Development of a new ligament tensioner

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Abstract

The increase in the number of people performing sports and the high physical intensity that professional athletes are subjected potentiate the appearance of injuries. One of the most common injuries is the ligament ruptures that can occur by a strong impact on the knee or during abrupt movements that force the joint to exceed its physiological limits. Currently, doctors' choice for reconstruction of the ligament recalls to the arthroscopy technique because of its non-invasive behaviour that allows exploring the interior of the joint without causing great damage to adjacent tissues. In a ligamentoplasty, the main objective is to recover mobility and stability of the affected zone. This surgery consists of removing the damaged ligament and replacing it with a graft from the patient or a corpse. In the final step of the surgery, the doctor applies tension to the graft and performs cyclical tests on the joint before the operation ends with the fixation of the graft or neo-ligament. Fixing the graft with a given tension value not only controls joint's amplitude and stability but also promotes the revascularization of the neo-ligament reducing the time of recovery after surgery. Therefore, the objective of this dissertation is to develop a device to help orthopaedic surgeons, informing them about the module and the direction of the tensioning force during graft's fixation. In this sense, the model of product development of Karl Ulrich and Steven Eppinger was adapted to the proposed objective, and two concepts were conceived, prototyped and tested together with an orthopaedic physician. After selecting the winning concept, the material was chosen and the mechanisms and respective components were dimensioned.

Keywords: medical device, knee ligaments, tensioning ligaments, product development, mechanical design.

1. Introduction

With the emergence of new materials and manufacturing methods, it has become possible to offer several solutions to the problems that arise in the field of orthopaedics, from prostheses, medical devices to monitor or assist during and after surgery, grafts and new techniques of high efficiency.

The growth in the number of citizens performing sports has led to an increase in the number of injuries. At the high-level, sport athletes have a relatively short career compelling them to be in peak form for as long as possible. However, workout routines and competitions constantly expose the body to an effort, increasing the risk of injury. One of the most common types of injury in the world of sports is the ligament rupture that occurs when the ligaments are suddenly stretched or torn. Anterior Cruciate Ligament (ACL) rupture ranks sixth in the list of the most common surgeries in orthopaedics, being performed between 75,000 and 100,000 per year in the United States, a number that is increasing every year [1, 2].

One of the main steps during the final phase of the operation is the graft's pre-tensioning. The graft is subjected to tension while the surgeon tests the joint and is also important to ensure that graft stays with the desired tension at the moment of fixation [3]. This step aims to guarantee the essential conditions for the neo-ligament to correctly perform the functions of the initial ligament and decrease recovery time after surgery, contributing to the patient's well-being. However, surgeons seeking for speed and simplicity, select in most cases to apply this pretension manually without knowing the stress modulus that they are applying to the graft.

Throughout this study, it was observed that almost every ligament tensioner available in the market was designed specifically for some techniques of ACL reconstruction, limiting the number of techniques and making it impossible to use them in ligaments of other anatomical zones. The

development of a medical device to assist specialists during ligament reconstruction, that uses a simple and practical system to help them regulate the direction and the magnitude of the applied force at the moment of graft tensioning, will increase surgical performance.

To achieve the main objective, several studies were carried out on the necessary topics for the creation of this new device, specifically literature review of the various anatomical elements and surgical techniques related to the reconstruction of the ligaments: devices already on the market, common materials used in the surgical environment and their properties, strategies and plans used in the development processes of similar products. Design of new solutions was possible with the 3D CAD software Solidworks. Prototypes were fabricated using additive manufacturing technologies for a more detailed analysis of the concepts. After the selection of the winning concept, a study of the design, sizing and tolerance was conducted.

2. Background

2.1. Ligamentoplasty

Surgical treatment of ACL rupture is an imprecise intervention. It is impossible to reconstruct the neo-ligament identical to the original, given the complex three-dimensional fiber orientation, guaranteeing the original insertion region and orientation [4]. When the neo-ligament is subjected to loads that act on the knee, it will never have an identical response as the original ligament, however there are some cases that provide positive results, similar to the original one.

