mechanical properties of the skin are discussed in detail, as well as the suturing equipment, techniques, and materials that are currently in use, to contextualize the reader on the requirements to be taken into account when developing this skin suturing support device.

Secondly, this chapter provides an overview of the general cycle of a product, from design to production, and describes the process of developing a medical device (MD). European and American regulations for the classification of MDs and their costs are presented.

Finally, several additive manufacturing processes are described for prototyping, in order to test and improve the product.

2.1 Anatomy and histology of human skin

In the abdominal wall, eight distinct layers can be recognized. These are, from the most external to the most internal: skin, subcutaneous tissue, superficial fascia, external oblique muscles, transversus abdominis muscle, transversal fascia, pre-peritoneal and peritoneal fat tissue [5]. The skin is part of the integumentary system and is considered as the largest organ of the human body, constituting about 8% to 20% of its mass, and extending from 1.6 to 1.8 m^2, in adults [6, 7, 4].

The skin plays a fundamental role in the normal functioning of the human body, as its main functions are protection, metabolism, thermoregulation, and sensation [6, 7].

Protection - the skin serves as the first barrier between the interior and the environment against pathogens, chemical stress, heat stress, and UV light [6, 7].

Metabolism - adipose tissue in the hypodermis is vital in the production of vitamin D and lipid storage [6, 7].

Thermoregulation - the hair and sweat glands allow temperature regulation to maintain homeostasis [6, 7].

Sensation - the skin contains many types of pain, temperature, pressure, and touch receptors [6, 7].

The skin is composed of three general layers, from most superficial to deepest: epidermis, dermis, and hypodermis, represented in figure 2.1. Each layer can be subdivided into its constituent regions [6, 7].

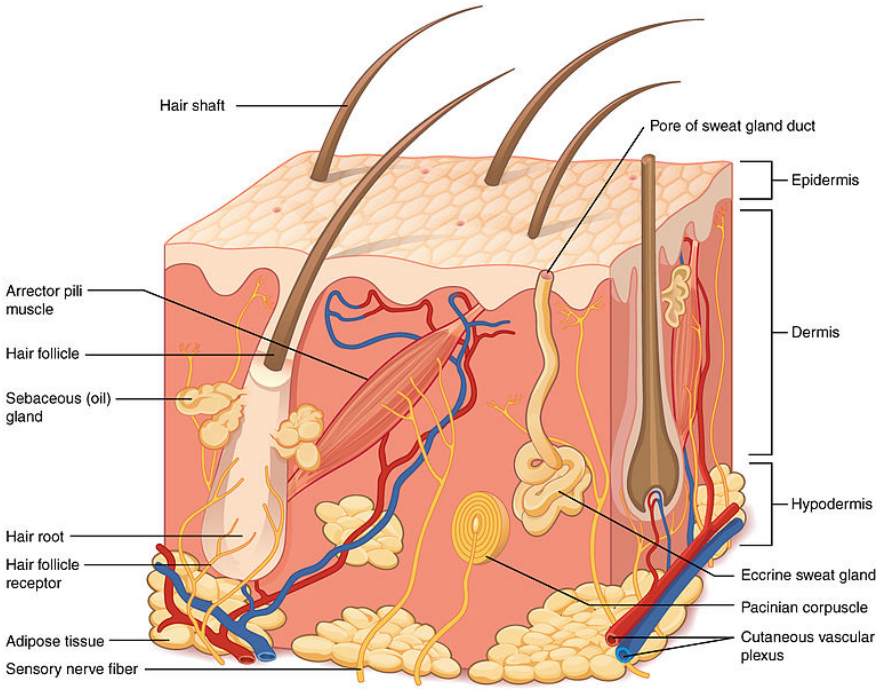

Figure 2.1: Layers of the skin. Image taken from Teach me anatomy. [4].

The epidermis is a stratified squamous epithelium, approximately 75-150 mm thick. It contains four to five layers, depending on its location, as shown in figure 2.2:

The *Stratum Basalis* (basal cell layer) layer is the deepest and closest to the dermis, rich in stem cells. It is mitotically active and contains melanocytes, a single row of keratinocytes, and stem cells. Melanocytes are the cell type responsible for producing melanin, the substance that gives our skin its color. The keratinocytes in this layer evolve and mature as they travel outwards and upwards to create the remaining layers [6, 7].

The *Stratum Spinosum* (spinosum layer) layer compromises most of the epidermis and contains several layers of cells connected by desmosomes, which allow the cells to remain firmly connected to each other and visually resemble "spines" [6, 7].

The *Stratum Granulosum* (granular cell layer) layer contains several layers of cells that contain lipid-rich granules. In this layer, cells begin to immortalize and lose their nuclei as they move away from the nutrients located in the deeper tissue [6, 7].

The *Stratum Lucidum* layer exists only in the thick skin of the sole of the foot and palms and consists mostly of immortalized cells [6, 7].

The *Stratum Corneum* (keratin layer) keratinized layer serves as a protective layer and is the outermost layer of the epidermis. Due to the keratinization and lipid content, this layer allows for the regulation of water loss by preventing the evaporation of internal fluid [6, 7].

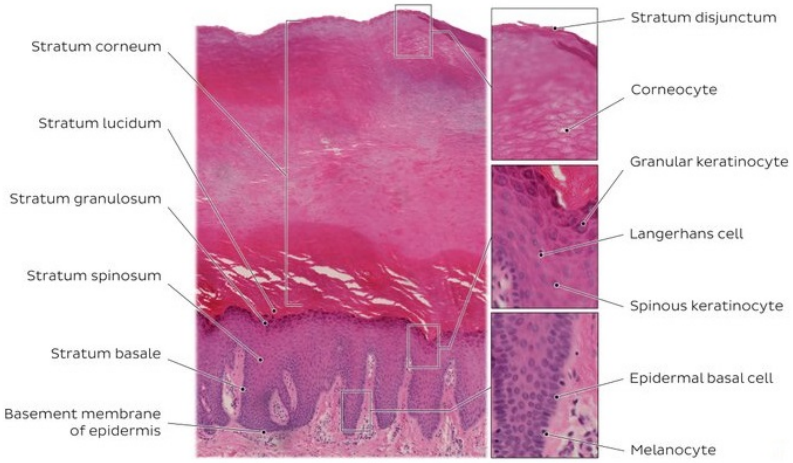

Figure 2.2: Layers of the epidermis. Stain: H&E. Image taken from kenhub [8].

The dermis, represented in figure 2.3, is a connective tissue layer that consists of an interwoven network of collagen and elastin fibers. It generally comprises most of the total thickness of the skin and consists of two layers [6, 7]:

Papillary layer - outer, thinner layer composed of loose connective tissue and contact epidermis [6, 7].

Reticular layer - deeper, thicker, less cellular layer, which consists of dense connective tissue/compact bundles of collagen fibers. The dermis houses the skin appendages (sweat glands and hairs), many sensory neurons, and blood vessels [6, 7].

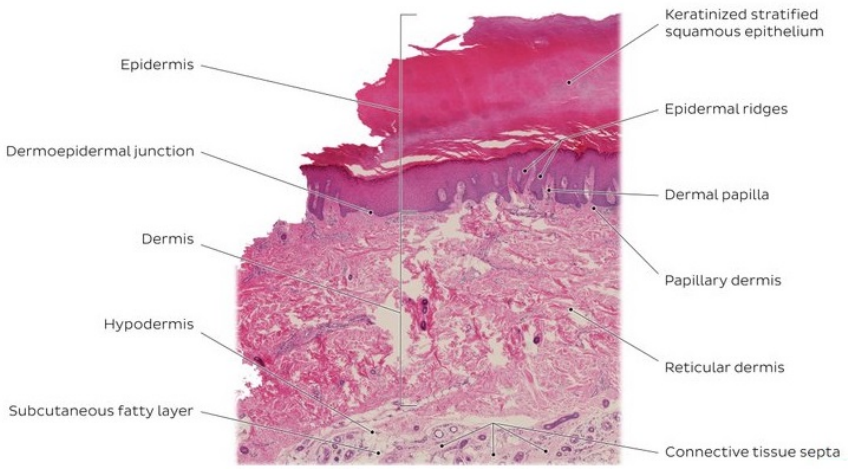

Figure 2.3: Layers of the dermis. Stain: H&E. Image taken from kenhub [8].

The hypodermis consists of a layer of loosely organized connective tissue, the main functions of which are to support, connect or separate different types of tissue and organs in the body. It contains fat and some collagen and elastin fibers. This layer contains blood and lymphatic vessels, roots of hair follicles, secretory portions of the sebaceous glands, skin nerves, and sensory endings. The amount of subcutaneous fat varies throughout the body and according to gender. The hypodermis main functions are to provide energy storage and insulation [9].

2.2 Mechanical properties

Studying mechanical properties is essential for exploring the material components that will best satisfy physiological conditions so that no intolerable levels of deformation and/or failure occur. The relationship between the force applied to a material and its response, or deformation to it, dictates the mechanical behavior of a material.

Throughout this chapter, concepts will be introduced which allow for the characterization of the mechanical properties of the skin.

Taking into account the previous histological description of the skin, it is possible to note that the mechanical properties of this tissue are essentially elasticity, plasticity, strength, and viscosity [10].

Loads tend to alter the shape of the material in several ways, namely by compression, where an external force tends to compact the molecules of the material; tension, when the load acts in such a way as to distend the material; and finally shear, where a right angle load acts in opposite directions. When various forces are applied to one body, they tend to form combined torsional and bending loads. In the specific case of muscles, their momentary response will depend on several factors, including the shape and strength of the tissue, the size, and direction of the forces [11].

According to equation (2.1), mechanical stress, σ ($[N/m^2]$), consists of the division of the force (F) applied to a material by its cross-sectional area (A_0) [11].

$$\sigma = \frac{F}{A_0} \tag{2.1}$$

Mechanical stress results in a displacement or deformation (ε), which is calculated according to equation (2.2), where L_0 (mm) corresponds to the length of the fabric at rest and L (mm) to the length of the fabric when a force is applied on it [11]:

$$\varepsilon = \frac{L - L_0}{L_0} \tag{2.2}$$

Both stress and strain have mechanical properties which are closely related to the calculation of the elastic force of the skin. This relationship is called Hooke's Law, a law which validates small strains in high elasticity materials, such as springs, and expresses the relationship between

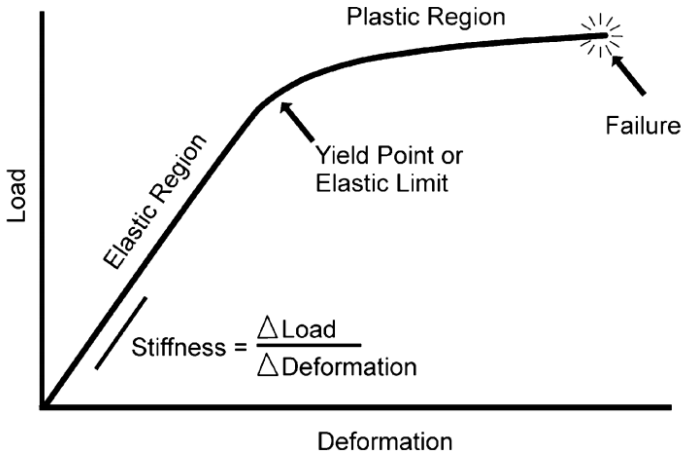

Figure 2.4: Load- Deformation graph of an elastic material. Image taken from Knudson (2007) [11].

Young's modulus (E), or commonly called modulus of elasticity, stress (σ) and strain (ε) of the material. Mathematically, Hooke's law is represented by equation (2.3) [11].

$$\sigma = E \cdot \varepsilon \tag{2.3}$$

In other words, Hooke's law presents the relationship of proportionality between stress and strain, up to a certain limit. Visually, this relation is represented, in figure 2.4, by the elastic region. Young's modulus consists of the measure of the rigidity of the material and is used to calculate the deflection of the material under force [11].

The stress-strain diagram provides valuable information on the amount of force a material can withstand before permanent deformation or failure occurs [11].

According to figure 2.4, the elastic limit point comprises the point from which the material, when subjected to a force causing deformation, is unable to return to its original position. A material that maintains the permanent deformation, even after the removal of the stress that it has been subjected to, acquires a plastic behavior. However, when the fabric cannot absorb more load, it reaches its breaking point [11].

Although longitudinal deformation is only considered when defining Young's modulus, any elastic material that is subject to strain also tends to suffer transverse deformation, the latter being proportional to the longitudinal deformation applied. Poisson's ratio (v) calculates the ratio of transverse strain (ε_x) associated with longitudinal strain (ε_z) in the direction of tensile stress (equation (2.4)) [12].

$$v = -\frac{\varepsilon_x}{\varepsilon_z} \tag{2.4}$$

With values between 0 and 0.5, where 0.5 corresponds to an incompressible material, the Poisson ratio is an adimensional measure. The negative sign is present in equation (2.4) since

the transverse and longitudinal extensions have opposite signs. Structurally, biological tissues are complex and have an equally complex mechanical behavior in response to the applied load. First of all, biological tissues are anisotropic, which means that their strength properties are different in each direction. Secondly, the nature of the protein fibers and the amount of calcification contribute to determining the mechanical response [12].

The viscoelastic property of the material indicates that stress and tension are dependent on the rate of loading, so the moment of force applied affects the stress response of the material. That is, the viscoelastic property consists of the ability of a fabric to resist deformation. The mathematical relationship that defines the viscosity of a material (equation (2.5)) states that stress is not only dependent on stress (σ), but also on the stress rate ($\frac{d\varepsilon}{dt}$), where t corresponds to time [12].

$$\sigma = \sigma(\varepsilon, \frac{d\varepsilon}{dt}) \tag{2.5}$$

Skin is a tensegrity tissue, and it is in passive tension at homeostasis. Once the mechanical properties of the skin are unable to support the external conditions or tissue is removed, the skin tensegrity is compromised. The wound healing process encompasses four interconnected and consecutive phases, namely, hemostasis, inflammation, proliferation, and remodeling. All of these phases are influenced by mechanical forces, and there is increasing evidence that mechanical influences regulate postinjury inflammation contributing to the closure of the wound and the formation of fibrotic tissue [10, 13].

The skin possesses properties of strength and flexibility due to the structural organization of the dermis and epidermis. The properties of elasticity and plasticity are thus a result of the existence of keratinocytes in the epidermis and elastic fibers and collagen fibers in the dermis, as mentioned in the previous section 2.1. The dermis has two proteins that are essential to the mechanics of the skin - collagen, and elastin [13].

Collagen is a set of glycoproteins produced through fibroblasts, which by the action of a peptidase originate fibrils that aggregate in the extracellular medium in parallel and compact sets, creating the collagen fibers which in turn aggregate in bundles. There are four types of collagen, classified according to the way the fibrils aggregate - type I collagen corresponding to 70% of total collagen; type II and type III collagen present in the papillary dermis and corresponding to a total of 15%; and type IV collagen which is mainly present in the basal laminae and nerves, in the vessels and epidermal annexes [14].

The reticular dermis is mainly made up of collagen fibers, and the papillary dermis has very fine collagen fibers, the reticulin fibers. While collagen is responsible for the skin's resilience properties, elastin in turn is responsible for its elasticity. Elastin is a macromolecule also synthesized by fibroblasts, which is mostly located in the papillary dermis. It is organized into fibers, the elastic fibers, which form a network around the collagen fibers, allowing them to reposition themselves after a tensile force. The elastic fibers are composed of elastin - an amorphous and irregular mass. There are also pre-elastic fibers which, in addition to elastin, have a fibrillar component - the oxyalan fibers. These oxytalan fibers are located in the papillary dermis and are transversal to the

elastic fibers themselves. They are the first to disappear during the natural skin aging process [15].

Thus, of the numerous functions attributed to the skin, described section 2.1, its plasticity property stands out, giving the skin the capacity to withstand the pressure of the tissues and liquids of the organism. It has an elastic character attributed to the arrangement of the elastin fibers and the collagen fibers, which when under tension, orient themselves parallel to the axis of the force applied. When talking about skin elasticity, it is necessary to consider the corneal layer of the skin, whose flexibility is very variable and depends on genetic factors, the environment, the use of detergents, among others. The skin's elasticity is therefore dependent on a correct balance between surface lipids, the quantity of water-soluble compounds, water and fibrous proteins made up of polypeptide chains, namely keratins. It is nowadays considered that water is an essential factor for appropriate skin elasticity, and that water content should remain between 10% and 20%, since for values below 10% the skin appears dry and rough [14, 15].

In figure 2.5 the overview of the mechanical properties of the skin is represented. Indentation tests using atomic force microscopy (AFM) have proved useful to examine the skin's mechanical properties at small length scales. Tensile testing is performed by elongating a skin specimen under uniaxial or biaxial loading until failure [10].

Table 2.1 shows the values of the mechanical properties extracted from [16].

Table 2.1: Mechanical properties of the skin. Taken from Sathis. K, *et al* [16]

Property	Average	Standard deviation
Tensile Modulus, E (GPa)	51.4	0.15
Peak stress, σ (MPa)	597	56.1
Peak strain, %	2.0	0.42
Shear Modulus, G (GPa)	8.7	0.48
Peak stress, τ (MPa)	184	28.0
Peak strain, %	8.2	0.36

2.3 Sutures

After surgical procedures, the closure of sutured skin cannot be underestimated, as skin dehiscence can lead to postoperative complications such as infection, which can lead to being left with a permanent scar; the sutured area of skin is not able to move as easily as the surrounding skin, creating a pulling sensation; a protruding scar called a keloid can form, causing itching or discomfort and occasionally causing aesthetic problems; internal tissues usually separate without proper healing, promoting hernia formation [17].

The best method for skin tissue closure remains undefined, however, each surgeon adapts their "suture routine" according to the technique and materials of their preference. The choice of suturing technique depends on the type and anatomical location of the wound, the thickness of the skin, the degree of tension, and the desired aesthetic results [18].

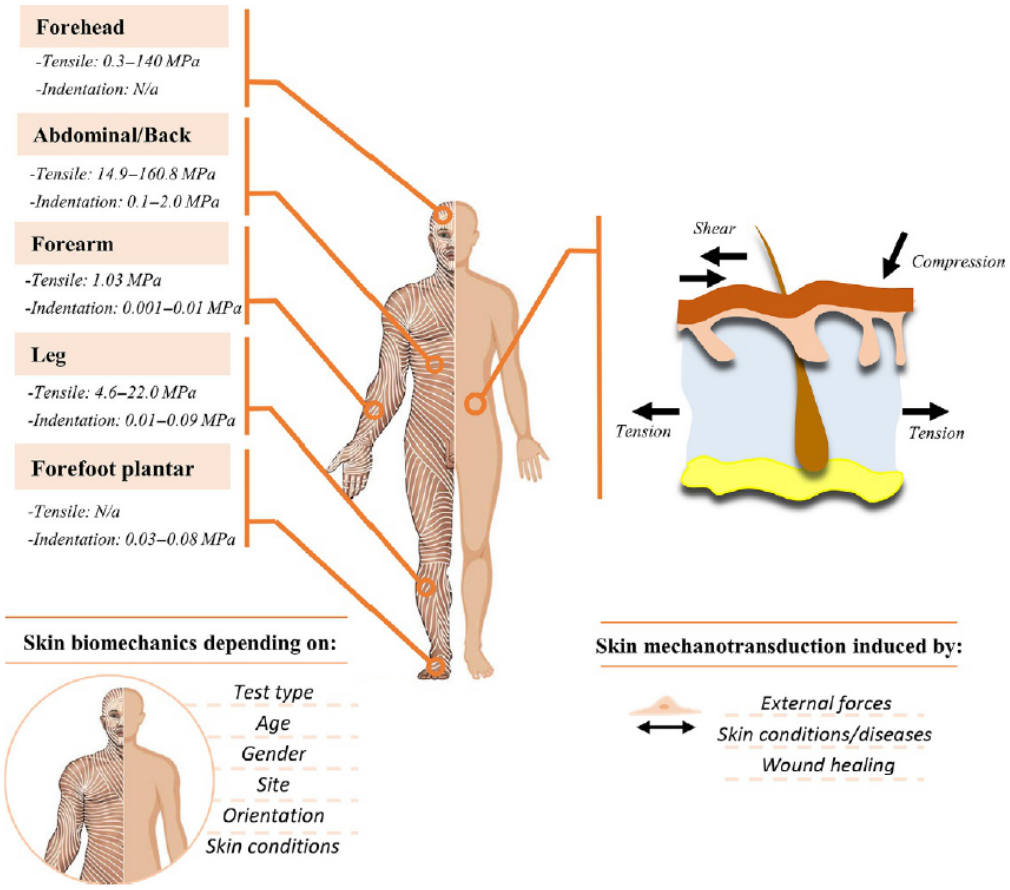

Figure 2.5: Overview of human skin mechanical properties and schema of external mechanical forces that are transmitted across the skin tissue. Image taken from Fernandes. M, *et al.* (2019) [10]

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In an ideal situation, the suture closure procedure should fulfill the following requirements: providing appropriate tensile strength for the incision until the wound heals, bringing the tissue closer in such a way that the normal healing mechanism can occur under ideal circumstances and remain safe, even in the presence of local or systemic infection, acceptance of the suture material in the short and long term; and finally, speed in performing the suture closure [19].

2.3.1 Equipment

The equipment needed to close a wound includes suture material (staples, thread or tissue adhesive), needle and needle holder [20].

It is essential to keep in mind that the suture material is a foreign body implanted in human tissues. Due to this, the material will naturally cause an immunological reaction in the tissue around it. Therefore, during the closure of the skin, it is important to obey certain norms to minimize the risk of infection and complications of healing [20, 21].

Staples are medical devices that can be used to close wounds, both internally and externally. These devices are used externally to close skin under high tension, such as the skull or torso, or internally to seal tissue or vessels [20].

Staples have the advantages of fast placement, minimal tissue reaction, low risk of infection, and strong wound closure. However, inherent to the advantages are the disadvantages of surgical staples, such as poor placement and the possibility of displacement, as well as the high cost and size of the equipment itself [22].

Suture threads are materials used to join the skin, close the muscles and seal blood vessels. They were the first material to be developed and improved over the centuries, as the man felt the need to somehow close people's wounds due to the growing need to control bleeding, help in the healing process of lesions and surgical incisions [21].

Tissue adhesives have entered clinical practice more recently. they are usually used to join the ends of small skin wounds or low tension incisions. They can also be used on the patient's buried or absorbable skin sutures (stitches). These sutures last approximately 10 days and are less expensive, however, the tape can lose its glue, especially when wet, and in this way it loosens and can lead to the wound reopening [20].

2.3.2 Suture Techniques

There are two forms of skin suturing: continuous suturing and interrupted suturing.

Continuous suturing, a useful method for long wounds, is a faster method in which the tension is evenly distributed across the suture line. Aesthetically, when submitted to a surgical procedure with this method of closure, the individual is subject to fewer scars. Although the number of times needle insertion occurs remains the same, fewer knots are made in the continuous suturing method than in the interrupted suturing method. This type of closure has the advantage of faster placement and reapproximation of the wound edges more quickly. Disadvantages include possible trauma, risk of dehiscence if the suture material breaks, difficulty in making fine adjustments along the suture line, and wrinkling of the suture line when the stitches are placed on thin skin [23, 18].

Compared to continuous sutures, interrupted sutures are easier to place, have higher tensile strength, and are less likely to cause wound edema and consequently, affect circulation in skin. With this type of closure, it is easier for the surgeon to make individual suture adjustments for tension and reversal of the extremities needed to correctly align the wound edges as the wound is sutured. In contrast, the placement of this suture tends to take much longer and there is a greater risk of suture lines crossing. This problem can be minimized by early removal of the sutures [23, 18].

According to Adams. B, *et al.* [18], continuous sutures and interrupted sutures seem to be equivalent in both wound closure strength and the likelihood of dehiscence, a surgical complication where the edges of a wound no longer meet. However, in the case of continuous sutures, if any complications arise, these would have to be removed completely; on the other hand, interrupted sutures can be removed individually as required.

2.3.2.1 Interrupted sutures

The following are the discontinuous suturing techniques.

Simple interrupted sutures

Simple interrupted suture, shown in figure 2.6, is the technique most often used by healthcare professionals, in which the needle is inserted perpendicularly to the epidermis, crossing it completely as well as the dermis, and exiting perpendicularly to the epidermis on the opposite side. The two sides of the stitch should be placed symmetrically, in terms of depth and width. The simple interrupted suture provides the advantage of facilitating and adapting the closure of the wounds and of being able to remove sutures individually to control the level of healing. However, this technique also has the disadvantages of slow placement and slow removal, as well as the tendency to cause "railway or crosshatch scars" [18].

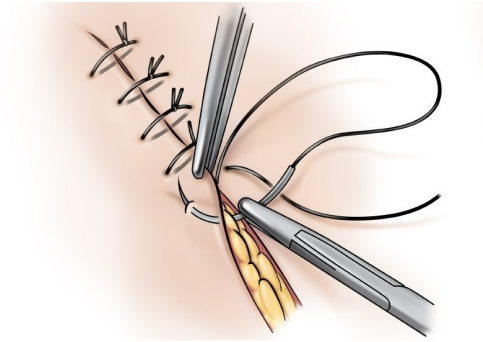


Figure 2.6: Simple interrupted sutures [24].

Interrupted vertical mattress suture

Modified from the simple interrupted suture, this technique present in figure 2.7 has deeper sutures and the stitch width is directly proportional to the amount of tension in the wound. That is, the greater the tension, the wider the stitch has to be. Therefore, in terms of advantages, it allows for more closeness and eversion, more contact between the edges, and is more effective. As a disadvantage, it takes longer to perform [17, 18].

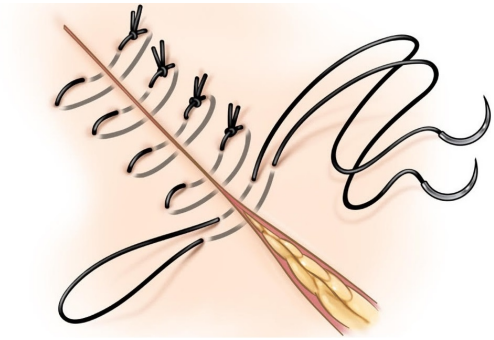


Figure 2.7: Interrupted vertical mattress suture [24].

Interrupted horizontal mattress suture

In this technique, depicted in image 2.8, wound tension is minimized by suturing. It is advised to close large wounds under significant or moderate tension, especially when faster closure is desired. The closure should be perpendicular to the wound, with the same depth and distance from the wound edge. Both the approach and the reversal with hemostasis are effective, however, it may cause tissue ischemia [18, 17].

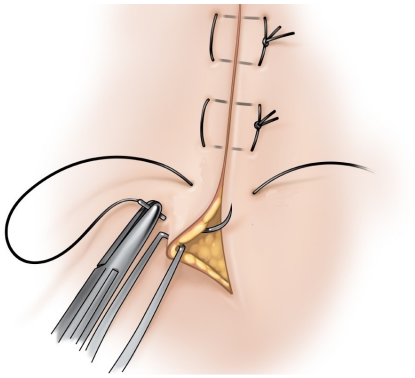


Figure 2.8: Interrupted horizontal mattress [25].

Subcuticular interrupted

The subcuticular suture technique, represented in figure 2.9, is the standard technique for cosmetic skin closure. Both the interrupted suture technique and the continuous technique involve the reapproximation of the dermis. The interrupted technique allows the inverted suture technique to ensure that the knot is buried. The needle should enter the subcutaneous tissue and then pass through the dermal layer before leaving the subcutaneous tissue again [25].

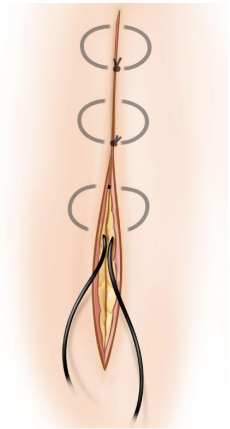


Figure 2.9: Subcuticular interrupted [25].

Staples

Most surgeons today prefer staple sutures, present in figure 2.10, a more economical option. They are rapidly placed, and less likely to cause infection than stitches, and can be removed individually for healing inspection. However, this method does not present the best cosmetic results, causing permanent scars. Furthermore, if the staples are not perfectly aligned and/or are placed improperly, this can lead to inadequate healing [18].

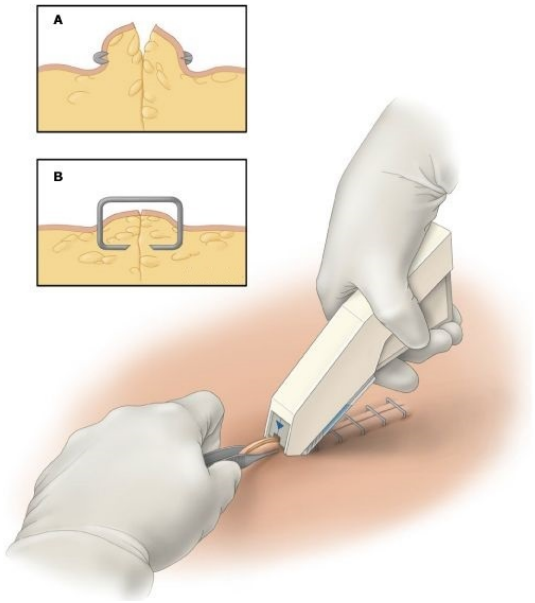


Figure 2.10: Staples [18].

Tissue adhesive

This method, present in figure 2.11, consists of applying adhesive glue to close wounds. Fabric adhesives offer the advantages of no risk of injury from needle prick or staples and no need to remove sutures afterward. In contrast, sutures may show reactivity of the tissue, requiring removal of the adhesive. Use of this method is not advised in mobile areas [26].

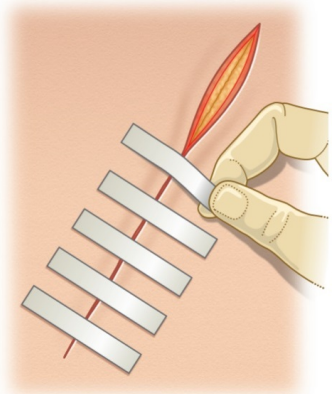


Figure 2.11: Tissue adhesive [26].

2.3.2.2 Continuous sutures

The following are the continuous suturing techniques.

Simple continuous suture

The technique shown in figure 2.12, is used to approximate tissues under low tension. The needle is inserted perpendicularly to the epidermis and through the thickness of the dermis. The suture must then run under the dermis to the opposite side of the wound, before leaving the epidermis perpendicularly [25].

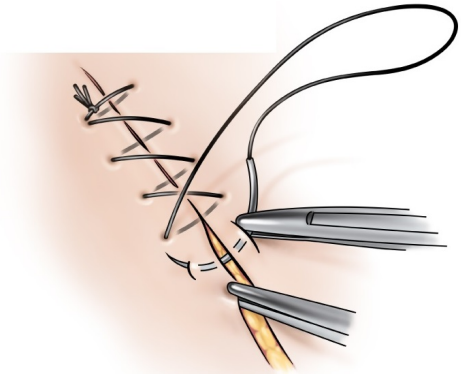


Figure 2.12: Simple continuous suture [25].

Continuous horizontal mattress

Figure 2.13 shows the suturing technique that allows the best approximation of the tissue under high tension, especially when the margins are fragile or after the operations. This type of suture can be combined with other techniques to obtain a better aesthetic result, such as simple interrupted suturing or vertical mattress suturing [25].

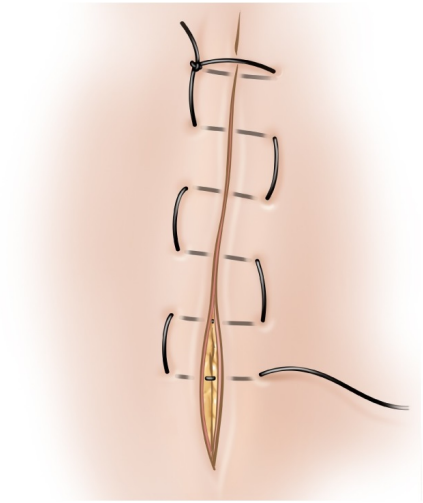


Figure 2.13: Continuous horizontal mattress [25].

Continuous vertical mattress

The vertical mattress suture, exposed in figure 2.14, results in better tissue evaporation and can thus be a good strategy to increase wound closure when the quality of the tissues involved is tenuous. This advantage is obtained by combining deep dermal and epidermal sutures [25].

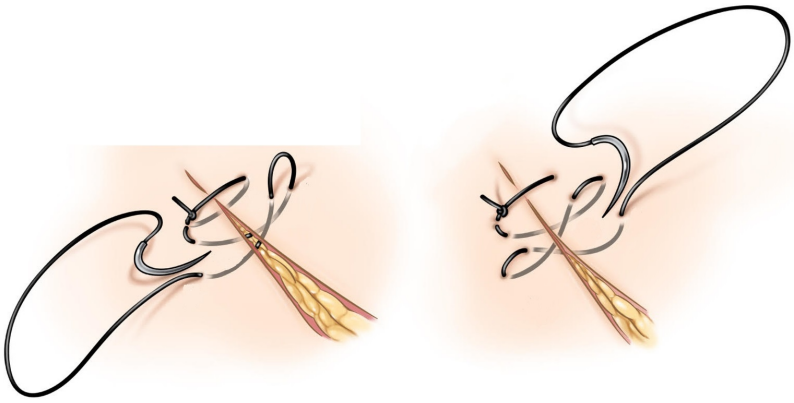


Figure 2.14: Continuous vertical mattress [25].

Subcuticular continuous

The subcuticular suture technique, presented in figure 2.15, is the standard technique for cosmetic skin closure. Both interrupted and continuous suturing techniques involve the reapproximation of the dermis. The continuous suturing technique requires an anchoring tie at 2-3 mm from the apex or if a knotless technique is being used, the needle can be passed through the dermis at the apex to initiate closure. The dermal approach should be performed using uniform depth bites parallel to the incision line [25].

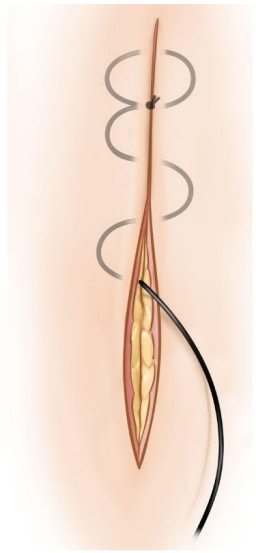


Figure 2.15: Subcuticular continuous [25].

2.3.3 Suture Material

The choice of the suture is a very complex task given the wide variety of materials available and the consequences that can arise from them. Depending on the suture chosen, the risk of complications and the delay in tissue healing may increase.

From a biological point of view, the ideal suture should be completely inert, biocompatible, and cause a minimal reaction in the tissues. In other words, the ideal suture should be anti-allergic, non-carcinogenic, non-capillary, non-electrolytic, and not promote bacterial growth. It should also have the following characteristics: easy to handle, easy to sterilize, uniform and predictable performance, low friction, high tensile strength, and resistance to infections [27, 28].

Currently, there is not a single material that meets all these requirements, so the choice of suture materials is based on physical and mechanical properties, handling characteristics, biological behavior and biodegradation, size and shape of the material. It should be noted that in the case of the use of yarn, the force exerted by it has to be adapted to the anatomical structure and the local force [29].

The mechanical properties to be taken into consideration are tensile strength, where there must be adequate parallelism between suture strength and fabric strength; percentage of elongation, modulus of elasticity, tension relaxation, creep, and coefficient of friction [29]. In addition to the previously mentioned properties, there are other characteristics of the suture material to be considered:

- Absorption - The suture material progressively loses mass and volume, but the absorption is not correlated with the initial tensile strength [29, 27];

- Suture strength - Limit of tensile strength in which the suture failure occurs [29, 27];

- Capillarity - Extension to which the absorbed fluid is transferred along the suture [29];

- Elasticity - Measure of the material's ability to recover its shape and original length after deformation [29, 27];

- Fluid absorption - Ability to absorb fluid after immersion [29, 27];

- Tensile knot strength - Tensile knot breaking strength of the suture material (10-40% weaker after knot deformation) [29, 27];

- Knot strength - Amount of force required to make a knot slip (this characteristic is related to the static coefficient of friction and plasticity of a given material) [29, 27];

- Memory - Inherent ability of the suture to return or maintain its original gross shape (this characteristic is related to elasticity, plasticity, and diameter) [29, 27];

- Unabsorbable - Surgical suture material that is relatively unaffected by biological activities of body tissues and is therefore permanent, except when removed [29, 27];

- Plasticity - A measure of the ability of a material to be malleable, this change is irreversible after relief of the deformation force [29, 27];

- Flexibility - Ease of handling of the suture material; ability to adjust the knot tension and hold them (this characteristic is related to the suture material, the type of filament and its diameter) [29, 27];

- Direct tensile strength - Linear breaking strength of the suture material [29, 27];

- Suture removal value - The application of suture removal force varies according to anatomical location and histological composition of the tissue [29, 27];

- Tensile Strength - A measure of a material's or tissue's ability to resist deformation and breakage [29, 27];

- Breakage resistance of the wound - Limit of the tensile strength of a wound is healing, in which separation of the wound edges occurs [29, 27].

2.3.3.1 Classification

Generally speaking, sutures are classified according to the origin of the material (natural or synthetic), the lifetime of the material in the body (absorbable or non-absorbable), and in the case of surgical threads, they can also be classified according to structure (monofilament or multifilament) [24, 27].

The materials of natural origin are made from natural fibers (silk), collagen from mammalian intestines, or synthetic collagen (polymers). These are less used than synthetic sutures, as the tissue tends to develop an antigenicity reaction of the suture, which triggers inflammatory reactions. Synthetic polymer-based materials tend to be more controllable than natural sutures in terms of loss of tensile strength and absorption [24].

Absorbable sutures retain their tensile strength throughout the recovery process. As the strength of the tissue increases, absorbable sutures are degraded by tissue metabolism until total dissolution, through enzymatic reactions if the material is of natural origin, or through hydrolysis if the material is of synthetic origin. The time between healing and absorption varies according to the material, the location of the suture, and the physiological conditions of the patient [24]. Non-absorbable sutures are used to provide long-term tissue support as they can stay in place forever unless they are removed in another surgery. The non-absorbable sutures generate a reaction of the tissue that results in the encapsulation of the suture material by fibroblasts.

Thus, to close fast-healing tissues (stomach, colon, and bladder) absorbable sutures are used, while to close slow-healing tissues (skin, fascia, and tendons) non-absorbable sutures or long lasting absorbable sutures are used [27].

Monofilament sutures are made of a single fiber and, although there is less risk of infection, they also have less knot security and less resistance to tissue passage. Unlike monofilament sutures, multi-filament sutures are composed of several twisted or braided threads together, and have higher tensile strength, better malleability, better flexibility, and are therefore safer. However, the materials used in these sutures present an increase in capillarity, which may promote increased fluid absorption and facilitate the penetration of pathogens, thus adding the risk of infection. The multi-filament suture material is less rigid than the monofilament suture, but it generates increased friction as it is braided. In this way, the multi-filament sutures are coated to facilitate the passage of the tissue and reduce damage to it [27].

Table 2.2 summarizes the materials that are available for surgical sutures and describes the companies that produce each type of material.

Table 2.2: Classification of suture materials [27].

Sutures			
Absorbable		**Non-absorbable**	
Natural	**Synthetic**	**Natural**	**Synthetic**
Collagen	Polyglycolic acid (Vicryl, Surgicryl, Polysorb, Dexon)	Surgical cotton	Nylon
Plain surgical gut	Polydioxane (PDS^{TM}II)	Surgical Silk	Polypropylene (Prolene,Surgilene)
Fast-absorbing surgical gut	Polytrimethylene carbonate (Maxon)		Polybutester (Novafil)
Chromic surgical gut			Braided poysters (Ethibond, Ethiflex, Mersiline, Dacron)
Fascia lata			

2.3.4 Staple Materials

Among the most commonly used materials for the production of staples are: stainless steel and titanium, both characterized as strong metals that cause few problems in patients during surgical procedures; polymers, used in patients who are allergic to metals; and polylactide-polyglycol copolymers [30].

Titanium and titanium alloy surgical staples are often used for the reconstruction of the intestinal tract and stomach. They are biocompatible, corrosion-resistant, non-absorbable, and non-biodegradable, so they cannot remain in the body indefinitely. In addition to the possible result of allergic reactions and the difficulty in adhering to tissues, these surgical staples can produce artifacts, which can be seen through the high X-ray absorption coefficient in computed tomography (CT) and other medical imaging examinations, thus increasing the risk of misdiagnosis in the area surrounding the staples [31].