Reconstruction surgery is used when ligament damage is significant and there are signs of pain and instability in the knee. In this case, the ligament is totally removed and replaced by a graft. Currently, the most used surgical technique is the arthroscopy, where three small incisions (portals) are opened around the indicated frontal area of the knee as shown in **Figure 1**.

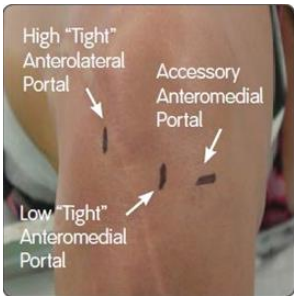

Figure 1: Location of the 3 portals used in knee arthroscopy surgery [2].

After the measurement and preparation of the graft it is necessary to open the tibial and femoral tunnels that will house the graft [5]. The graft is inserted into the tunnels and one tip is attached to the femur. Before attaching the free tip to the tibia, it is necessary to ensure that the graft is under the desired tension to perform a flexion-extension cycle test to the knee. The purpose of this test is to verify the correct functioning of the joint by simulating the flexion-extension movement and to accommodate the graft in the femoral and tibial tunnels. Only then the tip is fixated to the tibia with a predetermined tension.

2.2. Graft tensioning at the time of fixation

It has been shown that small changes in initial graft strain cause significant differences in knee stability [6]. The value of the tension to be applied to the graft depends on several factors, such as the height of the patient, the graft type and fixation technique [4].

When analysing how the ligament tension varies during the passive knee flexion-extension movement, two peaks of maximum tension were found, corresponding to the positions of maximum extension and deep knee flexion. The minimum value in ACL tension is recorded when the flexion angle is half the maximum flexion angle [7]. Figure 2 shows the range of knee flexion-extension angles.

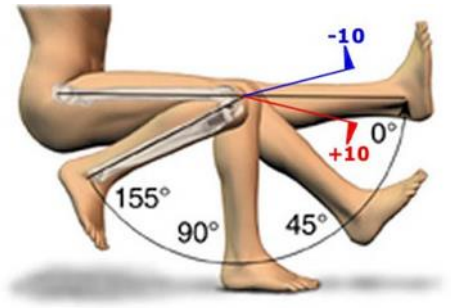

Figure 2: Range of knee flexion-extension angles [8].

To ensure that the graft is under the desired stress, the following factors must be considered: patient dimensions, graft material, size and type, accommodation tunnel dimensions and accuracy, contact surface graft-tunnels and bone's quality. Some of these variables depend on the surgeon level of experience, however many of them are peculiarities of the patient that cannot be controlled by the surgeon.

If the applied tension is much greater than the recommended, the mechanical properties of the neo-ligament can be changed leading to problems related to: revascularization and neo-ligament degeneration, increased compressive forces at the tibiofemoral joint, joint cartilage damage, conflicts with LCP , loss of mobility, restrictions on the amplitude of the flexion-extension movement [1], [10–12].

On the other hand, if the applied tension is insufficient, the stability of the knee is not guaranteed which could give rise to new injuries. Some experts suggest that a low initial stress can lead to rapid deterioration of graft properties by altering knee kinematics soon after reconstruction [12].

Manual tensioning is by far the most commonly used technique. However, it is based only on the instant graft behaviour which is not enough.

2.3. How direction affects graft tensioning

Inappropriate alignment between force direction and tibial tunnel axis causes changes in graft's tension during fixation affecting the biomechanical properties of the neo-ligament. The optimal position to apply and maintain a uniform tension along the graft, with the aid of a proper device, is the one that ensures the collinearity between force direction and the axis of the tibial tunnel. Any deviation in the medial and lateral planes with respect to the axis leads to significant variations in the graft tension values.

2.4. Graft's fixation techniques

The method of bone fixation is generally the most fragile aspect in reconstructive surgery of ligaments [14]. For it, is necessary to ensure the correct positioning of the fixation device so that the graft is fixed in tension and that the losses of tension are minimum.

Currently, the most commonly used fastening devices are metal or polymer interference screws and the cortical suspension system that uses an endobutton. These mechanisms are represented in Figure 3. These techniques allow the attachment zones to match with the attachment points of the original ligament and promote the biological recovery of the affected area.