On the other hand, surgical staples made of polymers of polylactic and polyglycolic acid are biodegradable and absorbable by the body. Polylactide-polyglycol copolymers are currently available on the market for skin closure, however, the mechanical properties of polymers restrict their applications when high closure strength is required [32].

Polylactic acid (PLA) is one of the most successful bioplastics due to its mechanical properties and good processability, a characteristic that allows a material to undergo a physical, chemical, or biological transformation process. It has better mechanical resistance, durability, and transparency compared to most biodegradable plastics. It can only be degraded at high temperatures (around 58°C), within months, and usually under industrial composting conditions. Furthermore, PLA has a low thermal distortion temperature and poor water barrier properties compared to conventional thermoplastics. Polyglycolic acid (PGA), like PLA, has a similar chemical structure, a high heat

distortion temperature, and good mechanical and gas barrier properties due to its high stereoregularity. PGA is a biodegradable polymer that degrades rapidly in a natural environment. PGA can be a beneficial supplement to PLA in certain single-use applications, or with relatively short lead times [32].

In table 2.3, the mechanical properties of PLA and PGA are described in more detail.

Table 2.3: Basic characteristics of PLA, PGA. Taken from [32].

	Tg (ºC)	Tm (ºC)	Tensil strength (MPa)	Young's modulus (GPa)	Elongation at break(%)	Flexural strength (MPa)	Flexural modulus (GPa)
PLA	57-58	140-180	53	2.4	5	92	3.4
PGA	35-40	220-230	115	7	16.4	222	7.8

Tg(ºC)-Glass transition temperature; Tm(ºC)-Crystalline melting temperature.

The co-polymerization of PLA and PGA has been studied over the years. PLGA is a linear copolymer of lactic acid (LA) and glycolic acid (GA) that can be prepared in different ratios, affecting the degradation rate as shown in table 2.4 [33].

The mechanical properties and degradation of PLA can be improved by blending PGA fibers into PLA through melt blending. In this way, PGA fibers act as reinforcement for PLA and increase the mechanical strength, flexural strength, biocompatibility, and modulus. The presence of PGA also increased the crystallinity and interfacial interaction of PLA, resulting in further modulus improvement [34, 32].

[32].

Table 2.4: Time of degradation of PLGA [32].

Ratio	Time of degradation (months)
PLGA(LA/GA=50/50)	1-2
PLGA(LA/GA)=75/25)	4-5
PLGA(LA/GA)=85/15)	5-6

Recently, both magnesium (Mg) and zinc (Zn), and zinc-derived alloys have been considered as potential materials for surgical staples as they have biodegradable, biocompatible, mechanical stability, and ductility properties superior to polymer properties. However, these materials carry the disadvantage of displaying low mechanical strength and, in the case of Mg, suffering corrosion, which can result in fractures triggered by the stress of tissue closure [30, 35].

2.4 General Cycle of Product Development

In the business environment, companies are obliged to develop new products and services efficiently and sustainably to ensure their long-term survival. This requires the adoption of a well-structured product development strategy that increases efficiency, productivity, and flexibility. The prior organization of information can facilitate future developments or even change the course of

the current project. This translates into both an increase in quality and a reduction in costs and development time [36].

Over time, several product development models were presented, for which the initial number of activities and actors was small. However, as this process has evolved, it has become increasingly complex. The number of actors involved in the product development process is tending to increase and so is the number of activities [36].

In 2008, Ulrich and Eppinger proposed an integrated set of methods and techniques to facilitate problem solving and decision making by the project team, through differentiated training [36].

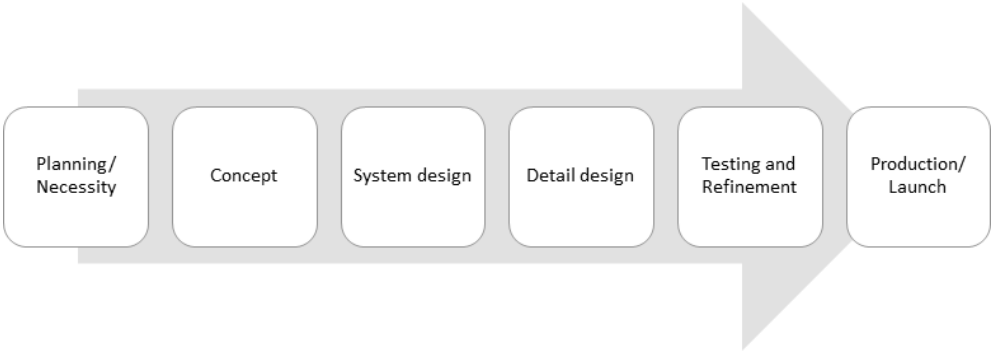


Figure 2.16: Model adapted from Ulrich and Eppinger (2008) [36].

According to figure 2.16, the generic product development process comprises 6 phases, from the presentation of the idea or need to the launch and mass production of the product [36].

The initial phases of the project are perhaps the most important, as they will define the direction the project will take. These are the phases as follows:

1. Presentation of the need and planning

   First, the idea, the needs, and the specific problems that potential customers want to be solved are identified [37].

2. Concept generation

   This phase involves the search for technical solutions that materialize the functions that the product must perform to satisfy the customer. Of the numerous concepts studied, only one is adopted, which is developed and optimized [37].

3. Concept development

   Represented in figure 2.17, as many alternatives as possible should be explored, gathering the contribution of as many sources as possible. The design team turns technical inputs into attributes that users understand, value, and satisfy their needs. Still in this period, it is important to have a multidisciplinary team with various skills, specifically in marketing, industrial, and production design. To implement the product, prototyping techniques are used to create prototypes with great proximity to the final product, already performing the functions of learning, communication, and integration in subsystems and/or components [37].

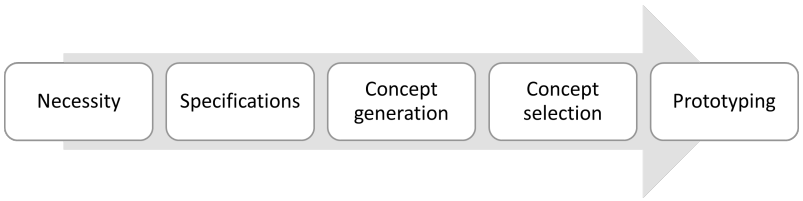


Figure 2.17: Concept development phase (adapted from Ulrich and Eppinger model) [36].

The process of generating concepts can be divided into 5 moments.

1st phase, Clarifying the Problem

It consists of conducting a careful analysis (causes and effects) and dividing the problem into sub-problems [37].

2nd phase, External Research

At this stage it is essential to find solutions to the problem and sub-problems identified above. This research is always beneficial, as using already designed solutions becomes much cheaper than creating a new solution. Thus, an outside study includes not only details of competing products, but also technologies used in products related to their subfunctions [37].

Outside research is an important method to ensure conceptual solutions. This capability can be developed through careful observation of what is happening in the world [37].

3rd Phase, Internal Research

Internal research is the procedure used individually or in groups, through knowledge and creativity to generate solutions. With the problem well defined, the process of designing the conceptual project begins. The biggest difficulty at this stage is to be creative to come up with original concepts [37].

4th phase, Systematic Analysis

As a result of external and internal research, numerous solutions to the sub-problems are obtained. The systematic analysis consists of going through the space of possibilities if an organization and systematization of the properly fragmented solutions. There are two tools to manage this complexity and organize the teams' thinking: the concept classification tree and the concept combination table. The classification tree helps the team to divide possible solutions into independent categories. The combination table guides the team in the selective consideration of fragment combinations.These tools are not the only management models of the process, however, they support organization and enable creative thinking [37].

5th Phase, Reflection on Processes and Solutions

At this stage the team is concerned with analyzing the whole process of generating concepts and the solutions created, i.e. it produces constructive feedback. Identifying opportunities, to develop in possible future interactions or projects [37].

Concept Selection

There are several possible methods of selecting concepts. This task is an evaluation process, with attention to the needs of consumers. The concepts generated are continuously reduced to a smaller set, but at the same time possible combinations, adjustments, and improvements between them emerge [37].

All the teams assigned to this selection function must choose the method they consider the most effective.

Implementation

For the implementation, it is first necessary to determine the final specifications of the product at the level of supports, fittings, components, dimensioning, etc. Next, it is essential to conduct performance simulations, using detailed 3D virtual modeling that allows an overall appreciation of the concept [37].

Finally, it is necessary to use the construction of prototypes, through additive manufacturing techniques that allow to foresee the product, identify possible errors, and make critical decisions to improve the characteristics of the final product [37].

Release into production

Launching into production requires rigorous preparation of documentation and certifications for production and product quality control. Still, at this stage, the production system is prepared, ensuring strict monitoring of the production start-up to introduce changes resulting from problems at this stage, although these must be anticipated in the previous stages of development.

The product development process is usually carried out sequentially and is controlled by interim assessments [37].

The risk in the development of the product is a function of the market uncertainty, which decreases over time, being maximum at the beginning of the project. This uncertainty results from the difficulty in predicting how the market will react to the product and how the competition will respond. Over time, knowledge of customers' expectations increases, contributing to the decrease of risk [38].

2.4.1 Medical Devices Development Cycle

Medical devices (MDs) have increasingly become an important brand in various areas of healthcare. They are important healthcare tools that encompass a range of products, from simple compresses to pacemakers and implants.

MDs can be used by health professionals and non-health professionals (consumers, patients, etc.), and are intended to prevent, diagnose, monitor, treat or mitigate pathologies, just like medicines.

According to Regulation (EU) 2017/745 the European Parliament and of the Council concerning medical devices, medical devices are defined as any instrument, apparatus, software, implant, reagent, material, or other article intended by the manufacturer to be used, either alone or in combination with humans, for one or more of the following specific medical purposes: diagnosis,

prevention, monitoring, prediction, prognosis, treatment or relief of disease; alleviation or compensation of an injury or disability, investigation, replacement or modification of the anatomy or a physiological or pathological process or state, providing information by *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations, and which do not achieve their principal intended action by pharmacological, immunological or metabolic means, on or in the human body, but which may be assisted in their function by such means. Also considered as medical devices are products to control or support the design, and products used for cleaning and disinfection or sterilization of MDs [39].

The development of a medical device, like in other products, begins with the emergence of an idea or need for improving an existing device or creating a new product or technology. After identifying the opportunity, one must study and understand the disease as well as the circumstances that gave rise to the need (causes, symptoms, diagnosis, and treatment) to develop something that is in line with what is intended [38].

Afterward, it is necessary to identify the customer and conciliate the limitations of the product with the wishes and needs of the customers. These can be distinguished into three different types of users, as shown in figure 2.18 [38].

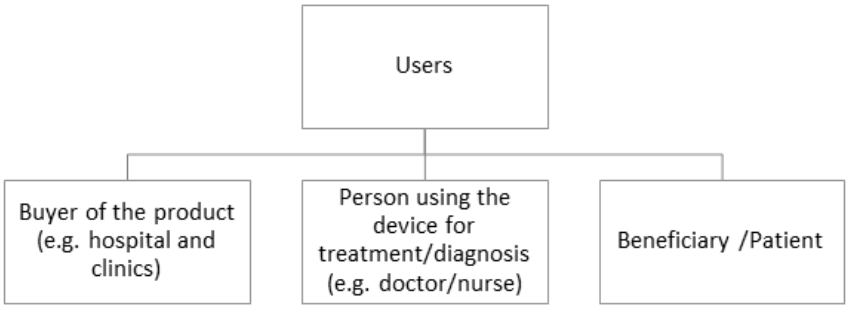


Figure 2.18: Scheme of MD users.

The next step, concept selection, is important since a concept and product development strategy is assumed, and its modification can lead to delays and additional costs. The decision taken at this point must consider that the introduction of sophisticated technology does not guarantee high quality patient care. It should also consider the incidence of the problem and the expected prescriptions [38].

Then, as shown in figure 2.19, in the life cycle of an MD it is important to qualify it, i.e. determine the type of product being built (for example a software, drug, or device) [38]. After all, this has been established, prototypes and optimizations are developed. Only then can the risk be assessed and classified, as described in the following section, for approval and certification both in the EU and US. When the approval is granted, the device is launched on the market. However, the manufacturer has to collect data to verify that the risk that was previously estimated is correct and they must perform a clinical evaluation of the device [38].

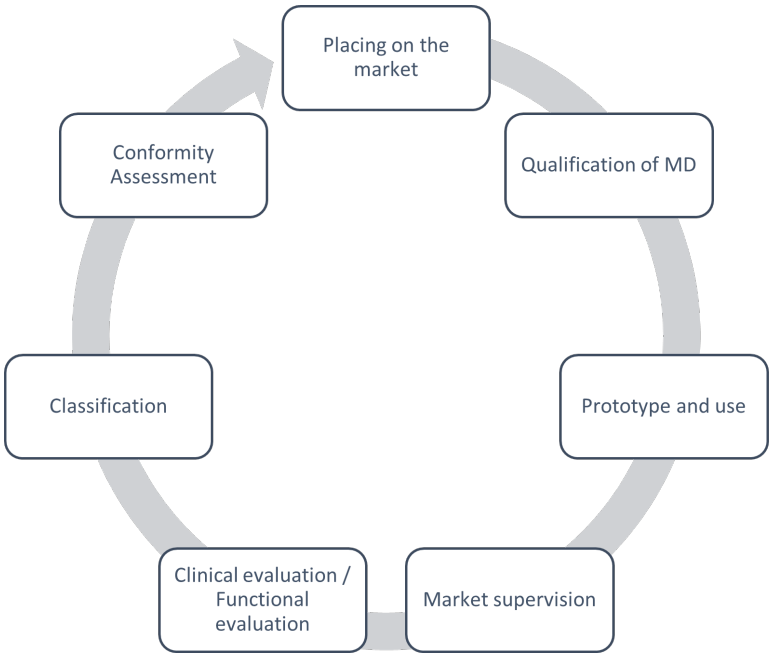


Figure 2.19: Life cycle of an MD.

2.4.2 Classification of Medical Devices

The classification defines the procedures that the device must follow until it is placed on the market, i.e. it indicates whether the product is self-certifiable (e.g. cotton wool used for wound cleaning) or whether it needs to be approved by a third party (e.g. endoscope) or undergoes clinical trials (e.g. stents or pacemakers) [39].

In both the EU and the US, the classification of medical devices depends on: the intended use and indications for use, which must be labeled on the device; the duration of contact with the human body; the invasiveness on the human body; the anatomy affected by use; and the potential risks arising from technical design and manufacture. Other factors to be considered are: whether it is an active implantable MD, which means that its functioning depends on one source of electrical or other energy, not directly generated by the human body or gravity and that it acts by converting that energy or not; *in vitro* diagnostic or MD [39].

The goal of these MD classification systems is to apply an adequate level of control to ensure their safety and efficacy, keeping the most demanding procedures for those which potentially manifest a greater risk to patients [39].

In short, as shown in the figure above, with the increase in class there is an increase in the regulations needed to make the device available on the market and, consequently, more time and money is required for its approval.

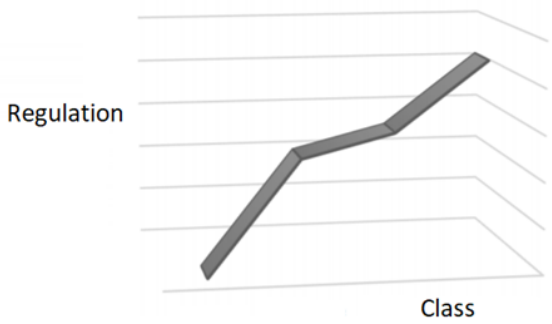


Figure 2.20: Relationship between necessary regulations and the MD class.Regulation accompanies the rise to higher risk classes. Image adapted from [40].

2.4.2.1 Classification of Medical Devices - United States (US)

In the US, the FDA's Center for Devices and Radiological Health (CDRH) is responsible for the protection and promotion of public health, i.e. they are responsible for regulating MD. Therefore, according to this identity, MD are classified into three classes, namely Class I, II, and III. Class I includes devices with lower risk and Class III includes those with higher risk. Both Class I and Class II can be subject to the 510(k) predicate and Class III devices require Pre-Market Approval [41].

Class I: Devices are subject to general controls which are applicable to all classes. With or without exemption from predicate 510 (K). It does not support or maintain human life and has a significant track record in terms of safety and effectiveness [41].

Class II: Devices for which general controls, by themselves, are insufficient to provide reasonable assurance of the safety and effectiveness of the device and for which there is sufficient information to establish special controls to provide such assurance. With or without exemption from predicate 510 (K). It has an intended use and a safety and effectiveness profile similar to other devices on the market but requires special controls [41].

Class III: Devices for which general controls, by themselves, are insufficient and for which there is insufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device. Class III devices typically require pre-market approval. It supports, maintains human life, or demonstrates the risk to the user, requiring clinical studies to demonstrate its safety and effectiveness [41].

A 510 (K) is a premarket presentation to the FDA to demonstrate that the device that a given identity wants to market is substantially equivalent to a legally marketed device and therefore the device seeking marketing approval is equally safe and effective [41].

Pre-market approval (PMA) is the FDA's most stringent scientific and regulatory review process for assessing the safety and efficacy of Class III medical devices [41].

2.4.2.2 Classification of Medical Devices - European Union (EU)

In the EU, MDs require both an assessment and approval by Notified Bodies (NBs), for example, independent laboratories where manufacturers are established on the territory of a member state, if the manufacturer does not have a registered office or place of business in the EU and has not yet appointed an authorized representative, the matter is referred to the competent authority of the member state. Where the notified body concerned is established in a member state other than that of the manufacturer, the competent authority shall take its decision after consulting the competent authority of the member state which designated the notified body [38].

The competent authority of the member state in which the manufacturer has the registered place of business or professional domicile shall notify the MDCG (medical device coordination group) and the Commission of its decision. The decision shall be made available on request [38].

In accordance with Regulation (EU) 2017/745 of the European Parliament and of the council of 5^{th} of April of 2017, the classification rules are set out in annex VIII. Classification is made not only based on the association of the level of risk associated with them and the evaluation of their safety and efficacy but also on the basis of the duration of use, invasive and active devices, and rules of application. MD are grouped in four classes known as I, IIa, IIb, and III, being class I the lowest risk and class III the highest risk, as shown in figure 2.21 [39].

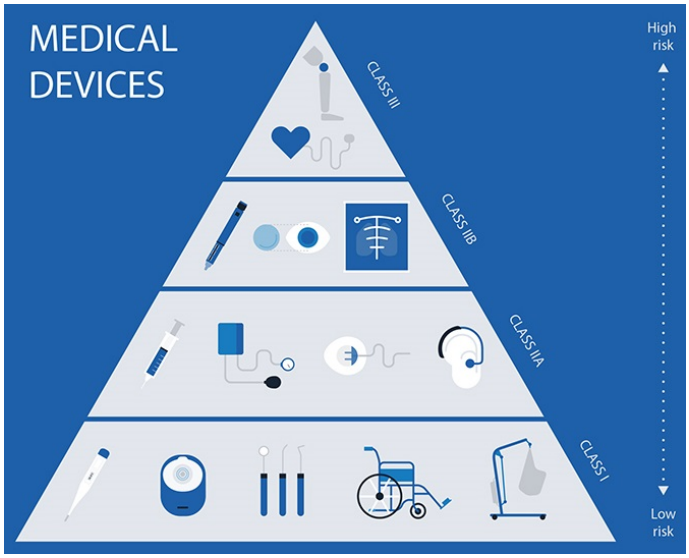


Figure 2.21: Relationship between class and risk level in the EU. Taken from [42].

Thus, the MDs that will be idealized in the dissertation will be the staples and the stapler. According to the regulation mentioned above, the staples will be considered an invasive, long-lasting, absorbable, class III device. The stapler, on the other hand, will be classified as class I, since it is a non-invasive, non-active, temporary use device and is a reusable surgical instrument.

2.4.3 Market

The development of MDs is both technologically and financially exhaustive. Before being established in the market, MDs have to be characterized by ISO (International Organization for Standardization) certification. This non-governmental organization certifies that a management system, manufacturing process, service, or documentation procedure is guaranteed to have all the requirements for standardization. For MDs, it is important ISO 13485: 2016 [43].

In addition to the clinical and non-clinical trials to which they are subject before entering the market to demonstrate quality, effectiveness, and efficiency, the cost-benefit study must also be submitted. This evaluation is important to create the relationship between quality and effectiveness of treatment. In addition, it is based on these results that national health systems and insurers decide which products/services they will co-finance [43].

2.5 Additive manufacturing

As mentioned earlier, before a product is implemented and launched on the market, it is essential to create prototypes, to test and refine the concept and characteristics of the product, assuring it performs its functions well, and that it meets the needs of its target users.

Additive manufacturing (AM), or 3D printing, one of the three main manufacturing techniques (fusion, subtractive and additive), is the most suitable for prototyping single units or small production series, which typically occurs in the concept development phase of the general cycle of product development. Also, it is more suitable for more complex models with more complex models which formative or subtractive methods are unable to produce, or when a single rapid prototype is needed [44].

Choosing the ideal AM process may be difficult. There is a wide range of methods and materials for 3D printing, which often means that several processes are suitable with each offering variating properties such as dimensional accuracy, surface finish, and post-processing requirements. This section introduces how 3D printing technologies and materials are categorized. In 2015, the ISO/ASTM 52900 standard was created to standardize all terminology, as well as to classify each of the different AM processes [45].

Table 2.5: Different categories of additive manufacturing according to ISO/ASTM 52900. Adapted from Gibson. I, *et al.* [46]

Category	Description
Material Extrusion	The material is extruded through a nozzle or hole and selectively deposited.
Material Jetting	The process of deposition of small building material particles together with supporting materials in specific areas of the building plate.
Binder Jetting	The process of selectively depositing a mixture of particles and bonding material to form a solid structure.
Sheet Lamination	The process of continuous deposition and gluing of sheets of material with a defined cross section.
VAT Photopolymerization	The process of curing (photopolymerization) of a photocuring resin by exposure to radiation of a fixed wavelength.
Powder Bed Fusion	Process with build surface filled with powdered material that is fused together by resorting to thermal energy.
Directed Energy Deposition	Process where materials are gradually deposited and then fused together by focused thermal energy.

2.5.1 Classification of AM technologies

AM technologies are classified as solid, liquid, or power-based, according to the initial shape of the material, as you can see in figure 2.22.

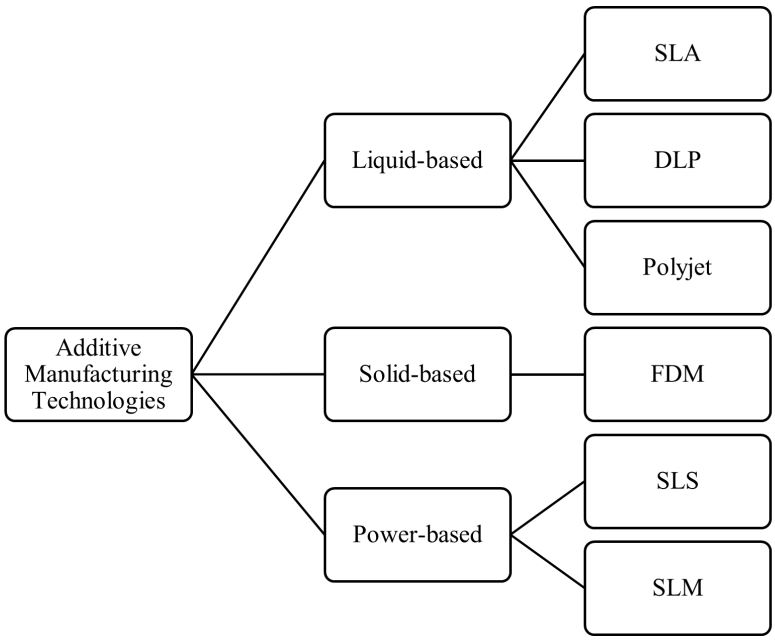


Figure 2.22: Classification of AM technologies based on the type of materials used.

In solid-based AM systems encompass all forms of solid-state materials. The solid form materials can be in the shape of the wire, laminate, pellets, or roll. These systems work on the following principles: cutting and bonding/joining method and melting and solidification/fusion method [45].

In liquid-based process of AM of the liquid base has the material in the initial form in the liquid state, resins, or a polymer. Liquid-based systems work on the principle of photocured, under which three methods are possible: single beam laser method, masked lamp method, and two-beam laser method [45].

In power-based processes, dust particles are largely considered solid-state particles. However, it is intentionally categorized in power-based AM systems to refer to powder in grain form. All powder-based AM systems work on the joining/bonding principle. The joining/bonding method differs for all systems, where some employ a laser while others use a binder/glue to obtain the bonding effect. The binder material is placed in designated regions of the dust particle layer to produce a layer of dust particles that are completely bonded in the selected regions. Post-processing is extremely important to remove the unbound dust particles [45].

2.6 3D part modeling in CAD system

Although there are different AM technologies, there are three main steps that are constant from conception to the final product, namely 3D modeling, printing, post-processing, visible in figure 2.23 [46, 44].

First of all, it starts with the production of a digital model using CAD. In reverse engineering, it can also be used to generate a digital model through 3D scanning [46, 44].

In order to print the part, a CAD model must be converted to a format that a printer is capable of intercepting. In this way, the CAD model is converted into a stereolithography (STL) file, also referred to as a standard triangular language file. STL uses a triangular mesh to describe object surfaces, often simplifying the CAD model. Most CAD programs are capable of exporting a model as an STL file, but there are also OBJ or 3DP files that are acceptable printer types, but not common [46, 44].

After the STL file is generated, the file is imported into a cutter that cuts the drawing into the layers that will be used to build the part. The cutter program turns the STL file into G code, which is a numerical control programming language to control automated machines with printers. The cutter program also allows the operator to adjust the construction parameters of the printers, such as the location of the substrate, layer height, and partial orientation [46, 44].

There are different ways of manufacturing the piece according to the different existing technologies, which will be discussed in more detail later [46, 44].

For some technologies it is enough to separate the printed part from the construction platform, however, there are other methods, in industrial cases, where the removal is more complex, involving the precise extraction of the print while still wrapped in the construction material or

attached to the construction plate. These methods generally also require rigorous removal procedures and highly skilled machine operators, along with safety equipment and controlled environments [46, 44]. Post-processing procedures vary according to the technology used for printing. For some technologies, a UV-curing component is required before handling, while for others it can be handled immediately. For technologies that use support, it can be removed at this stage. As the part is made in layers, in the end, it needs to be polished [46, 44].

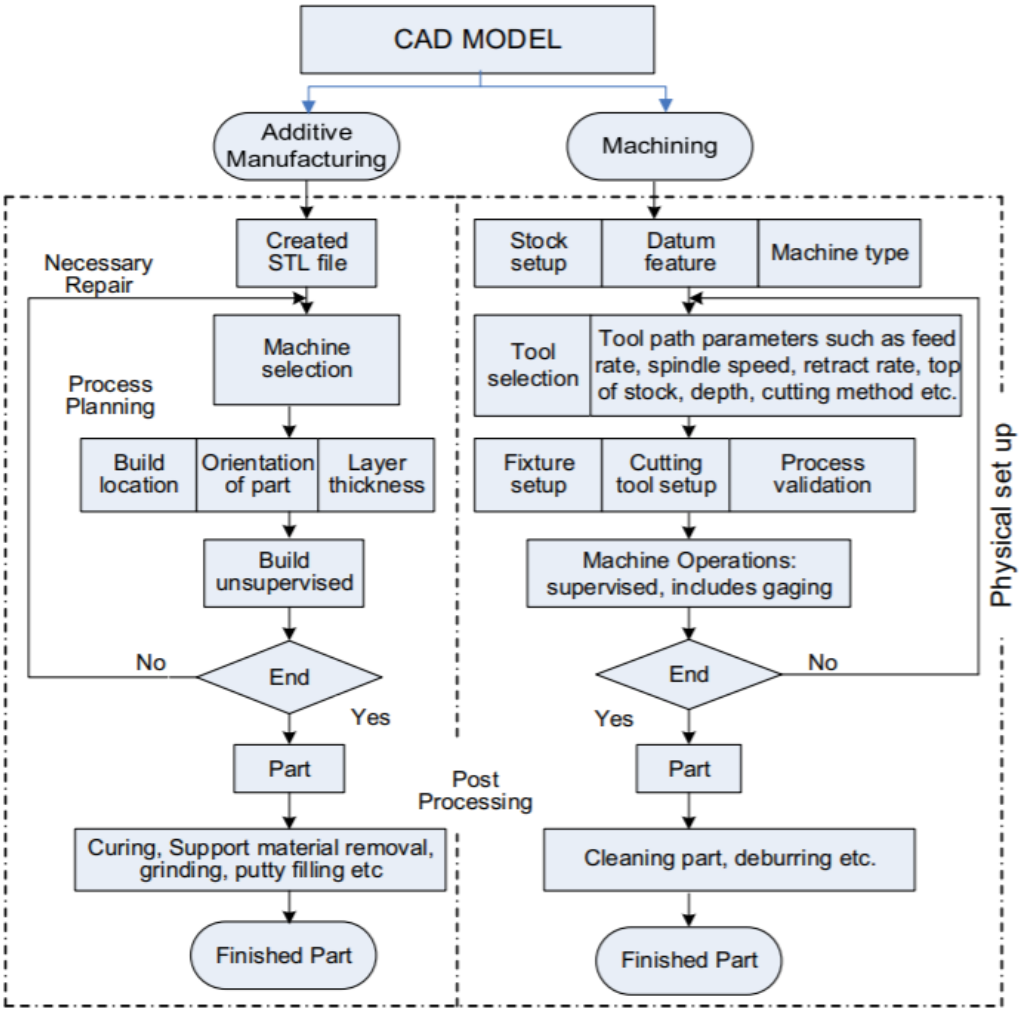


Figure 2.23: Generalized process planning flows for AM and machining, reflecting the decision-making and manpower aspects. Taken from [47].

2.6.1 Stereolithography (SLA)/Digital Light Processing (DLP)

Stereolithography was the first AM process, shown in the figure 2.24.

This technology consists of a tank full of liquid polymer (photopolymer), an ultraviolet laser (UV), a platform that can be lowered into the tank, and a computerized numerical control through the positioning of the platform and the movement of the laser [48].

In this technology of generating 3D objects through the successive building of thin layers, the pieces are constructed from a photocuring liquid resin that is exposed to a laser beam (photopolymerization), which sweeps the surface of the resin and provides the energy necessary for a chemical reaction to occur (curing reaction) to bind a large number of small molecules and form a highly cross-linked polymer. This way, the first layer of the object is created. Then the platform is lowered, to submerge and solidify the newly formed layer in liquid resin. This process is repeated until the whole part is finished [48].

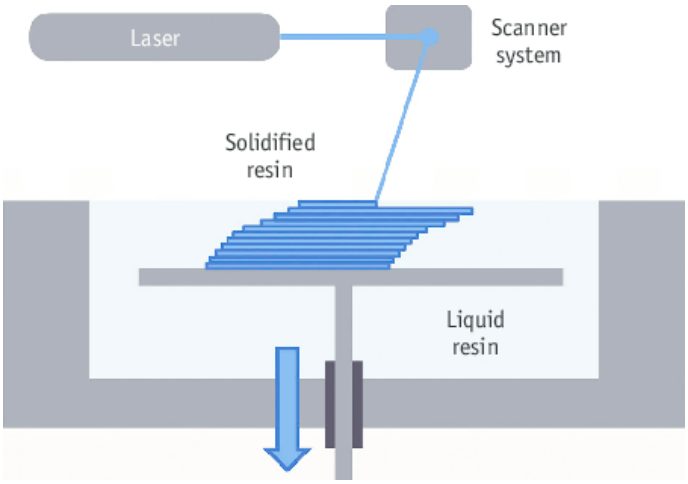


Figure 2.24: Basic principle of SLA method. Taken from [49].

Digital Light Processing is a process similar to SLA in that it is a 3D printing process that uses photopolymers as raw material. The main difference is that this technology uses a conventional light source, which is applied to the entire surface of the resin vat (photopolymer) in a single pass, making it generally faster than SLA [48].

In this process, as soon as the 3D model is sent to the printer, a liquid polymer vat is exposed to light from a DLP projector. This projects the two-dimensional image of the 3D model to be produced onto the liquid polymer. This solidifies when exposed to light, the construction plate goes down and the liquid polymer is once again exposed to light. The process is repeated until the part is finished. The process is shown in figure 2.25 [49].

Material

The materials used in SLA and DPL include photopolymer resins (resistant, durable, transparent, rubber-like) [48].

Applications in Biomedical Engineering

These technologies are capable of using magnetic resonance (MR) and computed tomography scan (CT) imaging to recreate prototypes identical to body parts, thus allowing doctors to train the surgery, decreasing the time of operations, and significantly reducing the risks involved. In oral surgery, it is possible to build perforation guides, increasing the implantation accuracy when compared to conventional surgical guides [48].

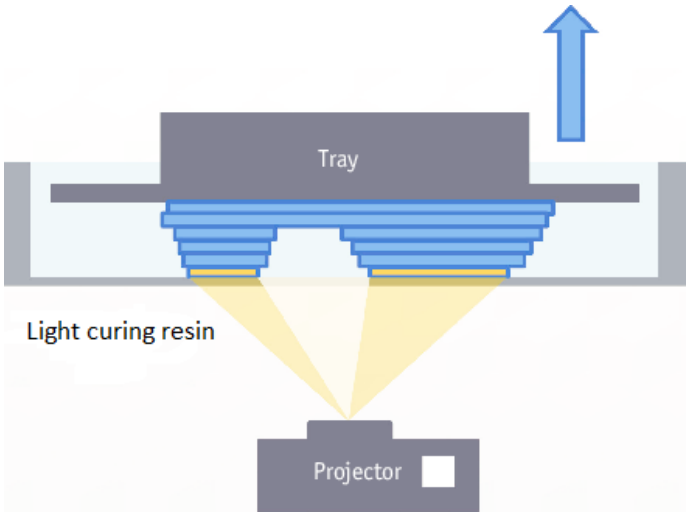


Figure 2.25: Basic principle of DLP method.Taken from [49].

2.6.2 Polyjet

This technology uses inkjets to produce physical models. The printers for this methodology can operate in both continuous and drop-on-demand (DOD) mode. In continuous mode, the ink is pumped through a nozzle to form a liquid jet. This operating mode is mainly used for high-speed graphic applications. However, the DOD method is the most widely used, where a movable inkjet head deposits a photopolymer, which is then cured by UV lamps after the respective coating is finished. This technology permits the printing of different materials and colors, and it can print soluble support material when necessary. The layers can have a thickness of 16 µm, which means that this method has a high resolution despite having a moderate surface quality. The produced pieces, however, have a lower resistance when compared to those printed through SLA and SLS [49]. In figure 2.26 it is possible to observe a schematic representation of the functioning of this technology.

Material

This technology uses two different materials, one photopolymer resin based on acrylate, UV curable, which will serve to form the model, and another gel-like material (also photo-curable) for the supporting structures. There is a wide range of rigid, flexible, opaque, or transparent photopolymers developed for printers based on polyJet technology. Some printers have the ability to combine materials in the same print, allowing for specific properties and hundreds of different colours [50].

Applications in Biomedical Engineering

The polyjet technique is very present in the area of dentistry, allowing direct printing of indirect bonding trays, soft gum masks for implantology cases, and surgical guides for dental implants or orthopedic procedures [51].

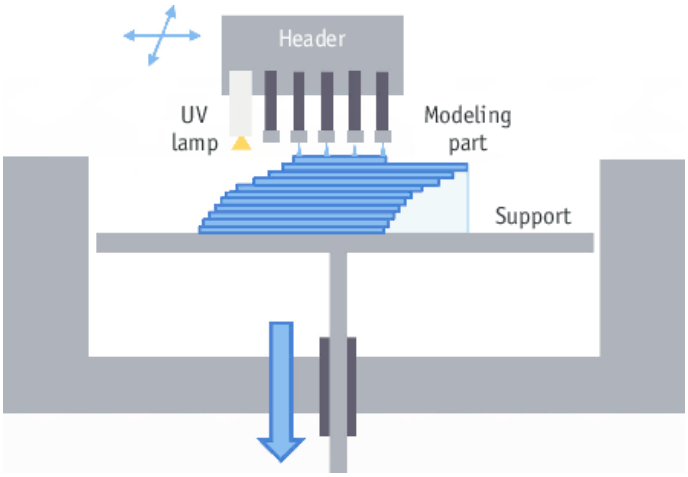


Figure 2.26: Basic principle of Polyjet method.Taken from [49].

2.6.3 Fused Deposition Modeling (FDM)

FDM is a process based on filament extrusion that integrates into the CAD system, material chemistry, computer numerical control, and the extrusion process to manufacture 3D parts directly from a CAD model. The filament is dragged to a liquefying head, where it is heated to a semi-liquid (melted) state and then extruded through a nozzle to deposit layer by layer on the platform. The head can move in three degrees of freedom (DoF) to deposit the polymer, according to the instructions in the G code [52].

The principle of the FDM process is illustrated in figure 2.27.

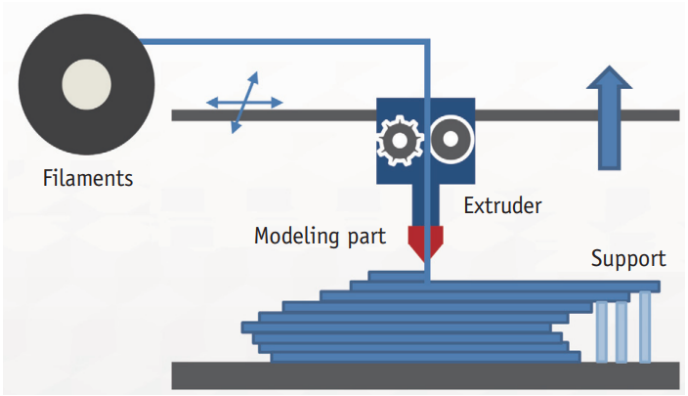


Figure 2.27: Basic principle of FDM method.Taken from [49].

Material

There are several materials used in FDM, such as PLA, polycaprolactone (PCL), polypropylene (PP), polyethylene (PE), polybutylene terephthalate (PBT), acrylonitrile butadiene styrene (ABS), wood, nylon, metals, carbon fiber, and graphene doped PLA [52].

However, PLA is the most widely adopted material by users of 3D printers at both domestic and industrial level, as it has the following characteristics [52]:

- It is a bioplastic, not harmful to human health [52];

- It has a glass transition temperature varying between 50 and 70 ° C and a melting point temperature varying between 180 and 220 ° C. It is harder than acrylonitrile butadiene styrene (ABS), although PLA has higher friction when compared to ABS and is therefore susceptible to blocking the extrusion nozzel [52];

- Decomposes quickly after disposal, unlike other plastics, which have posed serious challenges to disposal. It degrades into natural and non-poisonous gases, water, biomass, and inorganic salts when exposed to natural conditions, hydrolysis, or even when incinerated [52];

- In semi-crystalline form, it shows good bending behavior, better tenacity, and resistance to bending [52];

- PLA is preferred by most 3D printer users because it does not always need a heated bed for the adhesion to occur between the print and the platform [52]. Graphene-doped PLA, however, presents a great challenge for non-heated bed printers and it does not produce quality prints on non-heated build plates [52].

- It is commercially available in a variety of colors and textures [52].

Applications in Biomedical Engineering

FDM applications include the complete or partial manufacture of medical devices, customized implants, and prostheses, aid in controlled drug delivery systems, or even surgical planning. It should be noted that through data obtained by body imaging systems, such as MRI or CT, it is possible to create digital anatomical models, which can therefore be transformed into CAD files for later production of implants or prostheses from them [53].

Currently, in the research area, this method is very promising in what involves the deposition of biocompatible material utilizing 3D printers, dedicating for example to the production of various joints or load bearings in the form of implants. Tissue engineering has become nowadays an important area in AM technologies, as it allows the replacement of tissues or functional organs by precise modeling of extracellular structures similar to natural ones [53].