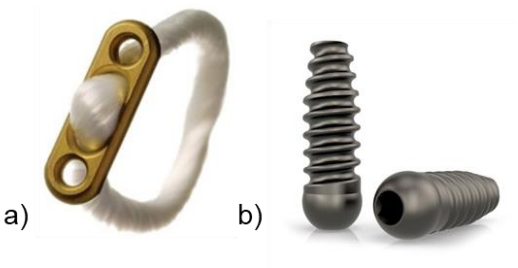

Figure 3: Fixation techniques: a) Endobutton b) metal interference screws [15], [16].

2.5. Possible technical errors caused by the surgeon

Representing about 90% of the causes of neo-ligament malfunction, the technical errors that depend on the orthopaedist are: the poor positioning of the tunnels; improper selection, harvesting or preparation of the graft; inappropriate graft tension; the poor fixation of the graft and the lack of correction of associated instability.

These errors can be caused either by excessive or insufficient stresses. These, besides not to guaranteeing knee's stability, do not generate moderate graft demand nor promote the beneficial effect of collagen deposition and orientation in the neo-ligament [4]. It is certain that a device that reduces the probability of these errors occurring will

be fundamental in increasing the performance of the neo-ligament and in the efficiency of reconstructive surgeries.

3. Design and new product development

The ligament tensioning device was developed using the product design and development model based on the one proposed by Karl Ulrich and Steven Eppinger. This work focused on the implementation of the first two stages: product planning and concept development - **Figure 4**.

To synthesize all the gathered information was used the tool house of quality (HoQ). This tool was used to guide the sub phases of concept generation, selection and prototyping by relating the identified needs with the product specifications and the concurrent market analysis.

3.1. Opportunity Identification

Identifying the opportunity came from an orthopaedic surgeon who specializes in knee ligament reconstruction surgeries, who launched the challenge of creating a device to be used in ACL reconstruction surgeries. The device must tension the graft with a predetermined tension and ensure that the direction is aligned with the axis of the tibial tunnel.

Devices available on the market have the sole purpose of assisting the reconstruction of the ACL. This has identified a new opportunity in which the new device will also serve to rebuild other ligaments beyond the ACL.

The main aspects that lead doctors to avoid using this type of device are: few information about the benefits that the applied force can provide; difficulty handling the device; another device to enter the instrument table in the operating room; costs of sterilization and the large volume occupied by the device, that may interfere with other devices. These opportunities are presented in **Table 1**.

Table 1: Mission Statement.

Mission statement	
Product Description:	Universal device for tensioning and directing grafts in reconstructive surgeries.
Benefit proposition:	Control of applied force magnitude; Control of force direction; Greater adaptability and usability.
Key product features:	Be easy to use; Be versatile; Be innovative; Be effective and simple.
Primary Market:	Orthopaedic doctors who perform ligament reconstruction surgeries.
Assumptions and constrains:	Sterilisable materials; adaptable to different anatomical regions.
Stakeholders:	Consumers (Hospitals, doctors); Manufacturers of medical devices

3.2. Identifying Customer Needs

To identify customer needs, data from potential users of the product was collected through questionnaires, interviews and meetings with orthopaedic doctors and witnessing ACL reconstruction surgery. To guide the design and generation of concepts for the new product, the qualitative assessment and understanding of the needs of the individual were made.

The needs were classified into four main groups: adaptability and universality, usability, variable control and design. The list of customer needs was used to fill the first column of the HoQ defining the line quantity – **Figure 5**.