2.6.4 Selective Laser Sintering (SLS)

SLS uses continuous or pulsed laser beams as a heat source to melt and bind powders in predetermined layer sizes and shapes. The print chamber is heated almost to the fusing temperature of the material to reduce the laser's energy consumption. The powdered material is resting on a bed controlled by a piston which is lowered to a height equivalent to the thickness of each layer, each time a layer is completed. This technology has a relatively low resolution, which depends on the size of the dust particles. For smaller particles, problems such as agglomeration and oxidation can occur. Other types of problems may include porosity, low density, and low resistance [49]. In figure 2.28 it is possible to observe a schematic representation of the SLS process operation.

Material

The SLS method allows the use of polymers, metals, and ceramics. The most commonly used materials include wax, polycarbonate, nylon (standard nylon, fine nylon, fine nylon medical-grade, and nylon composite), and acrylic [54].

Applications in Biomedical Engineering

SLS has shown great potential for biomedical applications. Through data obtained from medical imaging techniques such as MRI and CT, customized medical devices and surgical models can be produced. It allows the manufacture of 3D devices for the incorporation and distribution of drugs or biomolecules. SLS has been used to design defined models of structures such as the skull, mandible, and neuro network for simulation and surgical planning, particularly in the craniofacial and maxillofacial fields, and for neurosurgery [54].

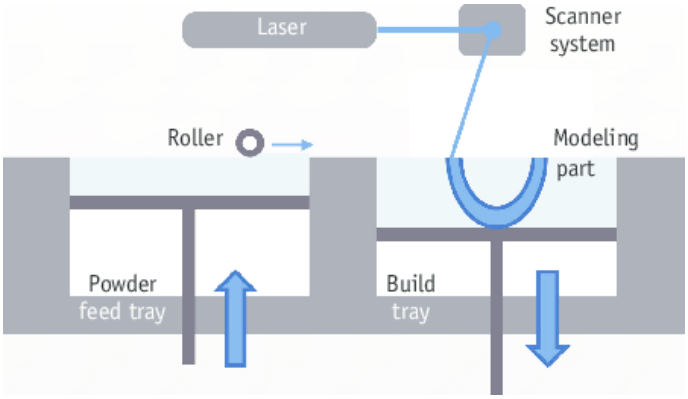


Figure 2.28: Basic principle of SLS method.Taken from [49].

2.6.5 Selective Laser Melting (SLM)

SLM is a method that enables the manufacture of metal components layer by layer according to a CAD model. This technology uses metallic powder to produce functional and high precision.

First, the 3D-CAD volume model is divided into layers and transferred to the selective laser melting machine. Then a thin layer of metal powder (10-45µm grain fraction) is placed on a substrate. A high-power laser is used which transmits information about the geometry of the individual layers according to the processed data. During the passage of the laser, the powder particles are fused and solidification occurs. When a layer is completed, the construction platform is lowered by the required layer thickness, and the construction process is repeated until the part is completed, as shown in figure 2.29 [55, 33].

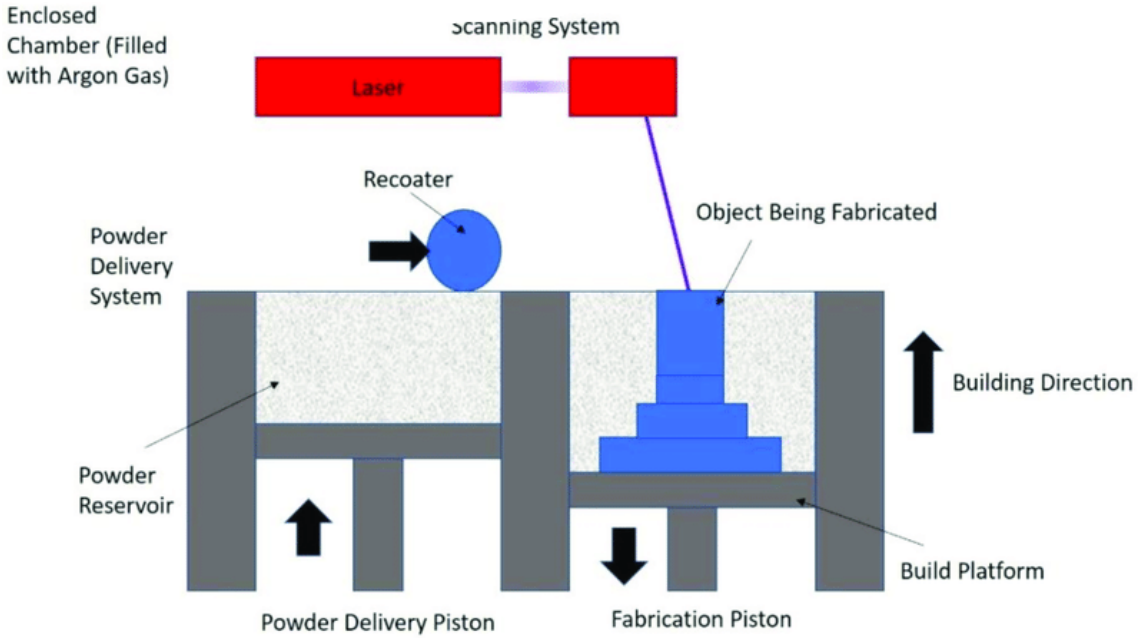


Figure 2.29: Basic principle of SLM method. Taken from [33]

Material

Most commonly used materials in SLM include stainless steels, tool steels, cobalt-chromium alloys, titanium, aluminum, among other metallic materials [56].

Applications in Biomedical Engineering

SLM technologies have wide application, allowing construction of implants used in dentistry, plates for osteosynthesis micro-screws, clasps, wires, nails, and bone screws. It is possible to adjust the implant shape individually to the patient's anatomy, and even to form a functional structure and surface [55].

2.6.6 Advantages and Disadvantages

Table 2.6: Advantages and Disadvantages of AM processes.

Process	Advantages	Disadvantages
SLA	Round the clock operation Good user support Build volumes Good accuracy Surface finish Wide range of materials Transparency Quick cast and skin and core processes	Requires support structures / post-curing / post-processing Limited choice of materials, especially biocompatible materials Cost of raw materials (resins)
DLP	High accuracy & intricate details Smooth surface ideal for visual prototypes Large range of specialty	Produces relatively brittle parts Materials degrade when exposed to sunlight Removal of support marks required
Polyjet	High accuracy & very fine detail Injection modeling-like finish Multi-material & full-color capabilities	The most expensive plastic 3D printing process Mechanical properties degrade over time Produces relatively brittle parts
FDM	Fabrication of functional termoplastic parts Allows the use of two materials Minimal wastage Ease of support removal Ease of material change	Limited dimensional accuracy Slow process Non isotropic behaviour Visible process
SLS	Ideal for functional prototypes Complex geometries No support needed Small batch production capabilities	Large physical size of the unit High power consumption Grainy surface & internal batch production Higher cost than FDM or SLA
SLM	Highly complex, topology optimized metal parts Parts with excellent material properties Ideal for high-end engineering applications	The most expensive 3D printing hardware Expensive parts

Chapter 3

Concept Generation and Development

To begin the development of a product, it is necessary, in a first stage, to make the preliminary study of the market, which is constituted by the analysis and in-depth study of solutions and patents, i.e., a compilation and synthesis of a set of information were made that allows, on the one hand, to build the starting knowledge base for the subsequent development tasks, and on the other hand, to produce the specification and feasibility of the solution. For this, at first, a benchmarking was carried out, in a first analytic phase, through catalogs consultation, existing products survey, bibliography, articles or Internet sites and that in a later phase should go through the physical study of competitor's specimens, involving the disassembly of the systems and their analysis. Next, the analysis of patents and applicable standards was carried out. Research of patents and standardization, analysis of their claims, and evaluation of their impact on the project.

A second phase focused on phases one, two, and three of product development, which are namely needs and requirements presentation, concept generation, and concept development, described in chapter 2. In other words, after the survey of the needs and requirements, the concept was chosen and developed, the mechanical systems were idealized and, finally, the first prototype was presented in 3D modeling.

3.1 Preliminary Market Study

Preliminary market research is the first phase in the development of any product that constitutes the analysis of the products already on the market, the verification of patents, and then the study of the cost of the patent application or product development.

3.1.1 Suture Equipment

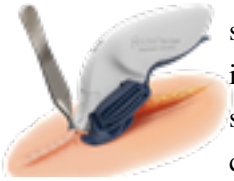
A survey was carried out on some of the medical equipment manufacturers, where B. Braun, Medtronic, and Johnson & Johnson stood out, through websites and online catalogs. Some of the models that refer in their descriptions to be able to suture with suturing elements (table 3.1), were selected. These devices represent the type of equipment on the market, for skin suturing.

The investigation aimed to identify the technical requirements. Since the devices existing in the market are devices that use only suturing elements, the analysis is limited to this type of device.

Table 3.1: Examples of available suture equipment on the market.

Brand	Products	Image	Description
B. Braun	Manipler® AZ		The Manipler® AZ product is a single use, sterile skin stapler designed to deliver 35 stainless steel staples in any surgical procedure. It offers reliable/intuitive handling, reducing the risk to the patient [57].
Medtonic	D ST Series™ TA™ Single Use Reloadable Staplers and Reload		The staplers of the DST™ Series TA™ are single-use rechargeable linear staplers with titanium directional stapling technology [58].
	Appose™ Single Use Skin Stapler		The Appose™ device is a single-use leather stapler that dispenses with a staple each time the instrument trigger is activated [59].
	SFS™ Reusable Skin Stapler and Reloads		The SFS™ device, together with disposable loading units SM™, places a staple each time the instrument trigger is activated. The staples first penetrate the skin or fascia and then close, holding the fabric together. There are different sizes of staples; each contained in its own disposable loading unit [60].

Medtonic	MultiFire Premium™ Single Use Skin Staplers Reloads and Remover		The MultiFire single use leather staplers Premium™ place a staple each time the instrument trigger is activated. There are different staple sizes, each contained in its own single-use loading unit [61].
	DFS™ Single Use Fascia Stapler with Stainless Steel Staples		The DFS™ stapler places a staple each time the instrument handles are activated. The staples first penetrate the fascia and then close, thus holding the fabric together [62].
	iDrive™ Ultra Powered Stapling System		The Appose™ device is a single-use leather stapler that dispenses with a staple each time the instrument trigger is activated [63].
Johnson & Johnson	PROXIMATE® Rotating Head		The PROXIMATE®Rotating Head Skin Stapler features a 360° rotating set for better visibility and a ratchet mechanism for easier staple placement [64].
	PROXIMATE® Plus MD		PROXIMATE® Plus MD Skin Stapler is a high value, low cost skin stapler that enables multidirectional release in an ergonomic design [65].
	PROXIMATE® PX Fixed Head		The PROXIMATE® PX Fixed Head Skin stapler provides many of the same features as the PROXIMATE® Rotating Head stapler, but in a fixed head format [66].

Coopersurgical	INSORB Skin Stapler		The patented INSORB® skin stapler is a unique, sterile device that uses 30 absorbent staples, enough to close an incision up to 21 cm long [67].

The equipment refills are specific to each manufacturer and equipment. There are staples with different diameters and widths. In the case of linear equipment, each recharge has several staples that are used simultaneously, allowing the suture of a linear extension of different dimensions, according to the equipment/ recharge used. In the case of refills, these can have different numbers of staples, with different dimensions, with specificity for different types of tissue. From the research of the catalogs, it was collected the information that the staples material of the equipment are made of titanium alloys and in the specific case of INSORB by Coopersurgical, the material is a PLA-PGA co-polymer.

3.1.2 Patents

A patent is a contract between the state and whoever submits the patent application, which gives the holder the exclusive right to produce and market an invention, in exchange for its public disclosure. In other words, it is a barrier that prevents competition from developing the same approach as our technology.

Patents found are described below.

1 - WO2018223207

This patent describes a surgical stapler and a method for approximating muscular or aponeurosis structures. This surgical stapler comprises structures for stapling, associated with a tissue alignment structure. These structures have at least one staple arrangement, which by bringing it close to the tissue alignment structure it is possible to staple, keeping the muscle or aponeurosis structures together through the use and arrangement of staples.

Table 3.2 summarizes the characteristics of patent WO2018223207 present in point a. Table 3.3 presents images with the device schematic described in the patent and Table 3.4 shows the diagrams of the staples used in the device.

Table 3.2: Characteristics of patent WO2018223207.

Source	Patent scope
Term Research	EN_ALL:(aponeurosis)
No. of results	1879
Patent	WO2018223207
Title	Surgical stapler, surgical staple arrangement and method for approximation of muscular or aponeurotic structures
Applicant(s)	Garcia, Diogo de Freitas Valeiro [BR/BR]; BR
Inventors	Garcia, Diogo de Freitas Valeiro; BR
Representative(s)	Remer Villaça & Nogueira Assessoria e Consultadoria de Propriedade Intelectual S/S; Rua Padre João Manuel, 755, 9º andar, Jardins, São Paulo CEP-01411-001 São Paulo, BR
Date of publication	13-12-2018
International order	No.PCT/BR2018/050186
Date of Archiving	11-06-2018
Link	https://cutt.ly/2jYObKy

Table 3.3: Scheme of the device described in patent WO2018223207.

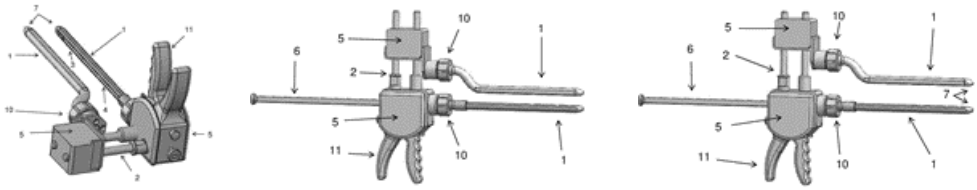
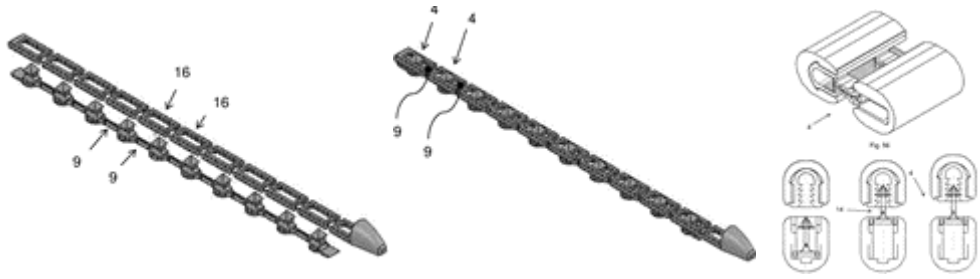
Device scheme


Table 3.4: Scheme of the staples used in the device of patent WO2018223207.

Staples scheme


2 - US201102074

The patent US201102074 describes medical equipment to suture as well as a method to apply the suture. The invention refers to a device that allows the implementation of a suture, including a housing system, a hollow needle through which the suture is guided using a booster rod. It allows the use of absorbable PLA or PGA sutures. It allows the use of polymeric, metallic, plastic, and tissue sutures, as well as sutures that result from the combination of the anterior sutures. This patent speaks of a method of suturing where it is always referred only to the use of two anchorage points for the suture, using coupling elements of polymer, metal, tissue, etc. It does not specifically refer to fascia, mentioning biological tissues, and anchoring can be done by both points in the same tissue, or not. In Table 3.5 are described the characteristics referring to the patent US201102074, present in point b. In Table 3.6 are presented schematics of the device referring to the patent US201102074. It should be noted that the patent also indicates the existence of a method of suture storage of the device to be used when applying it.

Table 3.7 shows the diagrams of the application of the suture method referred to in the patent. In the images of this table, the method of application used for the two anchor points is highlighted, using an anchor element. For the application under study, this device has the advantage of using sutures, not mechanical sutures as staples. As the patent is described, using a two-point anchor suture, the resulting suture from this device is simply discontinued, as identified in Table 9-(b). Regarding the positioning of the suture, this method will require complementary instrumentation to position the tissue in a saturated position, as well as the stitch node to the posterior.

Table 3.5: Characteristics of patent US201102074.

Source	Patent scope
Term Research	EN_ALL:(automatic and medical and medic and suturing and device and fascia)
No. of results	2889
Patent	US20110202074
Title	Devices and methods for deploying medical sutures
Applicant(s)	Talmo Paul A.; Lovuolo Michael; Jellison Thomas A.
Inventors	Talmo Paul A.; Lovuolo Michael; Jellison Thomas A.
Date of publication	09-04-2009
Date of Archiving	18-08-2011
Link	https://cutt.ly/SjYSGXZ

Table 3.6: Scheme of the device described in patent US201102074.

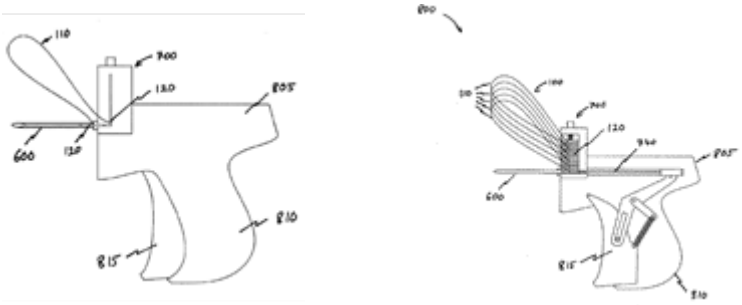
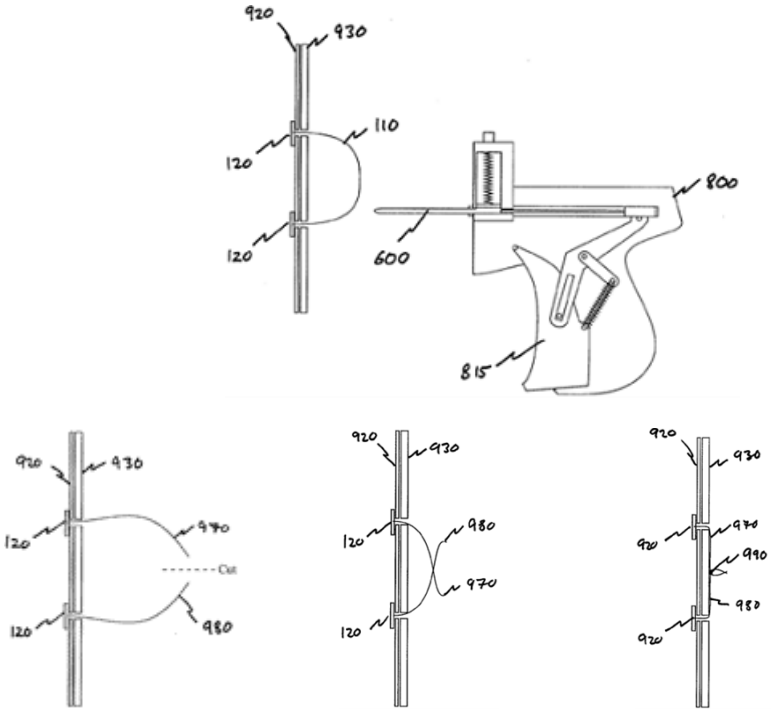
Device scheme


Table 3.7: Scheme with suture application methodology of patent US201102074.

Staples scheme


3 - WO2012103178

This patent (table 3.8) describes subcuticular, continuous, and automatic suture equipment to obtain reduced or minimized scars, simultaneously with reduced suture time. It also describes a variety of needles designed and built for use with the equipment to perform continuous suturing for reduced or minimized scars and achieve a reduction in suturing time. The patent refers to the use of sutures according to needs, including the use of resorbable sutures. It is stated that the equipment must have a needle with at least one spiral or one helical turn and that it produces a

suture in which the fundamental unit is circular. It is identified as an example in the patent the use of multi-filament sutures, and needles with an external diameter of 0.36mm and curvature of 11mm for suturing the skin. The use of equipment to suture fascia, muscle, and internal organs such as intestines, as well as in microsurgery of the eye is also mentioned.

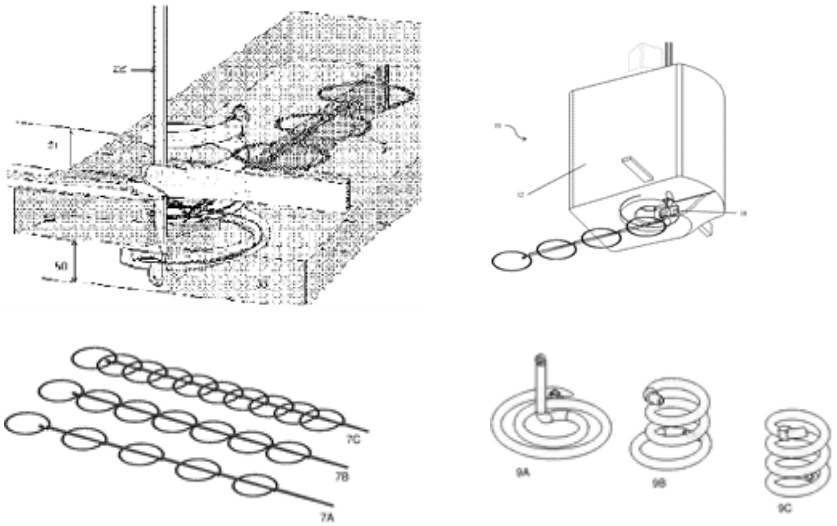
Table 3.8: Characteristics of patent WO2012103178.

Source	Patent scope
Term Research	EN_ALL:(automatic and medical and medic and suturing and device and fascia)
No. of results	2889
Patent	WO2012103178
Title	Devices and Methods for Continuous Surgical Suturing
Applicant(s)	Isuturing, LLC [US/US]; c/o Triangle Patents PO Box 28539 Raleigh, NC 27611-8539, US (AllExceptUS) Mohamed, Adel, W [US/US]; US (UsOnly) Mungalov, Dmitri [US/US]; US (UsOnly) Mohamed, Mansour, H. [US/US]; US (UsOnly)
Inventors	Mohamed, Adel, W; US Mungalov, Dmitri; US Mohamed, Mansour, H.; US
Representative(s)	Glasgow, Jinan; Triangle Patents PO Box 28539 Raleigh, NC 27611-8539, US
Date of publication	02-08-2012
International Archive Date	25-01-2012
Link	https://cutt.ly/UjYGhaK

Regarding the patents that were found and considered relevant to the nature of the project, none of the patents preclude the development of a device (or methodology) that allows skin suturing with the closure of the suturing elements. In the case of patent WO2018223207, this refers to the use of a device that uses staples as a resource to perform the suture. It seems, however, that the choice of the anchoring site of the suture is limited by the morphology of the device, more specifically by the shape of the area called the jaw. Regarding the patent US20110202074 the choice of the material may meet the intended material for this project, however, this patent refers only to the use of two docking sites, which does not conflict with the application required in the project. Considering patent WO2012103178 (table 3.9), this patent has common points with what is intended in this project, however, some factors allow development that does not conflict. This device claims to speed up the suture time, uses suture thread, however it always refers to sutures with a circular unit and with the needle having at least one spiral or helical turn. These points allow a suturing device/method to be developed that meets the design requirement, but without

conflicting with the patent. This device, unlike the device of patent WO2018223207, does not have any method for approaching the tissue to be sutured, which in the case of sutures with some extension will be necessary, leading to the need for complementary equipment to perform the suture.

Table 3.9: Scheme with suture application methodology of patent WO2012103178.

Staples scheme


Thus, it can be concluded, besides the existing products on the market, the consulted patents with relevance to the nature of the project, do not complete the requirements for the device with the idealized function of skin suturing, idealized by Dr. Pedro Lobo.

3.1.3 Certification costs

According to this characterization, it is possible to summarise the whole certification process in a simplified manner. Depending on the various factors and circumstances that may influence and alter the orientation of the certification process, the indication of time and costs are very rough estimates [39].

Therefore, to start the certification process, an initial cost of at least 50,000€ is assumed, adding to this an annual cost of 15,000€. The above costs do not include product testing, clinical trials, or a range of other tests that may be necessary, such as biocompatibility, biodegradability, and usability tests. In addition, other internal implementation costs may be applied, such as consultancy, whose typical cost is over 10,000€ [39].

- In addition to the costs mentioned above, there are also the associated overhead costs (depending on the notified body, device specificities, and size/structure of the manufacturer):

- Application fee of the notified body: 4000€

- Analysis of Technology Files: > 2500€/day

- Annual Management Fee: > 2000€/year

- ISO 13485: >1500€/year (not compulsory)

- Audit: > 1800€/day + travel costs (1000€ to 2000€ per audit, depending on location and time of notified body and audit hour) [39].

3.1.4 Intellectual Property Process

For the first phase of this development process, a provisional patent application (usually for one year) should be chosen. This allows for greater flexibility and less financial effort at this early stage, providing time to obtain a clear picture of what the product will look like at the end of the development. Only at the end of product development is the definitive application made (typically one year after the provisional application).

Thus, the submission for the national patent application, starting with the provisional patent application process, has a cost of approximately 3,000€, associated with maintenance of 20,000€, at 20 years. For an international patent, it will have a cost of submission of 6,000 €, adding to this a maintenance cost of 50,000 - 70,000€. Associated which these costs can be added to the costs of verifying patentability and respective patent writing. These can only be estimated in the course of the process.

3.2 Product Functionality and Requirements

Functionality is seen as a set of characteristics that describe the product and indicate its purpose, taking into account the needs of the target market to be satisfied. The set of requirements that the product must meet to satisfy the practitioner's needs, seeks to help define the project problem, leaving enough room to find satisfactory solutions.

The device to be created in this project has the function of suturing both skin and fascia with the closing system of the suturing elements.

The requirements and conditions presented by Dr. Pedro Lobo are: in the case for fascia suturing, the suturing element has to perforate fascia and portion of muscle; the extension of the suture is variable; there is an approximation of tissues by another element of the surgery team; suturing element in biocompatible material, inert, with the possibility of being absorbable in the long term (months); suturing element has to be compatible with MRI and CT; discontinuous suturing; shorten suture time and give the doctor good visibility of the incision.

3.2.1 Concept generation

Constant innovation and the introduction of new products on the market are crucial for competitiveness. Product design is often related to the appearance of the product, however, this does not only involve the addition of pleasing features to the final product, but also the realization and creation of an attractive, useful, ergonomic, and functional object. Design, therefore, plays an

important role in the creation and process development of new products, as well as in their functionality, aesthetics, ergonomics, and usability. However, a final design solution is not expected at this stage, but rather the understanding of the needs and opportunities to start generating the product.

The concept generation stage allows for a wide variety of creative solutions for the product in question to emerge through a creative process, sketches of possible solutions are matched to the identified needs. The sketches corresponding to the concepts generated in this project for the initial definition of the skin closure system are only initial solutions.

Initially, the sketches were designed in a way to avoid the need for a helper to bring the tissues to be sutured closer, so clamps were added to the front part of the device, before the suturing element exit. In figure 3.1, the blue button on the upper part would be for releasing the clamps and squeezing the tissues, while the handle would serve to push the suturing element to the exit.

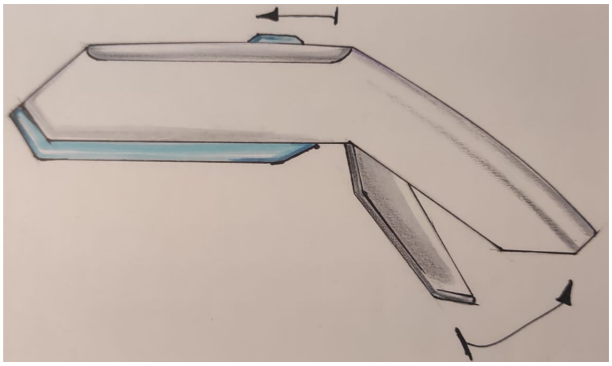


Figure 3.1: First sketch.

In figures 3.2 and 3.3, this present two sketches, which only changes the design, keeping the same reasoning of the previous sketch, however, the tweezers would be driven by the button that is in the middle of the device.

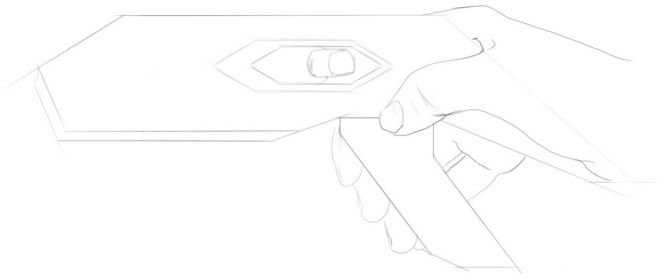


Figure 3.2: Second sketch.

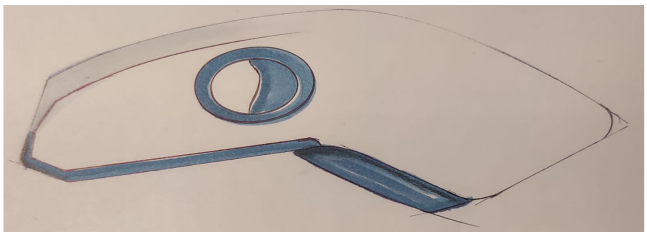


Figure 3.3: Thrid sketch.

In figure 3.4, the device would work by squeezing it horizontally to drive the exit of the suturing element.

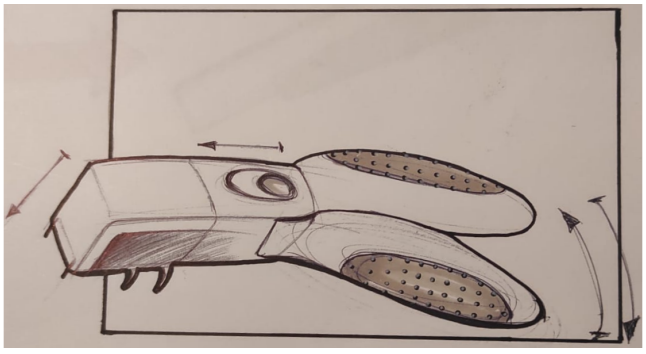


Figure 3.4: Fourth sketch.

In figure 3.5, to activate the device, the handle would work in two stages, i.e., the first squeeze of the handle would allow squeezing and grasping the tissues to be sutured with the clamps and the second squeeze would serve to release the suturing element and thus close the incision.

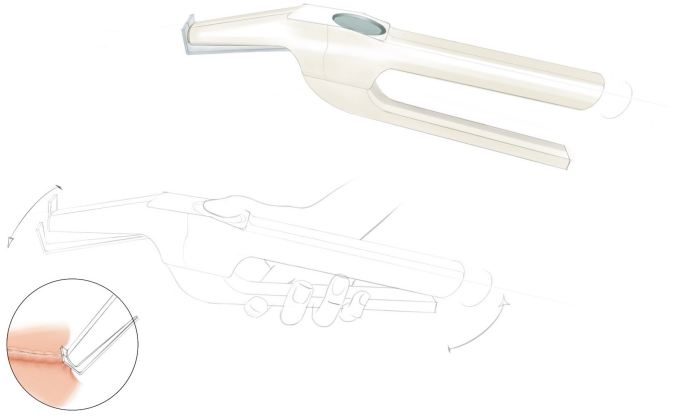


Figure 3.5: Fifth sketch.

After generating different concepts, it is then necessary to proceed to the selection of the concept that has the most attractive and functional characteristics, which could add value to the market and satisfy needs.

3.2.2 Final Concept Selection

The selection of the concept with the greatest potential is an integral part of product development and is based on a process of evaluation of the various concepts, taking into account the fulfillment of requirements.

The choice of the final solution was based on the conclusion drawn in the interview with Dr. Pedro Lobo, which can be found in appendix A. In summary, the clamp should be excluded, the device should be a vertical clamping device with a continuous force mechanism to fix the suturing element. It should also be mentioned that the device should contain a load of 40 suturing elements, since abdominal incisions are on average around 25 cm long and the suturing elements should be 8mm when closed, and these are placed every 0.5 cm.

The concept chosen is shown in figure 3.6 and will be the starting point for the development of a fascia and skin suturing system.

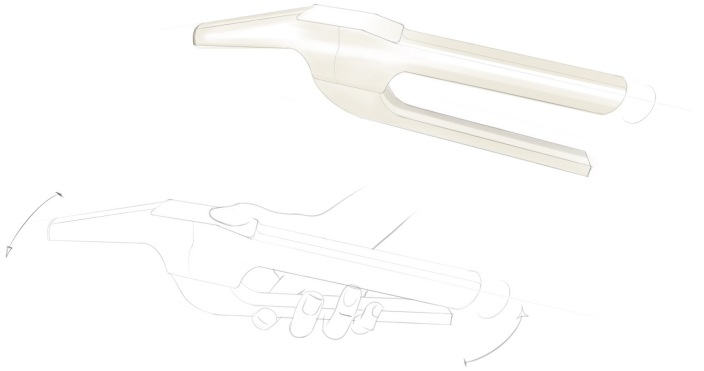


Figure 3.6: Selected concept.

3.3 Mechanical Design: Concept Development

Starting from the previously selected concept, it is necessary to think of a mechanical and functional solution for the device in question. This solution recognizes the functioning of the product in general, as well as the ideal structure of each of the components, to allow the correct stapling and closure of the suturing element, both for the skin and the fascial tissue.

Since this concept is somewhat original, and there is still no product on the market that generally resembles it, and that could work as a starting point for the development of this one, an in-depth approach was necessary, to think from scratch about a possible solution for the functioning of the skin closure system, using, however, already existing mechanisms from other products.

3.3.1 Identification of the Systems

After the logical process, a general solution then emerged for the development of a device that fulfilled the final goal, composed of several components and mechanisms. Initially, the process of

building the device was divided into four systems. The first one refers to the functioning of claws that will support the fastener closing, the second one refers to the fastener support that contains two systems: the device's suturing element expulsion and the door for opening/closing, and the fourth and last one refers to the handle, the piece that will trigger the whole process.

The sketches that resulted in the constructive solution thought and selected for this project, which facilitate the understanding of this solution, will be shown and explained below. The sketches were made with the use of two software: Sketchbook and Illustrator.

3.3.1.1 Handle System

The handle system is the only one that comes into direct contact with the user and is the means of connection between the two possible systems in the suturing element holder, described insection 3.3.1.2. It was first thought that its handling would be responsible for the expulsion of the suturing element. A representation of the handle is shown in figure 3.7. The upper part (E1) contains an axis that allows the rotation and the lower part a cylinder, which works as a "lever" (A1). These movements are represented by the red arrows.

The handle is moved by continuous pressure exerted by the hand. The continuous force has advantages for both the triggering of the mechanical system and for the surgeon. Thus, regarding the mechanical system, when the handle is pressed, first the axis rotation (E1) will drive the clamp system, as will be described later subsection 3.4. Then, when the handle returns to its rest position, the lever A1, which will be connected to a spring, will push the suturing elements horizontally out of the device, as will be demonstrated in the followingsection 3.3.1.2.

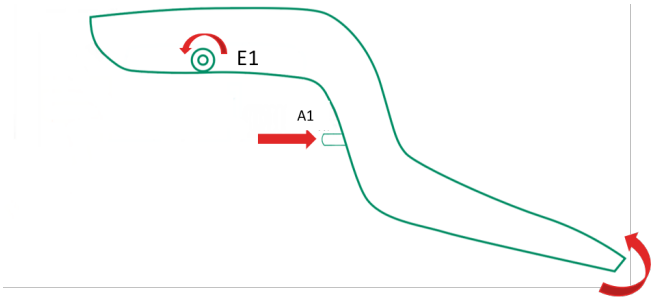


Figure 3.7: First handle system.

For the surgeon, since the anatomical structures vary from person to person and so if this mechanism is applied, it allows observing the suturing elements coming out, and thus, to control and adjust the required force, so that the suturing element is fixed more superficially or more in-depth in the tissue.

The representation of the handle is shown in figure 3.8. The upper part (E1) has an axle that allows the rotation and the lower part has two cylinders, which work as levers A1 and A2. A1 is the part that drives the suturing element output and A2 helps the opening/closing mechanism of the suturing element holder door. This system would be responsible for keeping the suturing elements inside the device and is described in more detail insection 3.3.1.2.

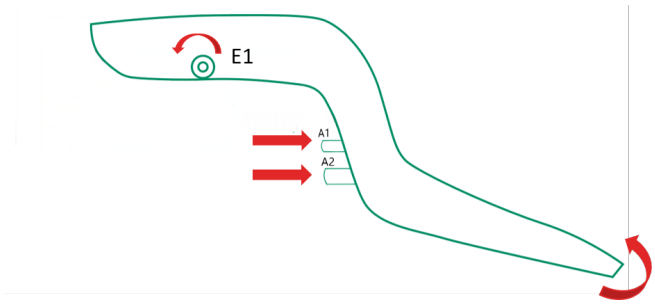


Figure 3.8: Second handle system.

3.3.1.2 Suturing Element Holder System

This system is designed to house two systems. The first is the door opening/closing system and the second refers to the storage and expulsion of the suturing elements.

The door opening/closing system would be responsible for keeping the suturing elements inside the device. In other words, in a resting situation, where no pressure is being applied on the handle, the door would be closed and the suturing elements would remain inside. However, when pressure is applied on the handle, the door would open and it would be possible for the suturing elements to fall out of the device. This system would be connected to the handle and is expected to be operated by lever A2, as already explained insection 3.3.1.1. For the opening/closing of the door, two mechanisms were designed, as described below.

The first mechanism, shown in figure 3.9, consists of a set of rods (3), which are connected to each other by shafts, which facilitate the movement of compression and distension, however, it should be considered that the central axis (4) is fixed to the suturing element holder (1) and a door (2). When a force is applied, in the same direction and direction as F1, the rods compress, promoting the opening of the door for the exit of the suturing element. On the other hand, when the force is no longer applied, the whole mechanism relaxes, leading to the closure of the door, ensuring that the remaining suturing elements remain trapped inside the device.

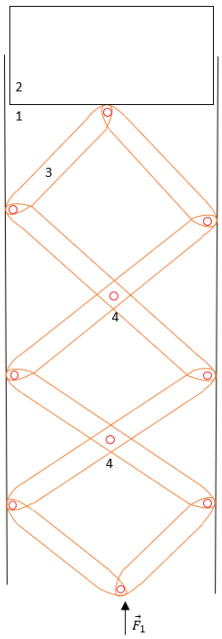


Figure 3.9: First door opening/closing system.

The second mechanism, shown in figure 3.10, consists of a cylinder (3) in the center of the holder (1), with two compression springs (4) on its side, one on each side, and the door (2). When force F2 is applied in the direction of force F2, triggered by pressure applied to the fastener handle, the springs extend, pulling the door backward, opening it, and allowing the fastener to fall. When pressure is released on the handle, the springs compress, closing the door.

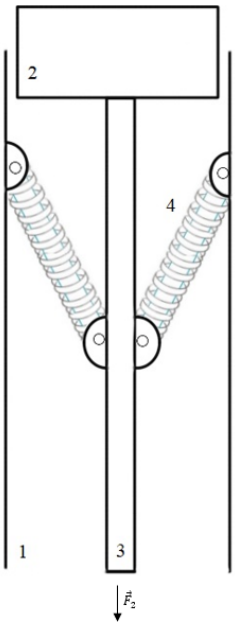


Figure 3.10: Second door opening/closing system.

The storage and expulsion system of the suturing elements, shown in figure 3.11. It consists of the handle system (1) of figure 3.7 insection 3.3.1.1, a spring (2), apart with the same shape as the staple (3), and the support (4), where the 40 staples will be stored. When the handle returns to its rest position, it forces the spring connected to the lever A1 of the handle to extend, making the piece (3) push the suturing elements towards the device exit, in the direction shown by the red arrow of figure 3.11.

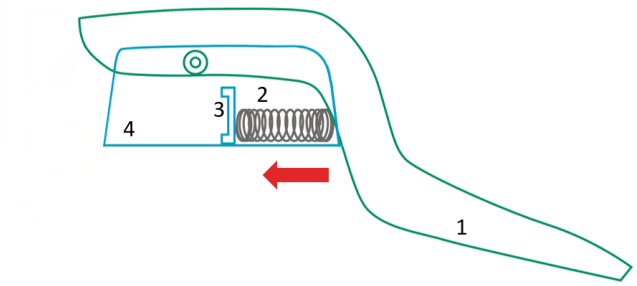


Figure 3.11: Storage and expulsion system for suturing elements.

3.3.1.3 Clamps System

Taking into consideration the function and design of the suturing element, there is the need to create a system that forces its closure when the two margins of the incision are approaching.

Firstly, a system was thought of, represented in 3.12, composed of a compression spring, which is connected to a shaft that allows the rotary movement of opening and closing of the clamps.