Each need was assigned a relative importance (from 1 to 5), so that the most important are the ones that allow the desired clinical effect to be achieved (adapts to various anatomical regions, compatibility with different surgical techniques,

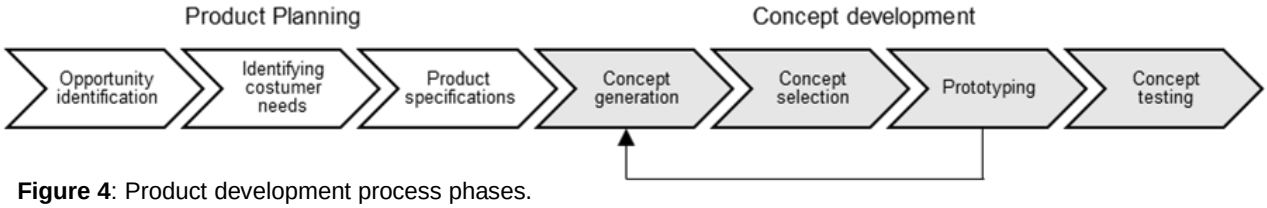

Figure 4: Product development process phases.

control of applied force module and direction) and that interfere with the acceptance of the device by the user (being easy to use and install, low weight, no blind spots, hands free and sterilisable).

3.3. Product Specifications

Product specifications quantitatively characterize product performance. To select them, the needs identified in the previous section were used and a market study of competing products was carried out. These specifications consist of a translation of the customer needs into technical requirements that can be worked out by engineers so that the new product can achieve the objectives settled. Product specifications define the quality house columns - **Figure 5**. Next to each specification, there is an arrow that indicates which direction engineers should follow, maximize or minimize, to achieve customer satisfaction.

3.3.1. Review of the competing devices

The analysis of these devices made it possible to understand the techniques used by the competition to satisfy certain consumer needs. The four devices analysed were divided into four different sections: patient-device interface (D-A), wire fixation, power transmission system and surgeon-device interface (A-M), characterized by the function / objective they perform.

According to surgeon's perception (from 1 to 5), all needs were classified to obtain a general performance for each of the competing devices. Needs: control of the direction of applied force; adaptable to the anatomical region; maintenance; compatible with different surgical techniques; easy to install; non-aggression, obtained ratings below 70%. These needs are features where the new product can be distinguished from the competition and for that reason they were taken into account during the concept generation phase.

3.3.2. House of Quality

HoQ organizes and relates all information collected. Through the analysis of the HoQ, the priority specifications for the generation phase of the concepts are obtained. The central matrix (relationships matrix) was built with the weight of the relationships between specifications and needs. The weight of each relation can vary between 9 (strong relationship), 3 (average relationship) and 1 (weak relationship). To understand how each specification might help satisfying customer needs, its relative importance was calculated by the sum of all relationships.

The highest values represent the group of specifications that may lead to the best overall need satisfaction. The concept generation phase should rely on: low total number of components; highest number of anatomical areas covered; highest number of compatible techniques; low volume; low manufacturing cost; low occupancy volume of the working area; ergonomics.

3.4. Concept Development

Initially, it was decided to divide the main problems into the following subjects: energy, brake, graft, adapter and steering. Afterwards, these main problems were divided into smaller problems.

By reconciling this top-down approach with the selection done in the previous section, it was possible to formulate a set of ideas and solutions for each identified problem, that gave rise to the concepts further developed. The first concept generation, selection and prototyping cycle started with a choice of direction, guided by the knowledge acquired from the previous phases. In total, 2 different concepts were developed, where the first concept gives a set of learning arguments used in the generation of the second concept.

	Customer Needs		Nº of anatomical areas covered - [1 a 4]	Nº of compatible surgery techniques - [1 a 5]	Materials elastic deformation - [Mpa]	Available force range - [10 ; 120] [N]	Nº of total parts - [1 a 50]	Nº of steps during utilization [1 a 10]	Nº of steps to (un)install [1 a 8]	Time for (un)install [s]	Percentage of standard parts [%]	Ergonomics [%]	Intuitive appearance [%]	Work occupancy volume [mm³]	Longest length [mm]	Bending stiffness [N/m]	Angle of applied force direction with tunnel axis [º]	Total weigh [g]	Total volume [mm³]	Fatigue resistance [Nº of cycles]	Erosion wear [m³/Nm]	Glass transition temperature [ºC]	Resistance to thermal cycles [Nº of cycles]	Liquid and gas reactivity	Production cost [€]	Production time [s]	Finishing [µm]	1	2	3	4	5
			↑	↑	↓	↑	↓	↓	↓	↓	↑	↑	↑	↓	↓	↑	↓	↓	↓	↑	↓	↑	↑	↓	↓	↓	↑					
Adaptable and universal	Adaptable to anatomical region	7,1	9	9			9		3	3	1	1		3	1		1		3						3				A C D			B
	Compatible different surgery techniques	7,1	9	9	3	3	9	3	3	3	1	1		3	1		1		3					9	3				A	C	B D	
	Non-aggressive	3,6	1				1			3																	3		C D		A	B
Usability	Maintain applied strength - Hands Free	5,7			9	3	1	1				3				1	1											B				A C D
	Easy to use	6,4	3	3			3	9				9	9	3	3			3	3												A	B C D
	Easy to install	6,4	3	3			9		9	9		9	9	3				3	3										C	A D		B
	Simple and intuitive	5,7	1	1			9	9	9	9	3	1	9	1					1										C		A D	B
	Minimize blind areas in surgeon's view	5,0	3	1			3							9					9										C	D	A	B
Variable control	Applied force module	7,1	9	3	9	9									9	9				9										A B	C D	
	Applied force direction	5,7	9	3	3											9	9											B	A C			D
	Retensioning	5,7			3	3		3								1				9								B				A C D
Design	Light materials	5,7	1									3						9								9				B C	D	A
	Low volume	4,3	1	1			3							9	9			3	9											D	A	B C
	Sterilisable	5,7																			9	9	9	9	3			A				B C D
	Easy cleaning	3,6	1	1			3												3		3			3						C D	B	A
	Low cost	5,0	3	3	1	3	3				9	3		3				3	9		3	3	3	3	9	3	9					
	Designed for manufacturing	5,7	1	1			9				9	3	3	3		3			1						9	9	3			C D	A B	
	Maintenance	4,3	1	1		1	9				9			1					3	9	9	1	3	3	3		9	A		C D	B	
	Relative importance (%)		**8,2**	**5,9**	4,2	3,3	**9,7**	3,6	3,6	3,8	3,9	**4,8**	4,3	**4,9**	3,2	3,4	1,7	2,8	**5,8**	3,6	2,7	1,7	1,9	3,6	**5,2**	1,6	2,6					

Figure 5: House of Quality.

3.4.1. Concept 1

The design effort of the first concept focused on the ease of installation, universality and maintenance of the constituents of the device. This concept uses two subassemblies, one responsible for applied tension and the second responsible for adaptability and to control the direction of the force – **Figure 6**.

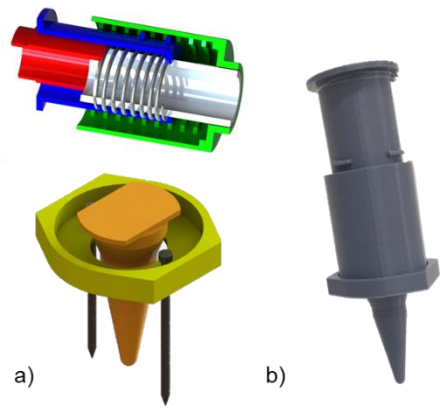

Figure 6: Concept 1: a) renders, b) prototype.

The subassembly "aplicador de tensão" uses two components with side flaps designed for the brake system, which is activated with the rotation of the inner part. The force transmitting spring is located between the outer flap component and the suture wires part. The subassembly "adaptador" uses an alignment cone to ensure that the direction of the force matches with the axis of the tibial tunnel.

After analysing the prototype, it was found that it occupied a large volume of the work area, was not compatible with all surgical techniques and that its closed geometry hinders visibility of the accommodation tunnel.

3.4.2. Concept 2

This concept emerges as a proposal to improve the previous concept, keeping the design focus on ease of installation and universality, adding compatibility with different surgical techniques and minimizing the volume of occupancy of the work zone. The option of two subassemblies was maintained as in

the previous concept, but this time with an "open" geometry that offers total visibility over the accommodation tunnel. This concept uses two gutter mechanisms, the first mechanism defines the brake system where the inner gutter has a toothed profile; the second mechanism defines the force transmission system by using the toothed rack and the gutter with notches for securing the sutures wires - **Figure 7**.