When pressure is applied to the upper part of the spring, in the direction (P1), by the handle, the spring (1) compresses exerting force, which will drive the opening of the clamps (2). In this way, when the force stops being exerted, the spring distends, promoting the closing of the clamps and thus also promoting the closing of the suturing element.

However, visually, it is expected that the system is not ideal, as it is fragile and unstable, thus hindering the intended movement. It still exerts a movement contrary to logic since, when compressing the spring, the system opens and when decompressing the spring, the system closes.

In this way, a new system was thought of, represented in figure 3.13, consisting of a compression spring (1), two gears (2), a part (3) with the function of facilitating the movement of the gears and pushing down the suturing element. When pressure is applied to the spring at the upper part, in direction (P1), by the handle, the spring compresses exerting force, which will cause part (3) to have a downward movement, promoting the rotation of the gears and then the opening of the clamps. In this way, when the force is stopped, the inverse process occurs and the clamps close, also closing the suturing element. When analyzing this system, it can be seen that the robustness of the system has increased, but it continues to perform a movement contrary to logic since when compressing the spring the system opens, and when decompressing the spring the system closes.

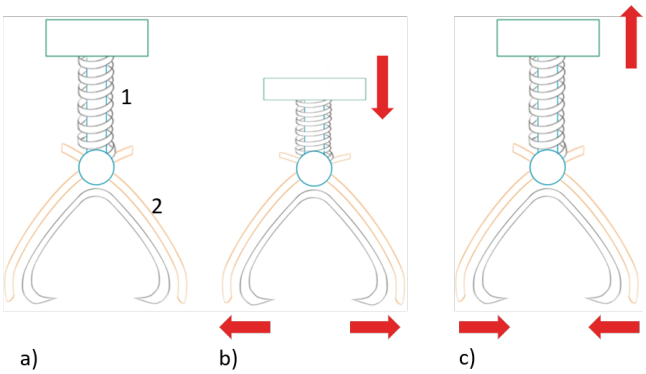


Figure 3.12: First sketch of clamp system. a) Movement at rest; b) Downward movement of part 3 and opening of the clamps. The red arrows indicate the movement of the opening of the clamps. c) Downward movement of part 3 and closing of the clamps. The red arrows indicate the movement of the closure of the clamps.

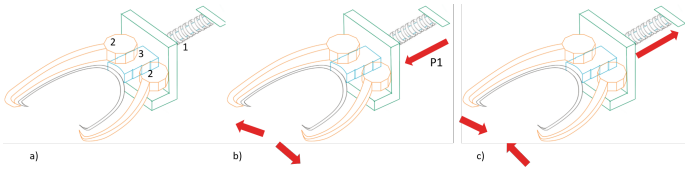


Figure 3.13: Second sketch of clamp system. a) Movement at rest; b) Downward movement of part 3 and opening of the clamps. The red arrows indicate the movement of the opening of the clamps. c) Downward movement of part 3 and closing of the clamps. The red arrows indicate the movement of the closure of the clamps.

To solve this adversity, it was thought of crossing the two clamps. This way, the movement is correct according to logic, i.e. when compressing the spring the system closes, and when decompressing the spring the system opens. However, the clamps cannot remain at the same height, so as not to limit the movement of one and the other. So, to solve the problem it is necessary to place the gears at different heights and at the lower limit increases the width of the clamp that is a lower level, as shown in figure 3.14.

Another weighted form for the clamping of the suturing element consists of: the piece (6), which is part of the external surface of the device, this piece will have openings on the sides to propitiate the rotation of the clamps; two gears (2) held by two compression springs (1); and the piece that pushes the suturing elements to the outside (3), with the support of a third spring (1).

The two gears (2) and the piece (3) will be joined at the back by a structure. Thus, when a force is exerted by the handle in the direction and direction of F1, the three springs compress and therefore cause the two gears (2) and the part (3) to descend at the same time, consecutively clamps open. Once the movement is finished, when pressure is no longer applied, the mechanism relaxes, gears (2) move upwards and the clamps close, as shown in figure 3.15.

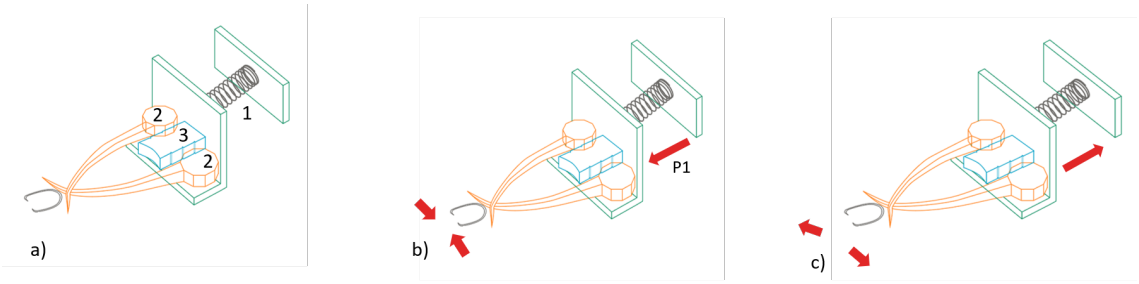


Figure 3.14: Third sketch of clamp system. a) Movement at rest; b) Downward movement of part 3 and closing of the clamps. The red arrows indicate the movement of the closure of the clamps. c) Downward movement of part 3 and opening of the clamps. The red arrows indicate the movement of the opening of the clamps.

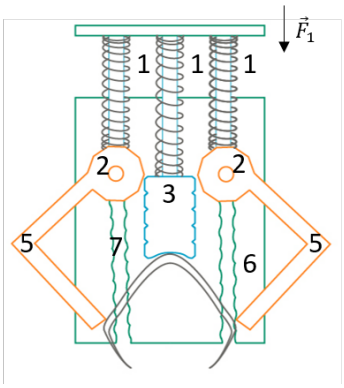


Figure 3.15: Fourth sketch of clamp system.

As shown in the same figure, the gears are held on both sides by racks (7), which makes it impossible to have a rotary movement. For this reason, and also following the same line of reasoning, but where movement is possible, two racks (7) were removed, one on each side. However, when force is exerted by the handle, the part (3) and the gears (2) descend, not closing the suturing element. However, when the mechanism relaxes, the gears go up, closing the stitching element, as shown in figure 3.16. In the two cases above, the top piece must be fitted with rails on all sides as shown in figure 3.17, to limit the movement of the pieces and only vertical movement is authorized.

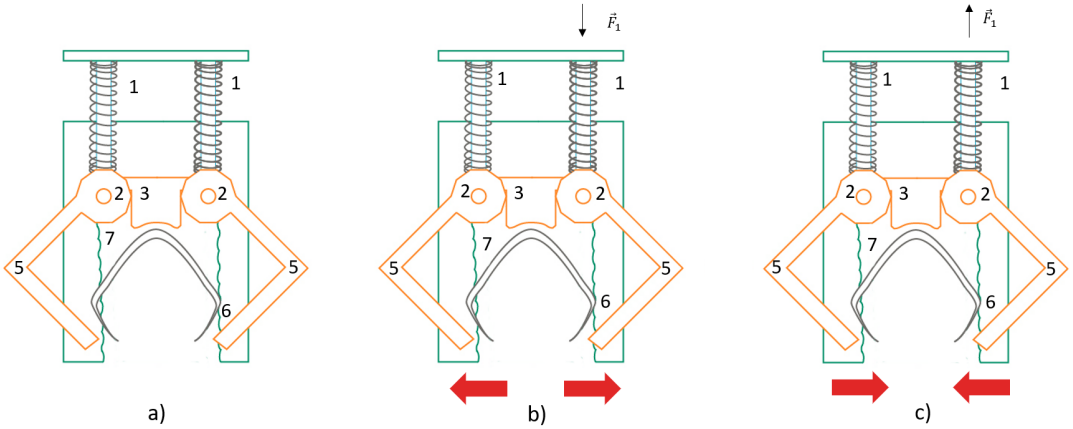


Figure 3.16: Fifth sketch of clamp system. a) Movement at rest; b) Downward movement when force is applied, forces the clamps to open. c) Upward movement when force is no longer applied, forces the clamps to close. The movement of the clamps is represented by red arrows.

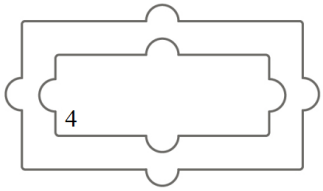


Figure 3.17: Part 4 top view.

Next, another option for the clamps mechanism demonstrated in figure 3.18, was studied.

The system consists of a compression spring (1) at the top, a mobile part (2) which houses the rest of the system two gears (6), in which the movement is possible because the lateral surface of the device has racks (4) where the gears (6) fits. In addition to these components, the system has two lateral openings, which allow movement of the clamps (5), and a part responsible for pushing the suturing elements out of the device (3), located in the center of the face of the mobile part (2).

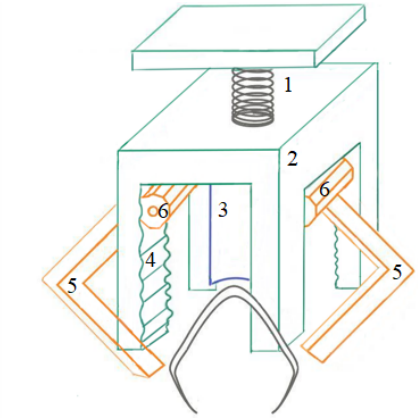


Figure 3.18: Sixth sketch of clamp system.

In this option, the axes of the gear wheels (6) will be fixed to the front face of the device and the mobile part (2) will facilitate the two movements: the vertical movement which causes the sutured element to be pushed downwards, and the rotating movement of the gear wheels, for the rotation of the clamps to close the suturing element.

The movable part will be attached to the front face of the device by a rail to limit vertical movement. For this, the movable face (2) will have a recess that fits into the rail on the face of the device.

In figure 3.19 it can be seen that the gears will be supported on both sides, to stabilize movement. When a force (F1) is exerted by the handle, the structure of the moving part (2) descends and this movement is facilitated by the gears fixed by the axle. As it descends, it also creates the rotary movement and the clamping movement of the clamps, providing the closure of the suturing element. When the force on the handle is released, the whole structure rises to the equilibrium position.

The way the mechanism of figure 3.19 is designed, it is expected that the load of the suturing elements will not be able to be placed, as previously mentioned in this chapter, there will be 40 elements. Thus, this mechanism was improved and the two back rods of the mobile part (2), were removed, to eliminate this limitation and contribute to the load of the suturing elements, keeping the axis attached to both the front and the back, maintaining the balance of movement, as indicated in figure 3.19.

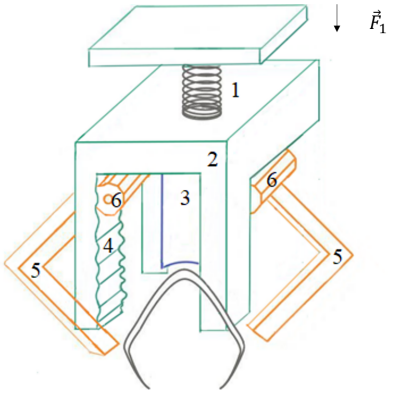


Figure 3.19: Seventh sketch of clamp system.

However, when analyzing this mechanism, it was noticed that, as it is essential that the clamps close as close as possible to the limit of the device because that is where the fall of the fastener occurs and it is at that time that the closing of the fastener has to occur. Thus, it is necessary to eliminate the two front rods of the mobile part instead of the two back rods as represented in image 3.19. The loading of the 40 suturing elements is still ensured since the mobile part will have a width equal to or greater than the width of the fastener, which will allow its fitting. This new mechanism is represented in figure 3.20 and works in the same way as the two methods described above.

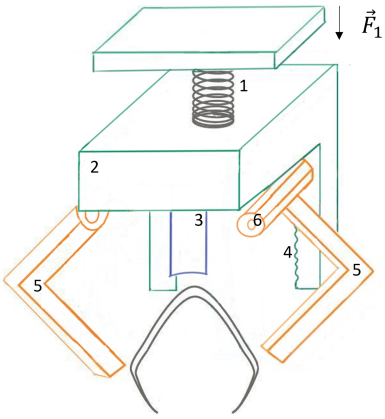


Figure 3.20: Eighth sketch of clamp system.

For the mechanisms in figures 3.18, 3.19 and 3.20 the system would be attached to the front of the device by rails between the front face of the outer part of the device (1) and the front rods of the movable part (2) as shown in figure 3.21. That said, the mechanism would be stable and it was possible to limit some unwanted displacements of the part.

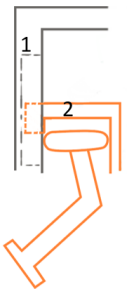


Figure 3.21: Side view of the clamp system with the outer part of the device.

3.4 Complete system

After evaluating the mechanisms previously thought and designed for each system, a mechanism was reached that may be the final solution of the suturing device. The device is composed by the handle system of the figure 3.7 (green), the suture elements support system will be constituted only by the suture elements storage and expulsion system of the figure 3.11 (blue) and the clamp system chosen will be the one shown in the figure 3.20 (orange). Piece (2) illustrates the outer part of the device, which is cut in the figures 3.22 and 3.23, but shows the inside of the device.

In this way, as shown in figure 3.22 when force is applied to the handle, it exerts a rotational movement through the axis (E1), which will compress the spring (1). This in turn will push the moving part (3) of the gripper system (the orange one) downwards as described insection 3.3.1.3, causing the sheaves (4) to rotate and consequently closing the clamps (5) and the suturing element.

The spring (1), as well as being the link between the handle and clamp systems, allows the handle to return to its rest position after being pressed.

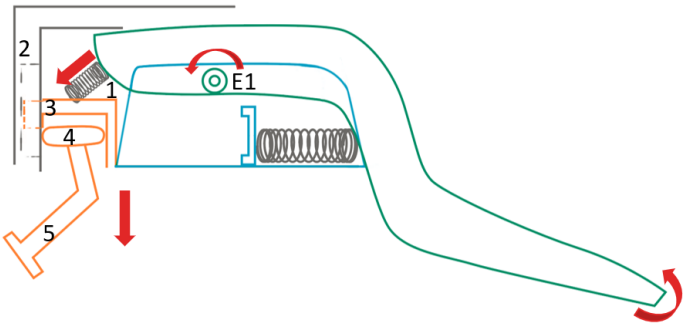


Figure 3.22: Sketch of the complete system for suture support. The red arrows indicate the expected movement when force is applied to the handle.

On the other hand, when the force is no longer applied to the handle, as shown in figure 3.23, the whole mechanism returns to its rest position, causing the spring (6) to distend, pushing the part (7) and consequently pushing the entire refill of suturing elements closer to the device's exit.

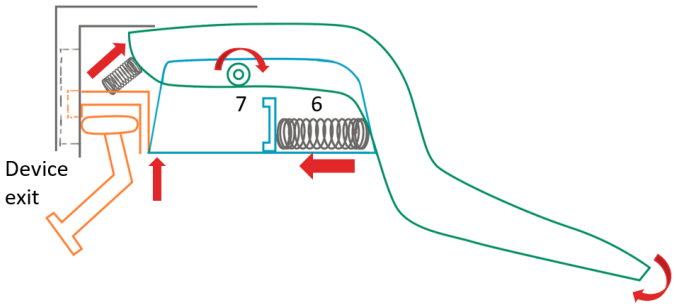


Figure 3.23: Sketch of the complete system for suture support. The red arrows indicate the expected movement when no more force is applied to the handle.

3.5 3D Modeling

After mechanically defining the systems that constitute the suturing device, we moved on to their 3D modulation. During this phase, improvements were made to the mechanisms, which had not been initially foreseen, to obtain a functional and more stable mechanism.

First, the clamp system, shown in figure 3.24, was drawn from the sketch in figure 3.19 ofsection 3.3.1.3.

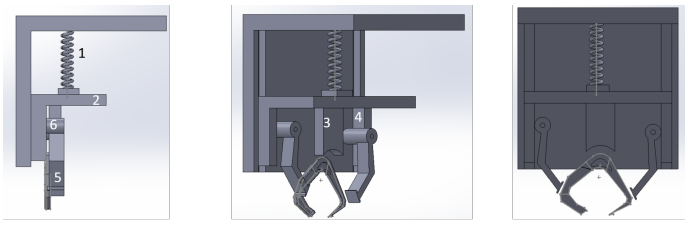


Figure 3.24: 3D modeling of the clamp system of the figure 3.19, where the numbering is identified there. a) Side view. b) Isometric view. c) Inside view.

Subsequently, on analyzing the previous mechanism, it was realized that, after all, it was essential to remove the two rods from the front of the mobile part (2),to allow the closure of the suturing element closer to the limit of the device from which the suturing elements come out. That is, in the mechanism of figure 3.24, the suturing element fell at a distance of the same dimension as the width of the rods of the mobile part (2), whereas this new system does not, falling closer to the limit of the outer part of the device, thus facilitating the closure of the suturing element, as shown in figure 3.25.

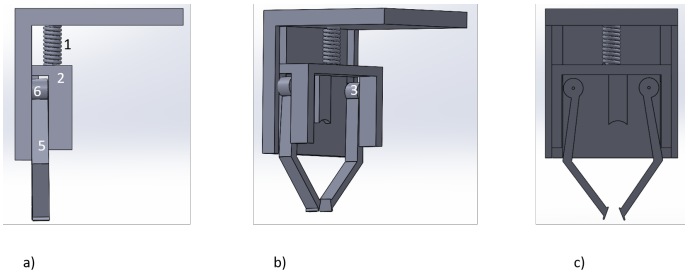


Figure 3.25: 3D modeling of the clamp system of the figure 3.20, numbered. a) Side view. b) Isometric view. c) Inside view.

The support system of the suturing elements, shown in figure 3.26, has been designed with the inside in the planned shape of the suturing elements so that the fit can be adjusted correctly.

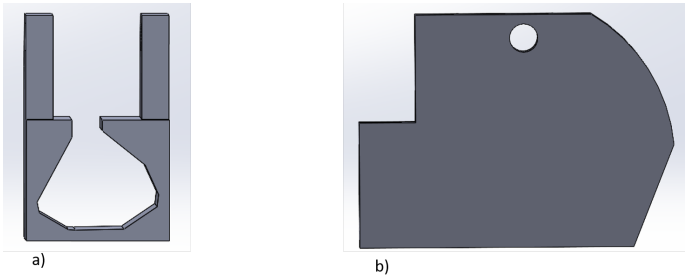


Figure 3.26: 3D modeling of the support of the figure 3.11. a) Front view. b) Side view.

The inside of the support of the suturing elements is also made up of a mechanism that allows them to be pushed towards the device outlet, i.e., as mentioned previously, made up of the part that pushes the suturing elements (3), as shown in figure 3.11, and a spring that will connect the part that pushes the suturing elements to the lever (A1) of the handle. In modeling, we created part (3) in the same shape as the suturing elements so that they are pushed evenly. To hold the spring and guide it in the right direction, a cylinder (1) has been designed at the back of the part which pushes the suturing elements (3). This mechanism is shown in figure 3.27.

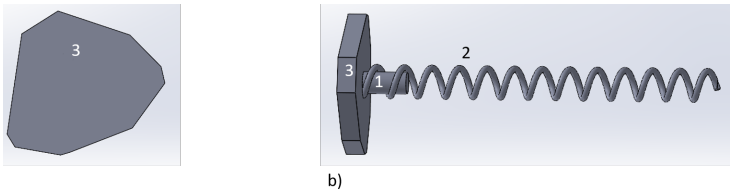


Figure 3.27: 3D modeling of the mechanism that pushes the suturing elements. a) Front view. b) Side view.

Next, the handle, shown in figure 3.28, was modulated, as foreseen when defining the mechanism in figure 3.7, formed with a lever A1 to join the spring of the previous mechanism, with the function of pushing the suturing elements towards the exit.

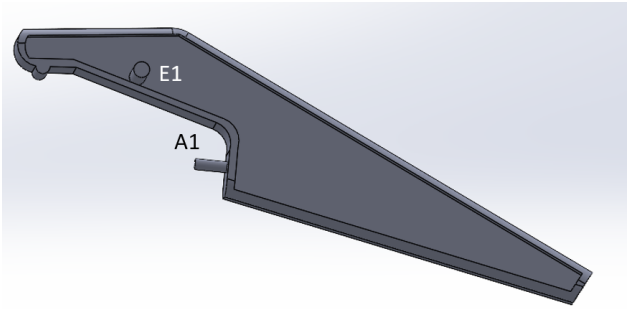


Figure 3.28: 3D modeling of the handle system of the figure 3.7. Side view.