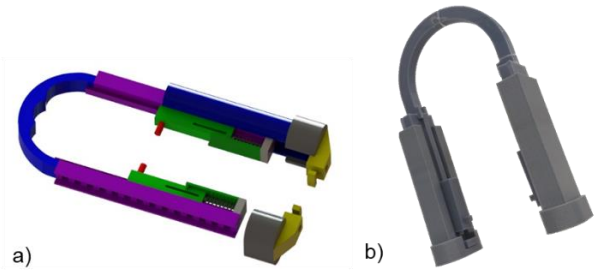

Figure 7: Concept 2: a) render, b) prototype.

After the analysis of the prototype, it was verified that this concept presents improvements regarding the customer's satisfaction of the following needs: compatibility for different surgical techniques, direction of applied force and reduction of blind areas in the field of surgeon's vision. The use of pegs still does not satisfy the need not to cause aggression. Compared to the previous concept the number of parts, the lower volume and ergonomics this concept presents worse results. On the other hand, it performs much better in relation to the greater number of compatible techniques, the low volume of occupancy of the work zone and the low cost of manufacture, reasons why this concept was chosen the one to proceed.

4. Winning Concept Design

In this phase of design, the subassemblies and mechanisms of the winning concept were developed, turning it into a functional product. The material selection, the mechanisms and components used are defined, the components are dimensioned, and the tolerance is defined for the correct operation of the device is defined.

4.1. Material Selection

The material selection took into consideration the following criteria: availability, design constraints, cost per unit, properties, regulatory compliance, aesthetics and usability, biocompatibility, sterilization and cleaning, manufacturing efficiency and sustainability [17]. The features that most influenced the process of material selection were the forces acting on the device, sterilization and low cost of production. In order to simplify the material selection process, the AISI 304 steel was chosen as the main material, because it is constantly used in medical devices and auxiliary tools in the operating room. To decrease the total mass of the device and the costs per unit some components should be manufactured in PPSU, a polymer that supports several cycles of sterilization without losing its properties. In addition to the common manufacturing processes for producing polymer parts, PPSU can also be used in additive manufacturing techniques such as 3D printing.

4.2. Subassemblies

The new device uses two subassemblies for ease of installation and handling. The subassembly called "aplicador de tensão" is responsible for applying the force that is tensioning the graft and the subassembly "adaptador" that enables the device to be used in different anatomical regions. The two subassemblies are presented in **Figura 8**.

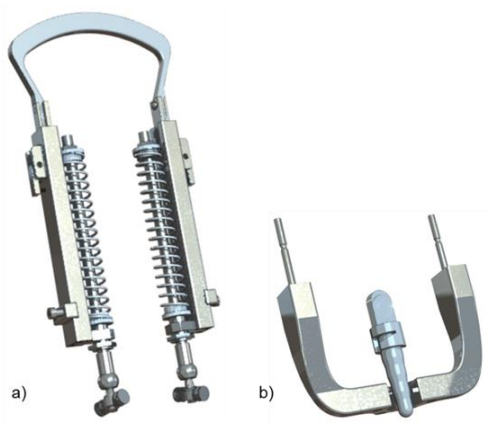

Figura 8: New device. a) Subassembly "Aplicador de tensão, b) subassembly adaptador.

To the "aplicador de tensão", three mechanisms were developed: the spring mechanism with a force range of 10 to 120 N with 10N increments; the brake mechanism which offers the possibility to maintain and / or change the applied force; and the handle mechanism which makes it possible to use other auxiliary surgical instruments simultaneously.

To the "adaptador" three mechanisms have been developed: the coupling system between the two

subassemblies that use connection pins locked by spherical spring screws, that act as decoupling force regulators; the system for removing the alignment piece from the accommodation tunnel; and the two methods of attachment to the body, the first one with pins which offers greater stability but causes aggression in the patient and the second with small spikes which is less stable and requires the support of the doctor but does not inflict damage into the patient.

4.3. Components Selection

To reduce costs and facilitate the maintenance of the device, standard components were used as much as possible. Rounded edges have been rounded to avoid causing aggression to the patient by making the device more ergonomic for the physician and to reduce stress concentration on the parts. The reconfiguration to an "open" geometry involved changing a central spring to two springs in parallel and it was necessary to design the springs and synchronized both of them with the chosen value for the tooth gap (5.1mm). With the 10 N increments 10 N in the device, each spring should have an elastic constant of k = 0.98 N/mm. An iterative process was used, and the final parameters obtained are shown in **Table 2**.

Table 2: Spring parameters.

Parameter	Values	Observations
L_0	**90 [mm]**	$L_s = pN_a + 2d$
k	**0,98 [N/mm]**	$k = \frac{Gd^4}{8D^3N_a}$
d	**1,44 [mm]**	-
D_m	**14 [mm]**	-
Material	**-**	wire 17-7 PH Stainless Steel CH900
Ends	**Closed Grounded**	-
D_{ext}	15,44 [mm]	$D_{ext} = D_m + d$
D_{int}	12,56 [mm]	$D_{int} = D_m - d$
L_s	24,77 [mm]	$L_s = dN_t$
F_s	63,93 [N]	Max Force
N_a	15,2	Active coils
N_t	17,2	$N_t = N_a + 2$
Index	9,72	$C = \frac{D}{d}$, $4 < C < 12$

4.4. Tolerances

To ensure a successful assembly of the device, some mechanical design details must be established to avoid flaws or defects in the final mechanism. The correct planning of constructive aspects, such as adjustments and the choice of machine elements, is a fundamental step to build an operating device. The tolerance class chosen followed standard ISO 2768-cL [18].

Since the permissible deviations of the dimensions for very coarse tolerance class are too high and could cause interference between parts, a coarse tolerance class was selected. This interference may cause the device to malfunction, causing unnecessary distractions to the physician.

The roughness class was taken from the tables 10.17 e 10.17, pages 361 e 362 from the book “Desenho Técnico Moderno”, based on the standard ISO 1302 [18]. Class N8 (3.2µm) was chosen because it had the desired roughness values and was available for a large number of manufacturing processes. These features can help to make manufacturing costs lower.

4.5. User instruction guide

This device is only called to act during graft tensioning and fixation phase. After the graft’s preparation and the accommodation tunnels are open, the adapter is installed into patient's leg near the accommodation tunnel and the graft is inserted into the knee. The alignment cone, selected basis on the graft diameter, is inserted into the tunnel until it is adjusted. Thanks to its variable diameter geometry this adjustment is almost automatic. The orthopaedic doctor has two options for attaching the adapter, fixing it with pins or fixing it with spikes. After the stability of the fastening is ensured, the alignment cone is removed with a slight rotation and the suture wires of the graft are placed in the empty space left by the cone. Then the tensioner subassembly is coupled to the adapter using the coupling dowels, the suture wires remain in the fixtures.

To apply tension to the graft, the user should place one hand on the handle and the other on the outside rails of the device and make it comfortable to perform the traction movement. By forcing the

handle away from the knee, the graft begins to be tensioned. The modulus of the applied force can be visualized on the scale as the inner spring veins emerge through the inner bore of the bushings (indicator pointer).

Upon reaching the desired tensioning force, the doctor can release the handle as the brake system is automatically actuated. If necessary, the doctor can change the force applied to the graft by pressing the tabs to unlock the brake mechanism. After graft fixation to the tibia, it is only necessary to remove the fastening bolts and disassemble the device from the leg. At the end of the operation, the device is sterilized by autoclaving together with the other used tools.

5. Conclusion

In the present work a new device to tensioning ligaments was developed to support arthroscopic surgeries. This operation is one of the most frequent orthopaedic surgeries and consists in removing the damaged ligament and replacing it by a graft. The neo-ligament must be attached to the bone under tension. In most of these surgeries the force is applied manually by the surgeon.

This device aims to assist surgeons during the fixation phase of the graft by providing them with the module and the direction of force applied in a simple and practical way. By controlling these two variables, will be easier to the physician to promote the correct functioning of the joint and decrease the recovery time after surgery. It is important to understand the role of the ligaments in the knee joint as well as the injuries and related treatments to recognize the importance of the developed product.