The next step was to join these two systems, the suturing element support system, and the handle system, to the clamp system. And here, it was noticed that, when exerting pressure on the handle to rotate shaft E1 to exert force to close the clamps, the spring that is attached to the handle by lever A1 and the part that pushes the suturing elements (3), it would be forced to change direction, that is, it would be forced to make the same rotary movement as the handle. This movement is illustrated by the red arrows in figure 3.29. Consequently, the cylinder (1), attached to part (3), would break with the repetition of the movement. Therefore, to solve this problem, a joint was created, which admits the rotational movement, to replace the cylinder (1), shown in figure 3.30. However, during assembly, when placing the spring coincident with the part (3) that pushes the elements suturing, will force it to change plane. In other words, the piece (3) is in the plane parallel to the plane of the clamps and performs the movement horizontally, to push the

suturing elements to the exit of the device, but when placing the coincident spring in the piece (3), it will make it move and change the plane, not performing the function correctly. Thus, a new surface 3.31 was created, as shown in figure x, in the plane parallel to the piece (3) and that also acquired the rotational movement.

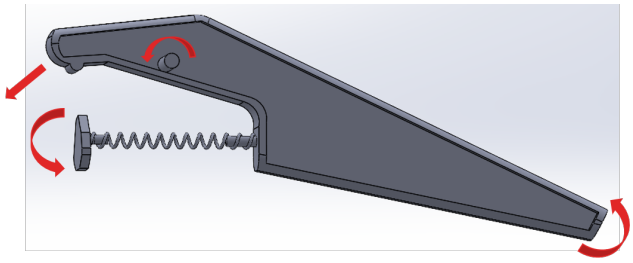


Figure 3.29: 3D modeling of the inside the suture element support system and the handle system. Side view.

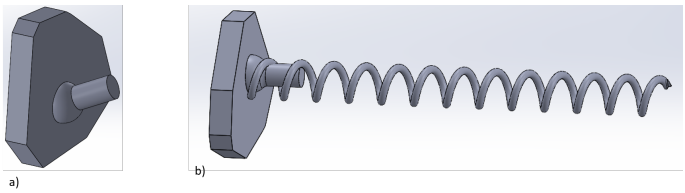


Figure 3.30: 3D modeling of the mechanism that pushes the suturing elements with rotary joint. Side view. a) Piece 3 with rotary joint. b) Piece 3 with rotary joint and spring.

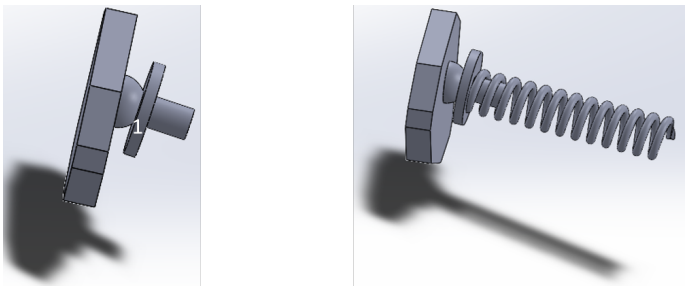


Figure 3.31: 3D modeling of the mechanism that pushes the suturing elements with rotary joint and new surface (1). Side view.

No further constraints to the operation of the device having been found, the three defined systems were assembled with the outer part of the device, as shown in figure 3.32.

It was found that there was a large opening diameter between the handle and the outer part of the device, represented with a red arrow, so the handle design was improved to minimize this opening, to facilitate handling by the surgeon, figure 3.33 shows the difference in opening diameter.

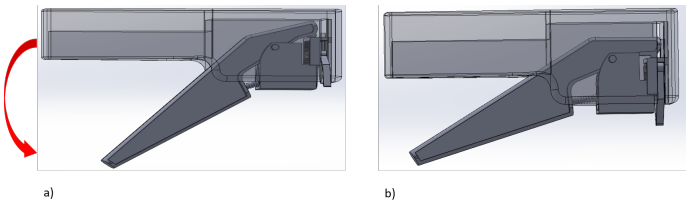


Figure 3.32: 3D modeling of the mechanisms of the three mechanisms together with the external part of the device of the figures 3.22 and 3.23. a) Position of the handle in rest position. b) Position of the handle when handled.

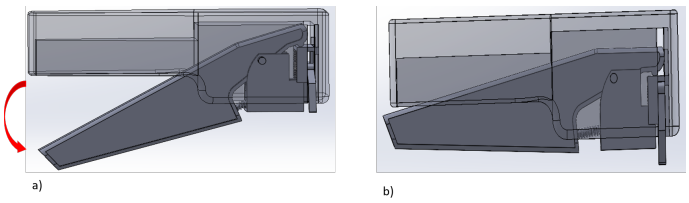


Figure 3.33: 3D modeling of the mechanisms of the three mechanisms together with the external part of the device of the figures 3.22 and 3.23. a) Position of the handle in rest position. b) Position of the handle when handled.

By observing the whole device, we immediately realized that its handling and consequent suturing was difficult, since, as can be seen in figure 3.34, there is no correct angle between the device and the patient. Thus, it was necessary to correct the shape of the handle. This time, it was designed as shown in figure 3.35.

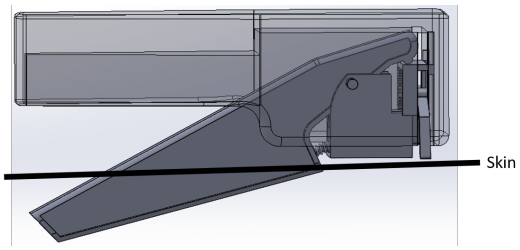


Figure 3.34: 3d modeling of the device, where the handle enters into the patient, during suturing.

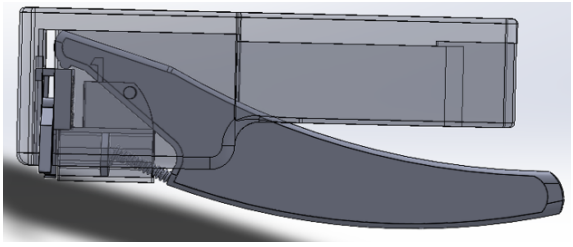


Figure 3.35: 3d modeling of the device with the new handle.

After all the rearrangements we arrived at the final modeling of the device, shown in figure 3.36. Some parts of the prototype can be made of FFF, and PLA, such as the body, i.e. the handle, the moving part, and the external part of the device. The mechanism and the gears can be made using SLA/DLP since these parts need a high detail.

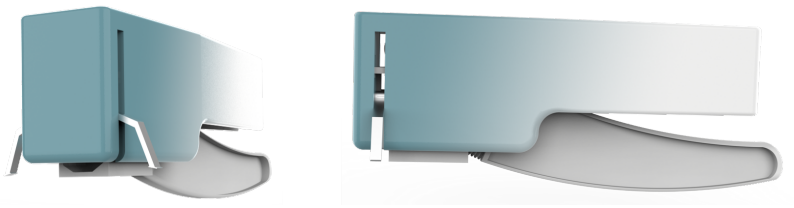


Figure 3.36: Final device.

Chapter 4

Discussion

In this chapter will be presented the comparison and discussion of the systems, mechanical thought in chapter 3. As already mentioned in the previous chapter, the device designed for the skin and fascia closure will presumably consist of four mechanical systems. And for each one of them, several solutions that could be possible and functional were considered. Still in this chapter, it is decided which will be the best systems found so far.

Before developing this mechanical system, a B. Braun Manipler AZ leather stapler, already on the market, was dismantled to analyze the interior and study its mechanical system. This stapler served as a reference to the handle system and support system. The clamp system is an innovative system, and there is still no device on the market that presents it. This is essential given the need for closure and the shape of the suturing element.

The support system for suturing elements is further divided into two systems.

For the storage and expulsion system of the suturing elements, figure 3.11, a system similar to the one already used for other skin suturing devices and paper staplers has been thought of, which will be operated by the lever of the manipulator system (A1). For this reason, it is expected to work well for this case as well.

For the door opening system, as presented in section 3.3.1.2, two distinct mechanisms were thought of. The mechanism in figure 3.9 presents two problems. First, when force F1 is applied, the rods compress causing the door to open, however, for the door to open fully, the rods would have to compress more than the width of the base of the device under construction, as shown in figure 4.1.

Second, it is intended that the mechanism is driven by lever A2 of the handle system to move the entire assembly. However, given that the rotational movement of the handle would make a force contrary to the necessary F1, it would force the door to close and be open in the rest position, i.e., it would be the opposite of the intended purpose.

Thus, a new mechanism was thought, this time in which it would be possible to use the handle to obtain the desired action, like the one shown in figure 3.10. For this mechanism, there would be no mechanical problem, and it could be operated by lever A2 of the handle. However, during the development of this project, it was foreseen that both the size and the shape of the suturing

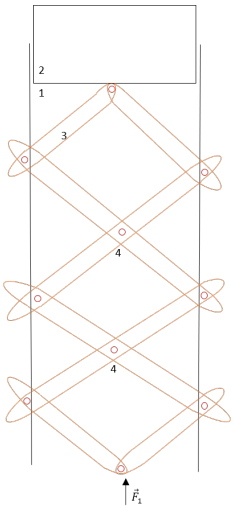


Figure 4.1: First door opening/closing system when F1 is applied.

elements would have to be changed and should be designed with two surfaces parallel to each other, to be able to stack them inside the device. In this way, make like the staples used in the paper that are glued to each other and only come apart when the part (3), represented in all the clamp systems in chapter 3, hits causing the staples to peel off and come out of the device. This ensures that the staples are trapped inside the holder and prevents them from falling out of the device inadvertently. As a result of this approach, the possible assembly of the door open/close system is ruled out.

Based on the conclusion drawn from the staple holder system, in which there is no need to create a door opening/closing system for the removal of the suturing elements, it can be concluded that a second lever (A2) will not be necessary, with the handle depicted in figure 3.7 being most suitable for the intended operation for the future prototype.

The creation of the clamp system was the most challenging for the development of the device since it is an innovative system that will allow the closure of the suturing elements.

The first system considered, shown in figure 3.12, works against logic, since pressing the spring causes the clamps to open, and only when the spring is no longer pressed by the action performed on the handle do the clamps close, thus forcing the element to close. Besides this, and although no mechanical test has been made, this system is expected to be fragile and unstable, since it is anticipated that it will be possible to limit the movement at the top of the system, in the green piece. Thus, this system was discarded.

The second system, represented in figure 3.13, was designed to function like the first one, however with a more robust part and with increased security of movement, in which the idea was to limit the movement both below the green part, which covers the gear (2), and in the part above the spring (1) that would connect to the handle.

However, since the movement remained antagonistic to logic, and in order to resolve this inconsistency, some changes were made to the clamps. To ensure that these would close when

pressed by the spring, the idea was to cross them and to prevent them from hitting each other and not performing their function correctly. The gears were placed at different heights so that the opening and closing movements occur without any surface coincidence problems. Although the system of figure 3.14 works mechanically as desired, in ergonomic terms, as the mechanism was designed horizontally, it will not be easy to assemble it with the other components and obtain the complete system.

In view of this, it was necessary to think of a new system, shown in figure 3.15, which was designed vertically, where the back of the part represents the outer part of the device, where the racks are designed, for the gears to perform the downward and upward movement. This mechanism was thought to be with three springs, where two of them are used to move the gears (2) and the other one to allow the movement of the piece that will make the suturing elements detach from each other. However, when placing racks on both sides of the gears, these cannot move, for this reason, this mechanism is not functional.

Moving on to the next mechanism, shown in figure 3.16, it was taken into consideration that the fewer parts and fewer connections between parts the mechanism has, the more stable the mechanism will be, and the less likely it to will break. Thus, the previous mechanism was updated, piece (3) was joined to the two gears (2), as designed, through support located after these three pieces. Furthermore, in order for the gears to work without constraints, two racks have been removed, one on each side, leaving only one rack for each gear. Given this, it is expected that this system will work, but not in the correct way because when pressing the springs (1), through the handle, the gears will descend and open, instead of closing, to close the suturing element. This makes the mechanism inadequate to perform sutures.

Since the previous mechanism did not work as intended, another vertical mechanism was considered for the clamp closure, shown in Figure 3.18. In this new mechanism, the gears are fixed to the front face of the outer part of the device and the mobile part (2) which acquires a downward or upward movement depending on whether or not force is applied by the handle. And in this same piece, the four racks in the four rods are illustrated so that the movement of the gears is facilitated and stabilized. However, the fact that the mobile part (2) has two back legs makes it impossible to load the suturing elements. In this way, it was necessary to update the mechanism and remove these back legs, as shown in figure 3.19, and in this way, we considered to have established a functional mechanism.

For the mechanisms of figures 3.18 and 3.19, the system would be attached to the front of the device by rails between the front face of the outer part of the device and the front rods of the moving part (2) as shown in figure 3.21. That said, the mechanism would be stable and it was possible to limit some unwanted displacements of the part.

After the study, the complete device will consist of the systems of figures 3.7, 3.11, and 3.19. For connection between the three systems, it was intended to use spring (1) of figure 3.22 and spring (6) of figure 3.23. With everything defined, we proceeded to the 3D design in SolidWorks of all parts of the device, and here we had to make some corrections. Firstly, in the clamp system, it was realized that the front rods would hinder the closure of the suturing element since its closure

should be as close as possible to where they fall after being pushed, as that is where the clamps are to allow closure. The way the mechanism of figure 3.19 is designed the suturing elements would fall at a distance of the width of the rods from the front of the moving part (2). Thus, it was necessary to update this mechanism again, and the front rods of the mobile part (2) were removed and the rear rods were put back in place. As the part is open in the center, there was no problem in loading the suturing elements since, if this happens, it is possible to increase the width of the part without interfering with the functioning of the complete system. It was thus concluded that the ideal mechanism for the clamping system was reached this drawn in 2D in figure 3.20.

Subsequently, in the mechanism that pushes the suturing elements of the storage system, the cylinder (1) of the piece that pushes the suturing elements would have to be replaced by a rotary joint, since, as it has more degrees of freedom, it allows the spring that is attached to follow the rotary movement that the handle has to make when it is pressed by the surgeon's hand, to activate the whole operation. With all this, it was also necessary to create a new surface near the rotary joint, to place the spring fixed there, without causing movement interference of the piece which pushes the suturing elements and maintains the necessary rotary movement.

In the handle system, two problems were found. The first referred to the opening angle between the handle and the external part of the handle, which was large and made handling difficult. The second was related to the format that is initially presented, in which, for the suturing to occur, the handle would have to enter inside the patient. To solve this problem, three solutions were found. The first would be to change the angle, to 45º, of the front of the exterior part of the handle. The second would be to change the shape of the handle so that it would be at the same level as the opening of the device for the exit of the suturing elements. Given the progress in the construction of the device, the second option was chosen, as it would be the easiest to implement without causing constraints in the functioning of the device. As shown in figure 3.22, the spring (1) was removed, since to implement it in the system it would be necessary to establish a mechanism that would help fix it and only perform its function, which would be to maintain the handle in the correct position.

Given this, a more simplified solution was found, which consists of replacing spring (1) of figure 3.22 with a metal band, attached to the handle. This metal band would make it possible to bend the spring without exceeding its elastic point. This way, after pressing the handle it returns to the initial position. However, this mechanism will be designed in the continuation of this project.

Chapter 5

Conclusion

To finalize this dissertation, this chapter epilogizes all the conclusions to be retained from this study and, in addition, some suggestions are made to give continuity to this work.

5.1 Conclusions of the project

This project provided an enormous learning experience, both in terms of product development and in terms of the manipulation of computer tools, in 2D and 3D design software.

According to Technology Readiness Levels (TRL), in this project we have moved from the TRL1 level to a level between TRL2 and TRL3. That is, we moved from a basic research phase to concept formulation and 3D development of the device.

Before developing the product itself, it was verified that there is no identical or patented solution on the market. Therefore, we studied the possibility of submitting a provisional request for this device, which we concluded would cost 3,000 euros nationally and 6,000 euros abroad. Therefore, before submitting it, we analyzed the certification process, which will have an initial cost of at least 50,000 euros, plus an annual cost of 15,000 euros. It should be mentioned that this does not include the value of additional tests such as usability testing, the application fee for the notified body, analysis of technological files, ISO, annual management, and audit fees.

In this project, the first three phases of product development, requirements presentation, generation, and concept development were completed. The requirements that had in their sights during the development were to shorten the suture time and consequently decrease the surgery time and maintain good visibility for the incision.

With this in mind, they proceeded to the concept generation phase, where they first planned the mechanical solution of the device and found that the most advantageous and functional solutions are those shown in figures 3.7, 3.11 and 3.20, and arrived at the device in figures 3.22 and 3.23.

In the concept development phase, and as a result of this dissertation, the mechanical system for a cutaneous suture support device was obtained, which is completely innovative for the market, due to the inclusion of a clamp system for closing the suturing elements. The prototype will be developed in PLA. The final product will be produced in Acrylonitrile butadiene styrene (ABS)

and metal. ABS has commonly used in the manufacture of OEM (Original Medical Equipment) parts and 3D printing manufacturing. It is an excellent alternative to engineering plastics or metals for structural parts due to its impact resistance, heat resistance, and hardness. It can be injection molded, blow molded or extruded, cast, remolded, and sterilized by gamma radiation or ethylene oxide (ETO). The use of ABS will allow obtaining a product with reduced weight and low cost since the device is intended to be disposable after the first use. This material also allows the acquisition of a product with specific structures and aesthetic characteristics. The metal would only be used for the gears, the clamps, and the metallic band.

5.2 Future Work

After the conclusion of this dissertation, there are still several tasks to be accomplished in the future to improve the device and make it functional and stable, until reaching the last phase of product development, which is the market launch.

First, to further develop this product it is essential to stabilize the parts, as a suggestion, could be built snap-fits in the support, to fit the outer part of the device.

Then, in future work, it is suggested the development of a physical prototype for the final solution of the suture support system. Using this prototype it could be possible to verify its functionality by assembling the different components. With this, it will be possible to verify that these components work with each other without any kind of restrictions.

The prototype could allow to understand what kind of changes should be made, or if more or fewer components should be incorporated for it to work as designed.

In the future this solution may be improved, resulting in a simpler solution, and the final product resulting in this dissertation may serve as a basis for the development of similar products. It is also required to proceed with the patent registration of this solution.

Regarding the resulting methodology, it is possible to continue its development, since it can always be improved. Once the size and shape of the suturing element are defined, it will be possible to redefine the dimensions of the parts of the device to make it functional and practical in a hospital environment, as well as to make a mechanical study of the gears. This study concerns the size and number of teeth it should have to achieve the correct closure of the suturing element without breaking.

The last suggestion is the concept validation, in which numerical simulations should be performed, based on the finite element method (FEM).

Appendix A

Annex 1

Interview with Dr. Pedro Lobo.

1. What is the ideal number of staples the system should have?

   The stapler must have approximately 40 suturing elements since the incisions have an average length of 25 cm and the staples are placed every 0.5 cm. The staples, when closed, should be approximately 8mm long.

2. Do you think the addition of the clamp would be useful?

   The forceps that grasp and approximate the structures to be stapled are dispensable because the approximation of the aponeurosis of the two structures to be closed is done with insertion forceps by the surgeon and the assistant since the two margins are sufficiently far apart to require someone to approximate them with some resistance.

3. Do you think it would help to overcome the need for another member of the surgical team to approximate the tissues?

   After the margins are approximated and fixed with this equipment clamp, it could be done, but that doesn't eliminate the need for the assistant and the surgeon to approximate the two edges.

4. When observing the sketches, which characteristics do you prefer the most?

   The characteristic that I prefer the most is the vertical tightening.

5. For stapling, would you choose a continuous force mechanism to fire the staple and close the edges, or an on/off model mechanism?

   I prefer the continuous force mechanism because the anatomical structures vary from person to person and so if this mechanism is applied, it allows me to observe the staples coming out and thus to control and adjust the necessary force so that the staple is fixed more on the surface or more in-depth.

   In summary, the clamp should be excluded, the equipment should be vertical clamping with a continuous force mechanism to fix the staple.

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