The product development model proposed by Karl Ulrich and Steven Eppinger guided the process starting with identifying the customer needs presented by an orthopaedic doctor to the presentation of the final product. To motivate physicians to use a ligament tensioning device, it was important to conduct an analysis of existing products and solutions on the market to identify their strengths and weaknesses. This analysis allowed us to focus on the most relevant needs and specifications, that made possible the creation of a new product. However, the difficulty of accessing information from competing devices prevented a more detailed analysis.

During the selection process of the winning concept, it was impossible to test concepts in the surgical environment, reason why they were realized in informal conditions with functional prototypes manufactured in PLA. Performance and usability should be tested in a real surgery scenario with a copy of the new device. For this to happen it is necessary to gather a group of medical specialists and patients who authorize these tests.

The selection of the proposed material considered a number of criteria that defined the design and manufacturing processes of the new device. These criteria, while requiring a careful and time-consuming analysis, improve the performance of all production and final device. The combination of AISI 304 steel and PPSU polymer strengthens the quality of the new product and reduces manufacturing costs. All details of mechanisms, dimensioning and tolerance of the components were discussed with the supervisors, to assure the assembly and the proper functioning of the device.

When analysing a new product, it is necessary to take into account three fundamental principles: functionality, applicability and usability. As shown in **Figure 9**, the new device has a functional character with high performance ratings that demonstrate customer satisfaction. One of the features that distinguish this device from competitors is that it offers two possibilities of fixing which meets a medical requirement, one of them is more stable using bone anchor bolts and the other with small spikes is less stable. Together these two conditions aim to entice orthopaedic doctors to use this product regardless the anatomical region and technique used.

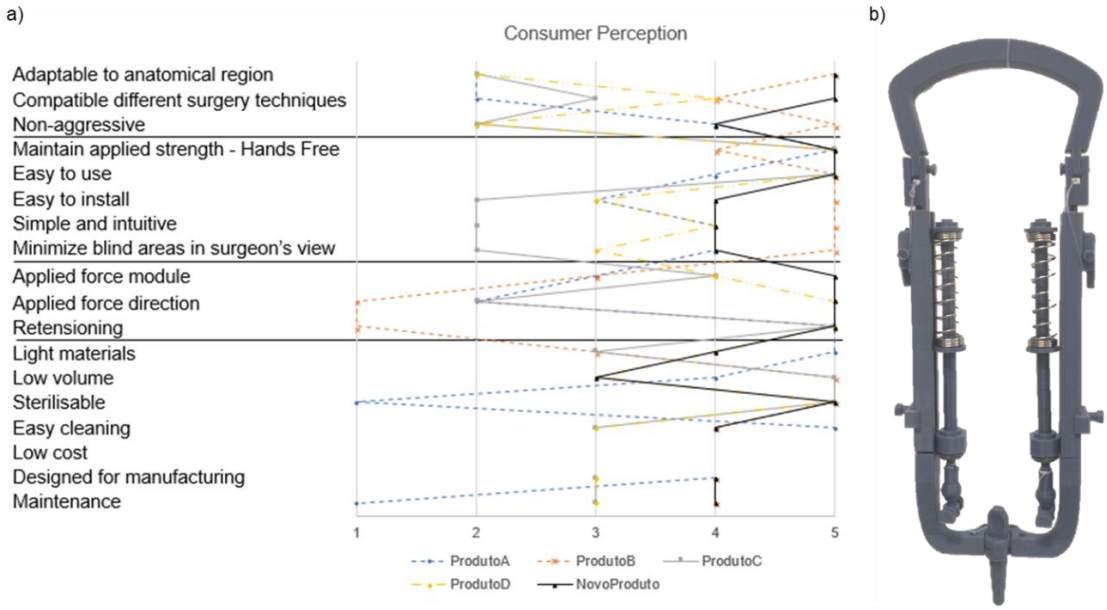

Figure 9: a) Comparison between the new product and competitors through consumer perception; b) New device prototype.

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